

**Abstracts****A557**

with and, if necessary, treated for knee cartilage defects by arthroscopy at one of seven centres in Germany. Patients were assigned to the initial operation (IO) group if the study physician was able to confirm that the study arthroscopy was the patient's first surgical procedure ever on that particular knee. All other patients were assigned to the re-operation (RO) group. Patients were interviewed on their postsurgical outcome with two disease-specific (Tegner Scale and IKDC Subjective Knee Form [IKDC-SKF] including a retrospective assessment of their pre-surgical health state) and a generic instrument (SF-36). **RESULTS:** Data from a total of 1708 patients were included in the final analysis. Of these, 1070 were assigned to the initial operation (IO) group (61% men,  $49 \pm 15$  years; 39% women,  $52 \pm 14$  years) and 638 were assigned to the re-operation (RO) group (64% men,  $44 \pm 13$  years; 36% women,  $47 \pm 14$  years). Participants experienced a level reduction of 1.5 (IO) and 2.5 (RO) resp. with the Tegner scale. Patients reported a functional knee status measured by the IKDC-SKF of 64% to 84% dependent on the surgical procedure performed. Significantly lower scores than the general population were observed with the SF-36 for the physical functioning, role-physical, and role-emotional scales, as well as for the physical health summary measure. The strongest limitations in the overall study population compared to the general population were seen on the physical functioning, role-physical, and role-emotional dimensions. In all three instruments the RO group experienced more severe reductions in quality of life. **CONCLUSIONS:** Despite extensive treatments participants experienced lasting reductions in quality of life. Surgical procedures differ in their long-term outcome. Longer history of interventions decrease the treatment related outcomes.

**PMS64****DIFFERENCES IN QUALITY OF LIFE ACCORDING TO THE REPLACED JOINT**

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**OBJECTIVES:** Total hip and knee replacement are very common procedures. Both of them improve function, pain and health related quality of life (HRQoL). The aim of this study was to compare baseline scores and improvements at one year in HRQoL according to the operated joint. **METHODS:** This prospective observational study was carried out in 15 hospitals with consecutive patients. All included patients fulfilled 3 HRQoL questionnaires at two times, 1 month pre surgery and 12 months post surgery. There were 2 generic questionnaires; EQ-5D and SF-12 and one specific, the WOMAC. We compare the baseline scores and improvements at one year by mean of Student's t test. **RESULTS:** The analysis was performed over 864 patients who fulfilled the included questionnaires. There were 355 hips and 509 knees. Mean age (mean  $\pm$  s.d.) was not different between hip ( $63.5 \pm 19.9$ ) and knee ( $64.3 \pm 23.8$ ) patients. At baseline, patients who were waiting for hip replacement had only worse score in the function dimension of WOMAC ( $64.8 \pm 16.6$  vs  $61.1 \pm 17.6$ ) ( $p = 0.002$ ). According to the improvements at one year, there were statistically significant differences in all EQ-5D and WOMAC dimensions. The patients in the hip group experienced higher improvements in EQ-5D index ( $p = 0.005$ ), VAS ( $p = 0.005$ ), WOMAC pain ( $p < 0.001$ ), function ( $p = 0.001$ ) and stiffness ( $p < 0.001$ ). There were no statistically differences in the improvements measured by SF-12. **CONCLUSIONS:** In the light

of these data we can conclude that at baseline patients have similar HRQoL scores, while at 1 year those who have undergone hip replacement experienced a higher improvement in the affected dimensions. In addition, the generic questionnaire SF-12 does not seem to capture the changes in HRQoL in these patients.

**PMS65****GOLIMUMAB, A HUMAN ANTI-TNF-ALPHA MONOCLONAL ANTIBODY, SIGNIFICANTLY IMPROVES SELF-REPORTED PRODUCTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS: RESULTS FROM THREE PHASE 3 STUDIES**

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**OBJECTIVES:** To evaluate the effect of golimumab (GLM) on self-reported productivity in rheumatoid arthritis (RA) patients.

