36 post-surgery using the Mann-Whitney test. Pearson correlation coefficients were calculated between utility scores and the KOOS overall, KOOS quality of life and VAS scores at each time-point. **RESULTS:** Significantly higher utility scores were observed in KOOS responders compared to non-responders at Months 30 (0.817 vs. 0.691, n = 25/14, p = 0.004) and 36 (0.775 vs. 0.618, n = 19/6, p = 0.006) and in VAS responders compared to non-responders at Months 24 (0.827 vs. 0.701, n = 17/9, p = 0.038) and 36 (0.764 vs. 0.600, n = 21/4, p = 0.015). A similar trend of borderline significance was measured at Months 24 (using KOOS, 0.818 vs. 0.728, n = 16/10, p = 0.136) and 30 (using VAS, 0.800 vs. 704, n = 21/4, p = 0.053). Utility scores correlated best with the KOOS overall (Pearson coefficients ranged from 0.579 to 0.721, p-values < 0.01) and VAS scores (–0.514 to –0.671, p-values < 0.01). **CONCLUSIONS:** Gaps in utility scores between responders (= successful surgery) and non-responders ranged from 0.091 to 0.164. This finding validates the assumption made in a previous Health Technology Assessment on Autologous Chondrocytes Implantation. Consistent gaps and significant correlations with validated tools provide valuable information for future economic modeling of CCI.

PMS55

EURO QOL (EQ-5D) BASED QOL (QUALITY OF LIFE) IN 5,023 JAPANESE PATIENTS WITH RHEUMATOID ARTHRITIS (RA) PATIENTS IN AN OBSERVATIONAL COHORT IORRA

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OBJECTIVES: QOL (quality of life) is critical in the management of patients with rheumatoid arthritis (RA). To evaluate the QOL of RA patients with different background, we evaluated the QOL by using Japanese version of EuroQol (EQ-5D) in a large observational cohort study of Japanese RA patients, IORRA. **METHODS:** We have established a large observational cohort of RA patients IORRA (Institute Of Rheumatology Rheumatoid Arthritis) in the Institute of Rheumatology Tokyo Women's Medical University since 2000. Essentially all RA patients who consulted there were registered, and clinical parameters including the disease activity, use of drugs and the occurrence of adverse events in daily clinical settings were assessed biannually based on patient's report, physician's examination and laboratory data. In this cohort, we evaluated the QOL of RA patients by EQ-5D, disease activity by DAS28, and disability by JHAQ, and then we analyzed the related factors for EQ-5D by Spearman's correlation. **RESULTS:** In September 2007, a total 5023 RA patients (female 84.2%, average 58.02 years-old, average disease duration 11.26 years, rheumatoid factor positive 74.8%, patients taking steroid, methotrexate and biologics were 51.0%, 63.6%, and 4.3%, respectively) fulfilled the questionnaire of EQ-5D. Mean ± SD of EQ-5D, DAS28 and JHAQ was 0.757 ± 0.178, 3.28 ± 1.147 and 0.737 ± 0.769, respectively, EQ-5D was worse in female (0.75 ± 0.177) than in male (0.798 ± 0.177) patients, and worse in rheumatoid factor positive (0.75 ± 0.178) than negative (0.782 ± 0.175) patients. EQ-5D became worse by older age and longer disease duration. No clear relationship was identified between EQ-5D and medications including corticosteroid, methotrexate or biologics in this cross-sectional analysis. **CONCLUSIONS:** EQ-5D based QOL was analyzed in a large number of Japanese RA patients using IORRA cohort.

