assumption of impractical unlimited vaccine supply, we developed a generalized methodology based on dynamic stochastic model utilizing the flow of limited vaccine supply to the individuals between two mutually exclusive subgroups (e.g. different age groups or different risk groups) in order to examine the long term impact of different vaccine strategies on overall health outcomes from the whole population. In this model, both age dependency and seasonality in FOI were explicitly considered. This study aims to answer two key questions: 1) what is the best vaccination strategy in order to attain maximal quantitative post-vaccination health benefits among two subpopulations? and 2) how different structures of age-specific FOIs influence our selection on the vaccinated population? Most of the time, one needs to have various parameter values in the models targeting spreading of infectious diseases in populations which cannot be estimated accurately. Therefore, a series of scenarios with different FOIs, demographic structures, vaccine efficacy and other model parameters were used in our simulation studies using this stochastic age-structured framework. In summary, our study dynamically acquired both important biomedical and mathematical implications by successfully analyzing the current mass vaccination strategy, evaluating the impact of different prevention and intervention options, and served as an accurate basis for outcome research that may facilitate further cost-effectiveness analysis.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Patient-Reported Outcomes Studies

Sensitivity of 15D, EQ-SD and SF-6D to Diabetes Complications: The Case of Coronary Heart Disease

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OBJECTIVES: Diabetes Mellitus (DM) patients typically suffer from comorbid conditions such as obesity, hypertension and micro- and macrovascular complications which, in conjunction to demographic, anthropometric, clinical and treatment satisfaction variables, have a confounding effect on health-related quality of life. Therefore, discriminative ability of measuring instruments is important. Three preference-based utility instruments were assessed in terms of their sensitivity to a common complication of diabetes, heart disease.

OBJECTIVES: To compare EQ-5D and SF-6D utilities in chronic heart failure (CHF) patients with varying levels of disease severity, proxied by the Duke Activity Status Index (DASI). METHODS: A consecutive sample (N = 251) of CHF patients undergoing elective cardiac surgery were surveyed with the EQ-5D, SF-36 and the DASI, with the latter used to perform a uniform 5-way split of the sample according to functional capacity, Association and level of agreement between instruments in each severity group compared to those with Pearson’s correlation coefficient (ICC) and the intraclass correlation coefficient (ICC) respectively. Paired-samples t-test was used to identify significant score differences, which were regarded as minimally important differences (MID) when exceeding 0.03. In a linear regression model, the DASI score was used as an anchor of disease severity to identify a potential “crossover point” between EQ-5D and SF-6D utilities. RESULTS: EQ-5D and SF-6D were in agreement and strongly correlated over the entire sample (ICC = 0.848, P < 0.001 and r = 0.647, P < 0.001), but correlation varied within the DASI-based groups. In the less severe groups (higher functional capacity) EQ-5D scores were significantly higher than SF-6D scores (P < 0.001) and differences constituted MDs. Contrarily, in the more severe groups SF-6D was predominantly higher than EQ-5D. The regression model indicated a utility crossover point at 0.716 and predicted that individuals with a utility score less than this would score higher on the SF-6D than on the EQ-5D, and vice versa. The DASI score at crossover was calculated at 31.99. CONCLUSIONS: In subgroups of patients differing in CHF severity, mean EQ-5D and SF-6D indices differed significantly, implying that the two instruments are not interchangeable and the choice of instrument for measuring health-related utility can lead to variations in cost-utility analyses. Based on evidence provided here, discrepancies in the instruments’ measuring range generate utility differences which require further investigation.

Assessing the (dis)agreement of EQ-SD and SF-6D across groups with increasing severity of chronic heart failure

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OBJECTIVES: To compare EQ-5D and SF-6D utilities in chronic heart failure (CHF) patients with varying levels of disease severity, proxied by the Duke Activity Status Index (DASI). METHODS: A consecutive sample (N = 251) of CHF patients undergoing elective cardiac surgery were surveyed with the EQ-5D, SF-36 and the DASI, with the latter used to perform a uniform 5-way split of the sample according to functional capacity. Association and level of agreement between instruments in each severity group compared to those with Pearson’s correlation coefficient (ICC) and the intraclass correlation coefficient (ICC) respectively. Paired-samples t-test was used to identify significant score differences, which were regarded as minimally important differences (MID) when exceeding 0.03. In a linear regression model, the DASI score was used as an anchor of disease severity to identify a potential “crossover point” between EQ-5D and SF-6D utilities. RESULTS: EQ-5D and SF-6D were in agreement and strongly correlated over the entire sample (ICC = 0.848, P < 0.001 and r = 0.647, P < 0.001), but correlation varied within the DASI-based groups. In the less severe groups (higher functional capacity) EQ-5D scores were significantly higher than SF-6D scores (P < 0.001) and differences constituted MDs. Contrarily, in the more severe groups SF-6D was predominantly higher than EQ-5D. The regression model indicated a utility crossover point at 0.716 and predicted that individuals with a utility score less than this would score higher on the SF-6D than on the EQ-5D, and vice versa. The DASI score at crossover was calculated at 31.99. CONCLUSIONS: In subgroups of patients differing in CHF severity, mean EQ-5D and SF-6D indices differed significantly, implying that the two instruments are not interchangeable and the choice of instrument for measuring health-related utility can lead to variations in cost-utility analyses. Based on evidence provided here, discrepancies in the instruments’ measuring range generate utility differences which require further investigation.