**METHODS:** The effect of GLM on self-reported productivity was evaluated in three multicenter, randomized, double-blind, placebo (PBO)-controlled studies in RA patients. Data from patients receiving GLM or PBO with or without methotrexate (MTX) are presented. The trials evaluated different patient populations and included patients naïve to MTX (GO-BEFORE), patients with active RA despite MTX (GO-FORWARD), and patients previously treated with anti-TNF-alpha agent(s) (GO-AFTER). GLM subcutaneous injections of 50 mg or 100 mg were administered q4wks. At wks0 and 24, patients were asked to indicate how much their disease affected their productivity at work, school or at home in the past 4wks using a 0 (did not affect productivity at all) to 10 (affected productivity very much) VAS scale. A negative mean change from baseline is an improvement in self-reported productivity. An ANOVA on van der Waerden normal scores was performed for between-group comparisons. **RESULTS:** In each of the trials mean baseline scores for self-reported productivity were comparable between groups (ranges were 6.3–6.4[GO-BEFORE], 5.4–5.7[GO-FORWARD], 6.2–6.7[GO-AFTER]). In GO-FORWARD, the mean( $\pm$ SD) improvements in self-reported productivity were significantly greater in the GLM 50 and 100 mg + MTX groups compared with PBO + MTX at wk24 ( $-1.97 \pm 3.12$ ,  $-2.00 \pm 2.53$ , and  $-0.45 \pm 2.98$ , respectively,  $p < 0.001$ ). In GO-AFTER, the mean( $\pm$ SD) improvements in self-reported productivity were significantly greater in the GLM 50 and 100 mg groups compared with PBO at wk24 ( $-1.77 \pm 2.90$ ,  $-2.10 \pm 2.92$ , and  $-0.52 \pm 2.79$ , respectively,  $p < 0.001$ ). In GO-BEFORE, numerical improvements in self-reported productivity were observed in the GLM 50 and 100 mg + MTX groups ( $-2.48 \pm 2.94$  and  $-2.90 \pm 2.80$ , respectively); these improvements were not significantly different from PBO + MTX ( $-2.27 \pm 3.02$ ). **CONCLUSIONS:** In two studies, GLM resulted in significant improvements in self-reported productivity. In the third trial, GLM resulted in trends towards improvement in self-reported productivity compared with PBO + MTX.

**PMS66****WILLINGNESS TO PAY VS. QUALITY ADJUSTED WAGES AS ALTERNATIVE WAYS TO MEASURE THE BURDEN OF DISEASE IN SPAIN: AN APPLICATION TO BALLOON KYPHOPLASTY**

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**OBJECTIVES:** To evaluate welfare changes in individuals using balloon kyphoplasty (BKP) for the treatment of vertebral body

compression fractures in Spain. **METHODS:** Two alternative models will be introduced here. One standard contingent valuation model (CV), where mean values for willingness to pay (WTP) for the treatment with BKP are obtained through a survey including patients with primary osteoporosis. A new quality of life adjusted wages model (QAW) is also introduced here. The main assumption of this model is that a disease acts on individuals as a tax, where wages are deflected here by a quality of life index (EuroQol 5-D) in the same way as a proportional income tax. The burden of disease is given by this model in terms of an equivalent variation or welfare changes in monetary terms. The model avoids different kind of biases introduced in many times by the CV approach and is a faster and more rigorous tool to find welfare changes determined by diseases and their medical treatments. **RESULTS:** A sample of 168 individuals who had been asked about their WTP for BKP was used to develop the CV model. A mean value for WTP of €3909 is revealed by the sample. A sample of 300 patients 21 years of age or older and both genders coming from a clinical trial designed by Kyphon, was used to develop QAW model, here is that BKP determines in the first month a yearly welfare gain of €2665, increased to €3311 after 12 months. **CONCLUSIONS:** The results using CV models and QAW model are similar in the first year of life. It can be explained through a temporal downward bias introduced by WTP responses that means that a patient doesn't include in his personal WTP an estimation of his life expectancy.

#### **MUSCULAR-SKELETAL DISORDERS—Health Care Use & Policy Studies**

##### **PMS67**

#### **HEALTH GAINS FOREGONE DUE TO THE SUSTAINED DELAY OF ADEQUATE UTILIZATION OF EVIDENCE BASED TREATMENTS: THE CASE OF BISPHOSPHONATES FOR THE TREATMENT OF OSTEOPOROSIS**