PMS56

FIBROMYALGIA MOLDOFSKY QUESTIONNAIRE (FMQ): VALIDATION OF A TOOL TO AID DIAGNOSIS

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OBJECTIVES: The absence of objective signs and lack of tests make patient complaints fundamental to a presumptive diagnosis of fibromyalgia. To make diagnosis easier, H. Moldofsky has developed a questionnaire of 6 items related to diffuse pain, fatigue, psychological distress, unrestorative sleep and impaired well-being. To validate the FMQ (Fibromyalgia Moldofsky Questionnaire) as a tool to aid diagnosis, **METHODS:** A representative sample of 1500 subjects from the general UK population was constituted using the quota method. The FMQ questionnaire, was administered along with two validated questionnaires (LFESSQ London Fibromyalgia Epidemiology Study Screening Questionnaire and CES-D Center for Epidemiologic Studies Depression Scale) and a questionnaire assessing a decline in the restorative effects of sleep (SQA Sleep Quality Assessment). The maximum score of 18 reflected a strong presumption of fibromyalgia syndrome. Internal consistency, structural and clinical validity were tested. The sensitivity and specificity were also assessed, **RESULTS:** Internal consistency was satisfactory ($\alpha_{Cronbach} > 0.7$). The items composing each dimension were pertinent to the dimension that they represented (R > 0.4) and were not correlated with any other dimension. Subjects responding positively on the LFESSQ had an FMQ score that was significantly higher than subjects who responded negatively (8.6 [7.9–9.3] vs 4.1 [3.9–4.3], p < 0.001). Similar differences were observed between those subjects who had or did not have probable depressive symptoms (8.0 [7.4–8.6] vs 4.0 [3.8–4.2], p < 0.001) and between subjects experiencing a decline in the restorative effect of sleep or not (7.3 [7.0–7.6] vs 3.5 [3.3–3.7], p < 0.001).The FMQ had a sensitivity of 46 to 54%, depending on the specific dimension and questionnaire studied. Specificity was optimal (90 to 95%), **CONCLUSIONS:** The results observed during this psychometric validation showed that the FMQ questionnaire responded to the objectives that we had established and therefore allows referring physicians to send subjects with presumed fibromyalgia to specialist investigation centres.

PMS57

VALIDITY AND RESPONSIVENESS OF THE WORK PRODUCTIVITY SURVEY: A NOVEL DISEASE-SPECIFIC INSTRUMENT ASSESSING WORK PRODUCTIVITY WITHIN AND OUTSIDE THE HOME IN SUBJECTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: To determine the validity and responsiveness of the novel disease-specific Work Productivity Survey (WPS-RA) in patients with active rheumatoid arthritis (RA). The WPS-RA captures the RA impact on work and home-related.productivity. **METHODS:** A total of 220 RA subjects were randomized to 400 mg of subcutaneous certolizumab pegol or placebo every 4 weeks, for 24 weeks (wks). The WPS-RA was completed monthly starting Baseline (BL) until withdrawal/completion. Validity was evaluated at BL, using the known-groups approach. Mean WPS-RA responses at BL were compared between subjects with different levels of physical function or health-related quality-of-life (HRQoL). Groups were defined by the median-cut of subjects' scores to Health Assessment Questionnaire Disability Index (HAQ-DI) and SF-36 (the physical and mental component sum-

maries [PCS and MCS], the physical functioning domain [PF]). To demonstrate responsiveness, mean changes in WPS-RA at wk24 were compared between ACR20 responders and non-responders. The Standardized Response of the Mean (SRM) was used to quantify responsiveness. Comparisons were conducted using a non-parametric bootstrap t-method. **RESULTS:** Subjects with lower physical function/HRQoL scores had statistically greater RA-associated productivity losses compared to subjects with higher scores (25/32 evaluations statistically significant). HAQ-DI and SF-36 PF thresholds lead to statistically significant differences between groups in 7/8 WPS-RA questions. The PCS showed differences in 6/8 questions; the MCS in 5/8. The smallest differences related to absenteeism and days with outside help. At wk24, ACR20 responders reported large gains in productivity, whereas the ACR20 non-responders reported mainly worsening (difference p-value ≤ 0.05). The effect size for changes in productivity in responders was moderate to large for 6/8 items (0.49–1.10). The effect size was small for absenteeism and days with outside help (SRM = 0.4 and 0.24 respectively). In comparison, in non-responders, the magnitude of change was negligible (SRM < 0.1) or small (SRM < 0.3). **CONCLUSIONS:** The WPS-RA is valid and responsive as measure of work and household productivity in subjects with active RA.

