and utility, providing an opportunity to evaluate estimates of utility from physical function. METHODS: A total of 2070 patients with active RA participated in 4 clinical trials (ARMADA, DE011, DE019 and STAR). The Health Assessment Questionnaire Disability Index (HAQ) measured physical function for all patients and the Health Utilities Index Mark-3 (HUI3) measured utility for 2000 patients at baseline and months 3 and 6. HAQ scores range from 0 (good physical function) to 3. HUI3 was regressed on HAQ using both repeated measure mixed models and cross-sectional models controlling for age, sex, disease duration, clinical trial and fatigue (measured by the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)). The cross-sectional models used end-of-study data with Last Observation Carried Forward (LOCF) imputation. These analyses include the 1990 patients with non-missing values for these variables. RESULTS: The mixed models and the cross-sectional models provided almost identical coefficient estimates. Disease duration and trial were not significant and were deleted from the model. Age (in years) was statistically significant but trivial ($\beta = 0.00087$). The basic estimated cross-sectional model was: HUI3 = 0.76-0.28*HAQ + 0.05*FEMALE ($p < 0.0001$ for each regressor, Adj. $R^2 = 0.49$). However, the relationship between HUI3 and HAQ appears to be nonlinear: coefficients for HAQ-squared and HAQ-cubed were significant ($p = 0.013$ and $p = 0.003$, respectively) when added to the regression. Adding FACIT-F to the basic cross-sectional model substantially improved model fit (Adj. $R^2 = 0.63$).

CONCLUSIONS: The basic algorithm developed in this study is consistent with published predictions of utility from HAQ (Kobelt et al., Arthritis and Rheumatism, 1999). However, these algorithms’ predictions are limited and should only be used when direct utility scores are not available.

SESSION III

INFECTIOUS DISEASE STUDIES II

ECONOMIC EVALUATION OF A LARGE-SCALE MENINGOCOCCAL C VACCINATION PROGRAM IN THE NETHERLANDS

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OBJECTIVES: In the Netherlands, the incidence of meningococcal C infections has strongly increased during the last years. Should the Netherlands follow the UK and start a large-scale meningococcal C vaccination campaign? We calculated the health effects and costs of such a vaccination program. METHODS: The health effects, the costs and savings, as well as the cost-effectiveness of vaccinating all persons aged 14 months to 19 years in the Netherlands against meningococcal C infection was estimated, from a societal perspective using a decision analytic model. Data were derived from the Netherlands Reference Laboratory for Bacterial Meningitis, the Dutch costing guidelines, PRISMANT Healthcare, and national and international literature. Direct and indirect costs
(friction cost method) were considered at 1998 price levels. Future costs were always discounted at 4% while future effects (QALYs and LYG) were only discounted for computing cost-effectiveness ratios. The study time horizon was 77 years. RESULTS: The vaccination program would prevent 228 deaths, 92 severe sequelae (amputations and neurological sequelae) and render 11,330 life years and 13,470 QALYs (no discounting). It would cost €75.6 million and aver €27.5 million direct costs and €0.4 million indirect costs. The cost-effectiveness ratio is €11,830/QALY or €14,070/LYG, when indirect costs are excluded. Considering indirect costs leads to slightly better ratios: €11,730/QALY or €13,950/LYG. These results are sensitive to the incidence of meningococcal C infections, the discount rate of health effects and the vaccine’s protection duration. CONCLUSIONS: The vaccination program renders a significant health gain and is cost-effective as its cost-effectiveness ratios lie significantly below the Dutch cut-off point for vaccines. These results played an important role in the Dutch government’s decision to implement this vaccination program in June 2002.

MIGRAINE/COPD STUDIES

DEVELOPMENT OF A FUNCTIONAL ASSESSMENT IN MIGRAINEURS MEASUREMENT TOOL BASED ON THE WHO’S ICIDH2 CLASSIFICATION

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OBJECTIVES: As new medications for migraine are introduced, it is imperative that valid tools exist to measure their impact on patient reported outcomes. The objective of this project was to develop a Migraine Impact on Functioning (MIF) Tool based on the “body and mind functioning (BMF)” and “activity and participation (AP)” framework presented in the ICIDH2. METHODS: The tool was developed using a multi-step process first proposed by Guyatt. 1) Researchers generated an extensive list of potential items based on focus groups in Germany and the US and on review of literature. An item reduction survey was designed including 71 BMF items and 50 AP items. 2) The item reduction survey assessing the frequency and importance of each item was administered to samples of migraineurs in Germany (n = 153) and the US (n = 148). 3) Item reduction was completed by selecting items with high frequency-weighted importance and by further analyzing these items using Principal Component analysis. Differences between items selected in the two populations were compared to determine if one tool could meet the needs of both. RESULTS: While results from the German and US populations identified BMF items as important, principal components analysis found similarity in the nature of the factors identified. In the US, a four-factor, 13-item model was identified, including: “energy”, “intolerance to stimulus”, “emotional impact”, and “attention/psychomotor issues”. In Germany, a 3-factor, 12-item model was found including “attention/cognition”, “intolerance to stimulus”, and “emotional issues”. CONCLUSION: Given the notable overlap in the factors identified in the two nations, we believe that the difference in individual item selection is a product of small translational or interpretational difference rather than an