

data from the United States. **METHODS:** We obtained data on jury awards for injuries that caused functional disabilities similar to RA. We identified a sample of jury awards involving limb disabilities and/or losses. With these award amounts, we computed the average jury award and calculated its annuity equivalence, assuming an average US life expectancy. For RA-associated early mortality, we employed data from the medical literature to compute the difference between the present value of sex-specific lifetime earnings of RA patients, with adjustments to reflect reduced life expectancy and average lifetime earnings in the United States. Tangible costs associated with RA (e.g., health care, workplace, paid/unpaid help, government disability) were derived from private insurance, Medicare, and Medicaid claims databases; disability and medical absence data; and the literature. Patient-level cost estimates were weighted by the prevalence of relevant populations to compute societal costs (2005 US dollars). **RESULTS:** The average annuity per jury award for injuries similar to RA disabilities was \$55,700. This corresponds to an annual societal value of disability/QOL deterioration of \$10.8 billion. The annualized reduction in lifetime earnings per RA patient (vs. those without RA) was \$7,420, or \$9.6 billion in total. Thus, the annual intangible costs of functional disability/QOL and mortality totaled \$20.4 billion. Total tangible societal costs were \$19.3 billion (\$8.4 billion for direct costs [patient health care]; and \$10.9 billion for indirect costs [other RA consequences]). **CONCLUSIONS:** Including intangible costs increased the annual societal costs of RA by \$20.4 billion in the United States, for a total of \$39.7 billion.

PODIUM SESSION IV: QUALITY OF LIFE & UTILITY STUDIES

COMPARISON BETWEEN THE EQ-5D AND THE SEVEN DERIVED HEALTH UTILITIES IN STROKE PATIENTS USING A NATIONAL REPRESENTATIVE SAMPLE IN THE UNITED STATES

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OBJECTIVES: 1) To assess the associations of EQ-5D index score, EQ-VAS, and seven estimated utilities with self-reported stroke in a U.S. national representative sample, and 2) To compare estimated utilities with EQ-5D and EQ-VAS in both stroke and non-stroke samples. **METHODS:** Data were extracted from the 2001 Household Component of the Medical Expenditure Panel Survey (MEPS). Seven estimated utilities were derived from the SF-12v1®, including HUI3/VAS item models (IM) and categorical models (CM) from the Sengupta-Nichol, Brazier SF-6D, Lundberg VAS, and Sullivan EQ-5D algorithms. An analysis of covariance was used to determine differences in mean utility scores between individuals with and without stroke. Covariate (social-demographic and comorbidity) adjusted effect sizes (ES) were calculated for utilities between individuals with and without stroke, as well as between estimated utilities and EQ-5D/EQ-VAS. **RESULTS:** A total of 19,475 individuals completed SF-12v1®, EQ-5D, and EQ-VAS. Mean age was 42.2 years, 40% were female, 14% had self-reported stroke. Individuals with stroke had significantly lower covariate adjusted mean EQ-5D (0.16 points difference), EQ-VAS (0.14 points difference), and estimated utilities (0.11 or 0.12 points differences) when compared to those without stroke (all $p < 0.0001$). Stroke individuals showed large effect in utility scores when compared to non-stroke individuals. HUI3-IM (ES = 1.20) and HUI3-CM (ES = 1.22) showed ES similar to EQ-5D (ES = 1.23), and both VAS-IM and VAS-CM (ES = 1.09) had ES similar to EQ-VAS (ES = 1.08). When comparing estimated utilities with EQ-5D, Sullivan EQ-5D (ES = 0.26) and SF-6D (ES = -0.29) showed small effect, while other estimated utilities showed no effect in stroke individuals; all estimated utilities showed small (ES = 0.23 for Sullivan EQ-5D) to large effect (ES = -1.00 for SF-6D) in non-stroke individuals. **CONCLUSIONS:** EQ-5D, EQ-VAS and estimated utilities in stroke individuals displayed clinical meaningful differences from those without stroke. Derived HUI3/VAS showed the similarity with the EQ-5D/EQ-VAS in stroke individuals. Our findings indicated that EQ-5D, EQ-VAS, and estimated HUI3 and VAS were sensitive to health state and could be used for cost-effectiveness analysis in stroke individuals.

DEVELOPMENT OF AN ITEM BANK FOR A COMPUTER ADAPTIVE MEASURE OF FUNCTIONAL COGNITION FOR STROKE

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OBJECTIVES: To establish an item bank for Computer Adaptive Measure of Functional Cognition for Stroke (CAMFC-S). The prerequisite for monitoring the effectiveness of pharmaceutical interventions for stroke-related cognitive deficits is the development of reliable and valid cognitive measures. Existing measures of post-stroke cognition: 1) are few in number; 2) lack precision and efficiency for stroke; and 3) fail to reflect cognitive functioning that is related to everyday activities (i.e., "functional cognition"). **METHODS:** A total of functional cognition items across 10 domains (Language, Reading/Writing, Numeric Calculation, Limb Praxis, Visuospatial Function, Social Use of Language, Emotional Function, Attention, Memory, and Executive Function) were administered to 128 individuals with stroke 49 acute (7–21 days post onset) and 79 chronic (83–372 days post onset). Rasch and classical test analyses were