Measurement of out-patient rehabilitation outcomes with EQ-SD

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OBJECTIVES: Experiences with generic health-related quality of life (HRQol) instruments in German rehabilitation facilities are very limited. The goal of this study was to assess the applicability of EQ-5D as part of the quality management system in a sample of neurological and orthopaedic patients. METHODS: The assessment was implemented as part of the regular optional patient satisfaction evaluation at the outpatient rehabilitation facility in Belefeld (Germany). Neurological and orthopaedic patients were surveyed by questionnaire at the beginning (T1) and the end (T2) of rehabilitation treatment. The survey period was September to December of 2008. HRQol was determined by the German version of EQ-5D self-report questionnaire (European tariff) and EQ-VAS (visual analogue scale). Wilcoxon signed rank test was used for comparison of T1 and T2. RESULTS: In total, 99 patient cases (mean age of 52 years, 58% orthopaedic and 32% female) were included in the study. The mean of EQ-5D index score increased from 0.66 (SD = 0.18) to 0.74 (SD = 0.18) at the end of the rehabilitation period (statistically significant with p = 0.001). Mean VAS utility value improved significantly (p = 0.001) from 0.57 (SD = 0.21) at T1 to 0.69 (SD = 0.19) at T2. The percentage of patients with any problems decreased for all five dimensions (mobility: 49% to 32%; self-care: 21% to 12%; usual activities: 66% to 48%; pain/discomfort: 82% to 63%; anxiety/depression: 29% to 24%). CONCLUSIONS: EQ-SD showed good sensitivity and practicability for generic measurement of rehabilitation outcomes and could supplement existing compulsory quality management systems. A comparable and widely accepted assessment of outcome also would be of interest for payers (statutory health insurance and pension insurance), owners and patients.

Patient Completion of ePROs: To Phone or To Web?

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OBJECTIVES: To identify trends in patient completion patterns between two modes of administration for electronic patient reported outcome measurement. METHODS: Retrospective review of eleven clinical research projects in which the patients were offered the option of completing daily questionnaires with one of two modes: an interactive voice response (IVR) system or a web-based response (WIR) system. Both systems were available to the patient at every assessment, independent of the mode used in prior assessment. RESULTS: In the 11 studies, data were available for 29,078 patients from 15 countries. On average patients completed 42 (min:1, max:1424) assessments during their study participation. Across the studies 2.6% of patients completed all assessments using only IVR and 48.5% of patients completed all assessments using only IVR. Of those patients using both modes (N = 8408), only 12.3% completed an IVR questionnaire more often than they completed an IVR questionnaire and fewer than 1% completed an equal number of IVR and WIR questionnaires. Younger patients (<25 years old) completed more WIR (30.5% of their assessments) compared to older patients. Patients between 46 and 65 years old completed the fewest questionnaires using WIR (6.1% of their assessments). Patients in Serbia (N = 37) completed the most questionnaire using WIR (46.6% of their assessments). Patients in Czech Republic (N = 28), Finland (N = 7401), Italy (N = 32), and New Zealand (N = 7) completed the fewest questionnaires using WIR (<5.0% of their assessments). CONCLUSIONS: Most patients completed their assessments using the IVR. Despite having the option, most patients did not alternate between the two modes. Younger patients were more likely to complete the assessments using IVR. Further work is needed to evaluate whether the completion patterns are due to patient preference or driven by access to the chosen mode, particularly in some geographic regions.

FHS 14: A SPECIFIC QUALITY OF LIFE INSTRUMENT FOR PATIENTS WITH HAND-FOOT SYNDROME

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Hand-foot syndrome or palmar-plantar erythrodysesthesia is a common adverse effect of certain chemotherapy agents, such as cepaclitabine or pegylated doxorubicin, where it is estimated to occur in 50% of cases. However, there is no specific, validated clinical instrument to measure its intensity and its impact on patients, apart from NCI-CTC grading which is relatively insensitive and is not specific. OBJECTIVES: The aim of this study is to develop and validate a hand-foot syndrome-specific quality of life scale in order to be able to measure the impact of the condition on patients and secondly to be able to assess the value of certain specific treatments in this indication. METHODS: The questionnaire was developed after conducting a series of structured interviews...