

There are multiple screening and testing tools for osteoporosis. We need to understand the most cost-efficient way to utilize these tools to identify postmenopausal women with osteoporosis. The objective of this study was to identify efficient strategies for detecting low bone mass in postmenopausal women and estimate the incremental cost per case found.

**METHODS:** The study sample consists of 392 women age >50. Each participant completed the Simple Calculated Osteoporosis Risk Estimation (SCORE\*) (a prescreening questionnaire), and bone mineral density (BMD) levels were collected at different skeletal sites. Assumed costs were: \$5 for SCORE, \$35 for peripheral site (pDXA) testing at the forearm, \$120 for single central (DXA) site testing at hip or spine, and \$200 for multiple site DXA. An osteoporotic woman was defined as a woman with BMD <-2 SD below peak adult mean at any site.

**RESULTS:** The cost, efficient frontier consisted of 7 strategies ranging in cost from \$33 to \$189 per patient, with corresponding sensitivity of 53% to 100%. The incremental cost per case found ranged from \$62.30 to \$1,100. Most importantly, the current gold standard (testing all women at the hip and spine) is not on the efficient frontier.

**CONCLUSION:** The efficiency of osteoporosis testing can be greatly increased through the appropriate use of sequential instruments to identify postmenopausal women with osteoporosis.

\* SCORE is a trademark of Merck & Co., Inc.

#### PHB2

### SF-12 OSTEOARTHRITIS-SPECIFIC HEALTH INDEX: DEVELOPMENT AND VALIDATION

Gandhi SK<sup>1</sup>, Salmon JW<sup>1</sup>, Zhao SZ<sup>2</sup>, Lambert BL<sup>1</sup>, Gore P<sup>1</sup>, Conrad K<sup>1</sup>

<sup>1</sup>University of Illinois at Chicago, Chicago, IL, USA; <sup>2</sup>G. D. Searle, Skokie, IL, USA

**OBJECTIVE:** To develop and validate SF-12 osteoarthritis-specific health index (SF-12 OASHI).

**METHODS:** Patient data on SF-12 and six osteoarthritis (OA) clinical variables (physician and patient global assessments, pain intensity, knee pain on weight bearing and motion, time to walk 50 feet) at baseline and week 6, from two placebo-controlled clinical trials (n = 422), assessing efficacy of NSAIDs in OA patients were used. Using canonical correlation analysis, a SF-12 OASHI was developed in 75% of the sample (n = 317) by adding individual SF-12 item scores at baseline, each multiplied by their respective OA specific weights (canonical cross-loadings on clinical variables). Validation (developmental sample) and cross-validation (25% holdout sample [n = 105], and another clinical trial sample [n = 170]) of the SF-12 OASHI were conducted by examining its correlation with clinical variables, and by computing the relative validity (RV) estimates of SF-12 OASHI as compared to physical (PCS12) and mental component summary scores (MCS12), using baseline and change scores at 6 weeks. Correlation between SF-12 component score and clinical

variable was divided by correlation between OASHI and respective clinical variable to arrive at the RV.

**RESULTS:** SF-12 OASHI demonstrated significant correlations with individual clinical variables ranging from -0.19 to -0.54 (p < 0.05). In general, SF-12 OASHI was more sensitive than the PCS12 and MCS12 scores as indicated by higher correlation coefficients with clinical variables, at baseline, in developmental and two cross-validation samples. At baseline, the RV coefficients for SF-12 OASHI ranged from 0.64 to 1.09 for PCS12 and 0.37 to 0.89 for MCS12. In general, SF-12 OASHI also showed more responsiveness to changes in clinical variables at 6 weeks as compared with PCS12 and MCS12 scores.

**CONCLUSION:** The SF-12 OA-specific health index is a comprehensive and more sensitive measure of patient quality of life in OA as compared with PCS12 and MCS12.

#### PHB3

### PSYCHOMETRIC EVALUATION OF SF-12 IN OSTEOARTHRITIS CLINICAL TRIALS

Gandhi SK<sup>1</sup>, Salmon JW<sup>1</sup>, Zhao SZ<sup>2</sup>, Lambert BL<sup>1</sup>, Gore P<sup>1</sup>, Conrad K<sup>1</sup>

<sup>1</sup>University of Illinois at Chicago, Chicago, IL, USA; <sup>2</sup>G. D. Searle, Skokie, IL, USA

**OBJECTIVE:** To evaluate psychometric properties of SF-12 as a generic health-related quality of life (HQL) measure in a patient population with osteoarthritis (OA) in clinical trials.

**METHODS:** Data were aggregated from three clinical trials, evaluating efficacy of different NSAIDs in OA patients (n = 651). Patient assessments were made using SF-36 and seven commonly used clinical measures in OA (patient and physician global assessments, pain intensity, time to walk 50 feet, knee pain on weight bearing and motion, functional capacity classification), at baseline, week 2, and week 6. The SF-12 items were extracted from the SF-36 items. For the SF-12, item missing rate, computability of component scores, factor structure, item convergent/discriminant validity, item-component correlations, and floor and ceiling effects were evaluated. Correlations of SF-12 physical (PCS12) and mental component summary scores (MCS12) with SF-36 component summary scores (PCS36 and MCS36), and clinical variables were used to establish construct and convergent validity of the SF-12 in OA patients.

**RESULTS:** A low individual SF-12 item missing rate (0.46% to 2.3%) and a high percentage score computability (91%) were observed at baseline. No floor or ceiling effects at baseline, week 2, and week 6 were observed. The scree plot confirmed two factor structure of the SF-12 items. Items belonging to the physical component correlated more strongly with the PCS12 than the MCS12, and vice versa. The correlations between PCS12 and PCS36, and MCS12 and MCS36 ranged from 0.94 to 0.96 (p < 0.0005), at baseline, week 2, and week 6. Significant correlations of -0.18 to -0.53 (p < 0.05) between SF-12