performed on 128 self-report ratings and 124 caregiver ratings. Neuropsychological testing was performed with 62 randomly selected patients. **RESULTS:** Confirmatory factor analysis of each domain supported both unidimensionality and hypothesized multidimensional structures for 5 of 10 domains with 1 domain only supporting a multidimensional structure. The all-item measure and separate domain measures showed excellent internal consistency (high person separation reliability and high Cronbach's alphas). The all-item measure and domain measures (except Limb Praxis) produced expected item-difficulty hierarchical orders. The all-item measure showed excellent person separation and except for Limb Praxis and Numeric Calculation (patient self-report), domain measures showed good person separation. While the All Item measure showed no floor or ceiling effects 5 of 10 domain measures showed ceiling effects. The domain measures showed fair-moderate correlations with analogous neuropsychological test performance. **CONCLUSIONS:** With the exception of Limb Praxis, the findings support developing all-item and domain-specific computer adaptive tests of functional cognition.

QL3

ESTIMATION OF UTILITY VALUES FOR DIABETES-RELATED COMPLICATIONS ON QUALITY OF LIFE FOR PATIENTS WITH TYPE-2 DIABETES IN ONTARIO, CANADA

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OBJECTIVES: The primary aim of this study was to analyze quality of life (QOL) data from a Canadian population with type-2 diabetes in order to estimate the impact of a number of diabetes-related complications on utility measures of QOL. **METHODS:** The EuroQol EQ-5D instrument was administered 1147 patients with type-2 diabetes. After controlling for age, gender and duration of diabetes, utilities were estimated by regressing the EQ-5D scores onto binary indicators for the presence of an event. The primary method of analysis was Ordinary Least Squares (OLS), and due to concerns over non-Normality, bootstrap standard errors (SE) were calculated. Both United States and UK scoring algorithms were used to estimate respective utility decrements. **RESULTS:** 1,143 participants were included in the analysis. Using the UK algorithm and the OLS model, the utility decrements were as follows: myocardial infarction (MI) = -0.081 (SE = 0.026), amputation = -0.098 (SE = 0.090), stroke = -0.067 (SE = 0.036), and kidney failure = -0.158 (SE = 0.073). The US algorithm produced the following values: MI = -0.059 (SE = 0.017), amputation = -0.063 (SE = 0.059), stroke = -0.046 (SE = 0.023), and kidney failure = -0.102 (SE = 0.047). Estimates of these effects based on both the Tobit and censored least absolute deviations estimator models were also reported and compared. **CONCLUSIONS:** This study used various regression models to estimate the decrements in EQ5D utility values associated with several important complications commonly experienced in patients with diabetes. The most significant impacts on QOL were associated with kidney failure and MI. The decrements estimated using US scoring algorithm were smaller than using UK scoring algorithm. These utility values can be used to assess the outcome of interventions that reduce these diabetes-related complications and will have a great impact on future economic evaluations of diabetes management strategies in Canada.

QL4

VALIDATION OF THE TREATMENT RELATED IMPACT MEASURE FOR DIABETES TREATMENT AND DEVICE; TRIM-DIABETES AND TRIM-DIABETES DEVICE

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OBJECTIVES: To fully understand the multi-faceted impact of diabetes treatments, patients' perceptions of health-related quality of life, treatment satisfaction and treatment behavior must be assessed. Available diabetes patient reported outcome (PRO) measures are specific to type-1 or type-2 diabetes, treatment or delivery modality or are not inclusive of all potential impacts. The purpose of this study was to validate the Treatment Related Impact Measure (TRIM) for Diabetes and Diabetes Device which were developed to assess the full range of impacts across diabetes type, all current delivery systems and diabetes treatments. **METHODS:** The 60 item TRIM-Diabetes/Device, developed in a prior study according to the draft FDA guidelines, was validated in a web-based survey for measurement and psychometric properties (factor structure, reliability, validity) for the total and each domain score. **RESULTS:** A total of 507 respondents completed the web-survey; 24 of 60 items were dropped due to redundancy, ceiling effects, poor factor loadings and/or poor conceptual fit, resulting in a 28 item TRIM-Diabetes and 8 item TRIM-Device. A five-factor structure for the TRIM-diabetes with domains of treatment burden, daily life diabetes management, psychological health and compliance and 2 domains of device function and device bother for the TRIM-Device were found. Internal consistency coefficients of the total score and each subscale ranged between 0.80 and 0.94 and test-retest reliability ranged from 0.71 to 0.89. All pre-specified hypotheses for convergent and known-groups validity were met. The estimated time for completion of the combined measures is four minutes. **CONCLUSIONS:** The development of these measures has been conducted according to well defined scientific principles, suggesting that the total score and each domain subscale, can be considered a brief, conceptually sound, rigorously developed PRO measure with strong evidence supporting the psychometric properties. Use of these measures in both clinical and research setting can facilitate targeted interventions with more positive treatment outcomes.