PMS58

FIBROMYALGIA MOLDOFSKY QUESTIONNAIRE (FMQ): USE OF A TOOL TO AID DIAGNOSIS

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OBJECTIVES: To establish pertinent levels of FMQ (Fibromyalgia Moldofsky Questionnaire) score to guide a subject's further treatment, **METHODS:** The FMQ questionnaire, was administrated to a representative community sample of 1500 subjects in UK along with two validated questionnaires (LFESSQ London Fibromyalgia Epidemiology Study Screening Questionnaire and CES-D Center for Epidemiologic Studies Depression Scale) and a questionnaire assessing a decline in the restorative effects of sleep (SQA Sleep Quality Assessment). A descriptive analysis of the score was carried out using socio-demographic data (gender, age, type of town and socio-professional class) and the complaints reported by the subjects interviewed, **RESULTS:** The FMQ score was higher among women and those over 50 (5.0; 5.3). Women aged over 50 had an even higher FMQ score (5.5), which agreed with existing epidemiological data on fibromyalgia. There was no relationship between the FMQ score and geographic location, income, profession and sick leave prescribed by a doctor (regardless of length). The FMQ score was 3.0 in subjects who did not state any pain and 4.1 in those who did not respond positively on the LFESSQ. It increased to 8.7 among those who screened positive on the LFESSQ. The FMQ score varied between 9.7 and 10.4 in subjects who responded positively on the LFESSQ and who also experienced depressive symptoms, fatigue or a decline in the restorative effects of sleep. The FMQ score was 10.7 for subjects who screened positive on the LFESSQ and who also experienced fatigue and depressive symptoms, and increased to 11.3 when the four symptoms were experienced at once, **CONCLUSIONS:** A FMQ score of less than 3 excludes a presumptive diagnosis of fibromyalgia syndrome and an FMQ score of above 8 should lead to specialist investigations.

PMS59

RESTORATIVE EFFECT OF SLEEP: VALIDATION OF THE SQA (SLEEP QUALITY ASSESSMENT)

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OBJECTIVES: To validate the SQA (Sleep Quality Assessment) questionnaire which will help to identify subjects who with an unrestorative sleep, **METHODS:** The SQA questionnaire, was administered to a representative sample of 1500 subjects from the general UK population along with three questionnaires (FMQ: Fibromyalgia Moldofsky Questionnaire, LFESSQ London Fibromyalgia Epidemiology Study Screening Questionnaire, and CES-D Center for Epidemiologic Studies Depression Scale). The maximum score of 30 showed a large decline in the restorative effect of sleep. Internal consistency, structural and clinical validity were tested, **RESULTS:** Internal consistency was highly satisfactory ($a_{Cronbach} > 0.8$). The items making up each dimension were highly relevant to the dimension that they covered ($R > 0.4$) and no item presented a significant correlation (>0.8) with another item. Subjects responding positively on the LFESSQ had an SQA score that was significantly higher than subjects who responded negatively (14.6 vs 8.7). Similar differences were observed between subjects with and without probable depressive symptoms (15.4 vs 8.4) and a strong presumption of fibromyalgia syndrome (16.9 vs 8.0). The SQA score was 7.0 in subjects who did not report any pain and 7.1 in those who did not respond positively on the LFESSQ. It increased to 14.7 among those who screened positive on the LFESSQ. The CES-D score increased significantly with the SQA score. The SQA score was 16.7 [13.9–17.4] among subjects who screened positive on the LFESSQ and who either experienced fatigue or depressive symptoms or both, **CONCLUSIONS:** The restorative effect of sleep is reduced when the SQA score is greater or equal to 14 and good when the SQA score is less than 7. An SQA score of between 7 and 14 necessitates further examinations, which may include investigating physiological function during sleep.

PMS60

QUALITATIVE STEPS FOR THE DEVELOPMENT OF A QUESTIONNAIRE ASSESSING THE BURDEN OF FIBROMYALGIA ON PATIENTS' DAILY LIVES

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OBJECTIVES: To explore functional impact, limitation of daily activities, burden and handicap related to FM in order to define the burden on patients' daily lives. To gather and organise this material to develop a new Patient-Reported Outcomes (PRO) questionnaire simultaneously in four European languages assessing FM burden on patients' daily lives. **METHODS:** PRO questionnaire development follows a rigorous protocol and methodology to ensure its reliability. An international committee of three fibromyalgia experts was set up and included in the whole process. A literature review was conducted using burden- and FM-related keywords. Concepts identified were organised into a model. Exploratory interviews were performed with a total of 15 patients in France, Germany and Spain. They were recorded, transcribed word-for-word and systematically analysed using a specifically developed coding grid. Concepts were organised into a separate model. Confirmatory interviews were