scores for application in OA. Researchers can estimate overall utility scores, compute QALYs, and perform cost-utility analyses within a defined range of uncertainty.

**PAR10**

**ARE THEY RELEVANT? A CRITICAL EVALUATION OF THE INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH CORE SETS FOR OSTEOARTHRITIS FROM THE PERSPECTIVE OF PATIENTS WITH KNEE OSTEOARTHRITIS IN SINGAPORE**

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**OBJECTIVES:** To determine the extent to which health items identified from the perspective of patients with knee osteoarthritis can be linked with the ICF; and to critically evaluate the ICF Comprehensive and Brief Core Sets for osteoarthritis.

**METHODS:** Items identified from a focus group study were linked independently by two researchers based on the 10 a priori linking rules. Both percentage agreement and kappa statistics were calculated to measure inter-observer agreement. Any disagreements were resolved by reaching a consensus among the researchers. The categories linked with all items were compared with the Comprehensive Core Set for osteoarthritis, while the categories linked with those items reported as important by over 30% of subjects within each of 3 local ethnic groups (i.e., Chinese, Malay, and Indian) were compared with the Brief Core Set. Both comparisons were made only at the second level of the ICF.

**RESULTS:** Totally 74 items were linked with 44 different ICF categories through 105 linkages with generally very good inter-observer agreement. The 69 items were linked with the ICF at the third or fourth levels. Both commonalities and disparities were found through comparison between the categories linked with these items and both Core Sets for osteoarthritis.

**CONCLUSIONS:** In this study, all items could be successfully linked with the ICF. The ICF Comprehensive Core Set demonstrated general conceptual validity, while the Brief Core Set needs to be supported by more empirical evidence in various socio-cultural contexts. This study specifically complemented the development and refinement of both Core Sets from the perspective of patients with knee osteoarthritis.

**PAR11**

**VALIDITY STUDIES AND SATISFACTION THRESHOLD OF THE ARTHRITIS TREATMENT SATISFACTION QUESTIONNAIRE (ARTS)**

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**OBJECTIVE:** The 18-item ARTS questionnaire measures 4 dimensions relative to satisfaction with osteoarthritis treatment: Effectiveness, Convenience, Tolerability, and Medical Care. Validity studies and discriminant properties are reported in order to establish a clinical relevant difference in the overall score and a satisfaction threshold.

**METHODS:** Two samples are compared: a normative group of 163 used for linguistic validation and an unsatisfied group of 1750 patients derived to a more tolerant treatment with COX-2. Groups are compared using t-test, ANOVA and Tukey’s HSD. Sensitivity and related figures are estimated using the ROC curve using as criteria the patients’ need of change in treatment (judged by the clinician).

**RESULTS:** The normative group renders a normal distribution of scores (65.4 ± 13.4, mean ± SD), slightly biased above the 0–100 scaled mid-point. The total score mean value for the unsatisfied sample (52.5 ± 11.1) was significantly lower (p < 0.001) than for the normative group, and much lower than the satisfied subgroup (76.5 ± 13.9). By dimensions, the larger difference between the satisfied subgroup and the rest of patients who needed change was observed in the Effectiveness dimension (dif = 34.1, t = 11.3), followed by Convenience (dif = 27.3, t = 10.1), Tolerability (dif = 26.5, t = 5.3), and Medical Care (dif = 14.0, t = 5.7). No differences were found between genders, neither in the normative group nor in the unsatisfied group. Sensitivity = 72%, specificity = 77%, positive predictive value = 89% and negative predictive value = 53% are obtained using a cut-off point of 69.18 determined from the clinical judgment of a need of change in treatment (threshold value). Significance differences in mean score are also found between groups differing in tolerance to actual treatment.

**CONCLUSION:** ARTS is a sensitive instrument and can be used to detect differences in the patients’ satisfaction with osteoarthritis treatment. Differences between groups of known satisfaction level are significant and meaningful, although it should be noted that the normative mean score is above the scale midpoint.