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**OBJECTIVES:** Evidence-based guidelines recommend treatment for postmenopausal women with osteoporosis to prevent fractures. The study aims at determining since when this was known and whether the utilization of bisphosphonates in Germany from this point onward was adequate and to what extent health gains might have been foregone due to a limited use of bisphosphonates. **METHODS:** To determine since when the beneficial effect (prevention of fractures) was known, cumulative meta-analyses of randomized controlled trials derived from systematic reviews were conducted. The evidence-base was considered as established, when a significant (5%-level) reduction of fractures was observed in trial populations combined in meta-analysis compared to therapies without bisphosphonates. Utilization figures for bisphosphonates and epidemiological estimates where taken from published sources. **RESULTS:** The hip/femur fracture risk was significantly lower if treatment included bisphosphonates compared to treatment without bisphosphonates (RR 0.62; 95%-CI 0.40–0.97/RR 0.45; 95%-CI 0.23–0.90). In principal, this was known since 1995/1996. Utilization of bisphosphonates in 1996 was sufficient for the continuous treatment of about 8,200 patients (440,000 patients in 2006). About 1.6 to 1.9 million patients annually might have benefitted from treatment. About 22,800 fractures might thus have been avoided, had all patients with potential benefit continuously received bisphosphonates since 1996/1997. **CONCLUSIONS:** The delay in the wider use of bisphosphonates for osteoporosis treatment has resulted in a considerable loss of potential health gains in terms of avoided fractures. An arguable

lack of evidence for the expected benefit from bisphosphonate therapy does not sufficiently explain this finding. Other factors (e.g. cost considerations) might have contributed to this result. Limitations of the present analysis are primarily associated with uncertainties of epidemiological estimates and the application of study results to the entire patient population.

##### **PMS68**

#### **ANTI-TUMOUR NECROSIS FACTOR-&ALPHA; INHIBITOR DOSE CHANGES IN RHEUMATOID ARTHRITIS PATIENTS IN A PROSPECTIVE PATIENT REGISTRY SETTING**

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**OBJECTIVES:** Real-world data on long-term dosing patterns in first time anti-TNF $\alpha$  inhibitor treated rheumatoid arthritis patients is lacking. Such data are important for the calculation of treatment cost, especially for products where the label allows for varying doses and frequency of administrations. **METHODS:** The Dutch Rheumatoid Arthritis Monitoring (DREAM) project is a longitudinal, multi-centre patient register monitoring biologic DMARD usage in clinical practice since February 2003. Patients meeting the Dutch reimbursement criteria (DAS28 > 3.2, inadequate response to  $\geq 2$  DMARDs including methotrexate, no prior bDMARDs) were assessed at three-month intervals for 48 months. Dosing was determined by the attending rheumatologist guided by the recommended labelled doses (adalimumab 40 mg every other week, etanercept 25 mg twice weekly, infliximab 3 mg/kg at week 0, 2, 4, 8 and every 8 weeks thereafter). Mean dose was calculated based on the actual dose prescribed at each visit and the change over time evaluated for each anti-TNF $\alpha$ . **RESULTS:** The mean baseline doses for adalimumab (N = 374), etanercept (N = 432) and infliximab (N = 325) were 39.9 mg/two weeks, 24.2 mg twice weekly, and 3.4 mg/kg per eight weeks. Mean baseline DAS28 and HAQ ranged from 5.2–5.4 and 1.3–1.4, respectively. Nearly one-third of infliximab patients were prescribed greater than the labelled dose at baseline (32%, N = 105) compared to 2.5% and 0.2% for adalimumab and etanercept. At 12, 24, and 48 months follow-up, mean doses were: adalimumab, 41.5, 43.3, and 45.7 mg/two weeks (42 months); etanercept, 24.0, 24.9, and 23.9 mg twice per week (45 months); infliximab, 4.3, 4.9, and 4.9 mg/kg/every eight weeks (48 months). Mean doses in infliximab patients prescribed greater than the recommended labelled dose at baseline were 4.7, 5.2, and 5.6 mg/kg at the same follow-up intervals. **CONCLUSIONS:** Longitudinal patient registry data from The Netherlands show a marked and continued dose escalation in RA patients prescribed infliximab as a first-line anti-TNF $\alpha$  when compared to either adalimumab or etanercept.

##### **PMS69**

#### **PATTERNS OF MORBIDITY AND DIRECT COSTS ASSOCIATED IN THE OSTEOPOROSIS SPANISH POPULATION SETTING**

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**OBJECTIVES:** To determine the co-morbidity and direct cost influence in patients with osteoporosis in a Spanish population setting in under usual medical practice. **METHODS:** We performed a transversal retrospective study realized beginning from registers of subjects older than  $\geq 44$  years appertaining to seven centers of primary care (year 2,006). A control group without osteoporosis was formed. Main measures: general (age, gender), general co-morbidities and specific (ICPC-2), Charlson index