**PAR12**

**IMPROVEMENT IN HEALTH UTILITY IN PATIENTS WITH PSORIATIC ARTHRITIS TREATED WITH ADALIMUMAB (HUMIRA®)**

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**OBJECTIVES:** To estimate change in quality of life (QoL) in patients with psoriatic arthritis (PsA) receiving adalimumab vs. placebo, as measured by the health utility measurement Short Form 6D (SF-6D).

**METHODS:** In a placebo-controlled, Phase III trial of adalimumab (ADEPT), patients with active PsA received adalimumab 40mg every other week (eow) or placebo for 24 weeks. The SF-6D was estimated at baseline, 12 weeks and 24 weeks using responses to the Short Form 36 (SF-36) patient questionnaire. Multiple linear regression models were estimated to explore the effects of age, sex, disease duration, concomitant therapies, baseline Health Assessment Questionnaire Disability Index (HAQ DI), and the Psoriasis Area and Severity Index (PASI). Patients were further differentiated as responders or non-responders using the Psoriatic Arthritis Response Criteria (PsARC) and an improvement in the PASI by 75% (PASI 75).

**RESULTS:** Baseline SF-6D values were 0.66 and 0.65 for the adalimumab and placebo arms respectively. Overall, adalimumab improved health utility by 10.6% (SD = 18.9) in comparison to 2.9% (SD = 16.2) for placebo. Adalimumab was particularly efficacious in patients with skin involvement (13.7% (SD = 20.9) versus 0.3% (SD = 17.0)). PsARC response was a significant predictor of utility improvement, and, for patients with skin involvement, PASI 75 was also important CONCLUSIONS: These findings demonstrate that adalimumab was efficacious in improving PsA patients’ quality of life; and this efficacy was observed to an even higher degree in patients with more skin involvement. Health utilities, when modeled with associated costs over a patients’ lifetime, will facilitate the economic evaluations of adalimumab.

**PAR13**

**THE DIRECT MEDICAL COST OF RHEUMATOID ARTHRITIS IN HONG KONG**

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OBJECTIVE: To evaluate the direct medical cost in the management of rheumatoid arthritis (RA) as well as the extent of resource use in current practice from the perspective of public health organization in Hong Kong. METHODS: This study was a retrospective design. Subjects recruited must have RA diagnosed and attended the follow-up visits, receiving RA treatment in the Prince of Wales Hospital (PWH) between the period of 1st January 2002 to 31st December 2002. Data was collected by medical chart review. The direct medical costs included inpatient care, outpatient visits, laboratory monitoring, radiological procedure, drug cost and side effects management. RESULTS: A total of 147 patients were included in our study. The average age and the duration of disease of our subjects were 54.7 years old (SD: 10.9) and 12.6 year (SD: 7.0) respectively. The annual direct medical cost per each RA patient was HK $18,657 (US $1 = HK $7.8). The inpatient care contributed 43.8% of the total, which was the highest. The cost for laboratory monitoring was the second (19.2%) where the outpatient cost ranked the third (15.4%). The cost for RA-related drugs accounted for 9.8%. The cost for the management of the side effects shared 3.1% of the total. Based on a local epidemiological study, the RA prevalence rate was 0.3%. The annual direct medical cost for the management of RA in Hong Kong would be HK $443 million, which shared 1.4% of the total health care budget in 2002. CONCLUSION: This study demonstrated that RA was a significant economic burden to the health care budget of Hong Kong.

PAR14 EVALUATION OF ACCESS TO HIGH-COST MEDICINES IN AUSTRALIA USING NATIONAL CLAIMS DATA
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Effective high-cost medicines, for example, tumour necrosis factor inhibitors (TNFIs), are subsidised in Australia under the Pharmaceutical Benefits Scheme (PBS), but access is restricted to ensure cost-effective use. An application for initial or continuing access to TNFIs requires detailed information on each patient, including laboratory markers and previous pharmacotherapies. OBJECTIVES: To examine the access to TNFIs in Australia for treating rheumatoid arthritis. METHODS: Both aggregated, and individual de-identified information were requested from the Health Insurance Commission (HIC) including the number of applications received and approved, patient demographics, use of other disease-modifying anti-rheumatic drugs, changes in clinical outcomes, the time interval between application and decision to approve, and geographical pattern of usage. Prescription and expenditure data (August 2003–March 2005) for the TNFIs, etanercept, infliximab, and adalimumab, were examined. RESULTS: The detailed clinical information submitted with the applications was not captured by the HIC database. A total of 19,629 prescriptions was reimbursed: etanercept (15,675), infliximab (570), and adalimumab (3384), at a total cost of AUD$43.5 million. The uptake of these agents was considerably lower than expected. The number of patients using a TNFI under the PBS could only be approximated from these aggregated figures—more than 2,000 patients had been commenced on TNFIs. The proportion of patients that were approved to continue or switch between TNFIs was not available. CONCLUSION: The HIC is positioned to capture subsidised prescription-drug usage and clinical outcome data on a national basis. Unfortunately, it is impossible to access detailed data. Information on utilisation of TNFIs is far from adequate. Comprehensive drug usage and patient health outcome data need to be accessible in order to define the most appropriate use and access to these agents. Update of, and arrangements for access to the HIC database are encouraged.

PAR15 TARGETED ACCESS TO HIGH-COST MEDICINES IN AUSTRALIA: EARLY ANALYSIS FROM A QUALITATIVE STUDY
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Access to high-cost medicines such as to the tumour necrosis factor inhibitors (TNFIs) for the treatment of rheumatoid arthritis is tightly regulated under Australia's Pharmaceutical Benefits Scheme (PBS) to ensure their cost-effective use. OBJECTIVES: To explore stakeholders’ perceptions and experiences associated with the restricted access to TNFIs and the process of collaboration between key stakeholders who formulated the access criteria. METHODS: Thirty-three, in-depth semi-structured interviews were conducted between 2004 and 2005. Participants included rheumatologists, patients treated with TNFIs, consumer representatives, government health advisors, public servants, and representatives from pharmaceutical companies involved in formulating and implementing the access restrictions. Participants were asked to comment on the access restrictions that have applied since August 2003, and their views on the collaboration between stakeholders were collected. Interviews were recorded, transcribed verbatim, and thematically analysed. RESULTS: The principle of “controlled access” to TNFIs was in general accepted by all, despite the different perspectives each person represented. However, there were concerns regarding some of the specific PBS criteria. Overall, the collaborative approach that was taken to formulate the criteria for access to TNFIs was perceived by key stakeholders as a valuable advance and has set a new paradigm for subsequent PBS subsidy decisions. However, a wider and more transparent decision-making process, and a more structured and continuing communication between stakeholders were judged desirable. Some degree of flexibility with respect to physician prescribing, and a need to increase education to health care professionals and the community were proposed. CONCLUSION: Targeting access to high-cost medicines through a national subsidy system was agreed to be practical and equitable. Increased transparency, communication and education were identified as the main elements needed to secure support of the final access criteria by all involved. In order to confirm these primary themes, further interviews are being undertaken until data saturation is achieved.

PAR16 POTENTIAL PROBLEMS IN USING RCT DATA TO ESTIMATE COST-EFFECTIVENESS: RESULTS FROM AN ANALYSIS OF ETANERCEPT USE IN RHEUMATOID ARTHRITIS
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Data from randomized controlled trials (RCTs) are often used in economic evaluations when estimating cost-effectiveness. The data generated from RCTs represent ideal experimental conditions (efficacy) and the applicability of this data to real world settings (effectiveness) may be questionable. OBJECTIVES: 1) To conduct an economic evaluation of etanercept (a competitive inhibitor of TNF-a) use in rheumatoid arthritis patients in Canada, and 2) To compare the results of a cost-effectiveness analysis conducted with efficacy data obtained from a RCT, to results derived by using effectiveness data obtained from community-based clinical practice. METHODS: The data used to perform the analyses were obtained from a trans Canadian community-based cohort study conducted between 1999 and 2003. A cost-utility analysis was preformed and incremental cost-effec-