and the variance-covariance matrix from the model. **RESULTS:** The advantages of this new approach over the traditional methods are two-fold: 1) The variance of Q-TWiST can be estimated directly, and 2) It is possible to restrict or to compare parameters across different health states. **CONCLUSION:** Q-TWiST represents a unique quantitative method to simultaneously evaluate the risks and benefits of treatment on successive health states. We present a single survival model that addresses data censoring, covariate adjustment and variance estimation. This new approach provides opportunities for expanded use of the Q-TWiST method beyond the clinical trial such that application to observational studies is possible.

Health Related Quality of Life Based Patient Reported Outcomes: Session 1

QL1

DETERMINING THE MINIMALLY IMPORTANT DIFFERENCE OF THE OVERACTIVE BLADDER QUESTIONNAIRE (OAB-Q)

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OBJECTIVE: The Overactive Bladder Questionnaire (OAB-q) assesses symptom bother and health-related quality of life (HRQL) among patients with overactive bladder (OAB) and has been shown to be reliable, valid, and responsive. The purpose of this analysis was to establish the instrument's minimally important difference (MID), which is the smallest difference in score that patients perceive as beneficial. **METHODS:** Data were from four clinical trials (1 US, 3 international), totaling 3426 patients. All trials involved 12 weeks of tolterodine treatment. Distribution-based (e.g., effect size, standard error of measurement (SEM), and half-standard deviation) and anchor-based approaches were used. **RESULTS:** The mean age of the 4 trial samples ranged from 58.7 to 61.3 years. Patients were predominantly female (65.0%) and Caucasian (87.8%). At baseline, half-standard deviation of the OAB-q Symptom Bother subscale ranged from 9.4 to 9.9, and SEM ranged from 7.00 to 7.28. Half-standard deviation of the HRQL subscales (Coping, Concern, Sleep, and Social Interaction) ranged from 9.8 to 15.6, with SEM ranging from 6.8 to 8.3. The OAB-q subscales had moderate to large effect sizes in all trials, with Symptom Bother having the largest effect sizes (range = −0.61 to −1.23). Anchor-based analyses found significantly greater OAB-q change scores were associated with greater patient perceived treatment benefit and satisfaction. The difference between change scores of patients perceiving "no benefit" and "little benefit" ranged from 6.9 to 16.8 for all scales except Social Interaction (4.3 to 7.8), with the majority of differences greater than 10 points (possible subscale scores range from 0 to 100). Greater OAB-q change scores were associated with greater improvements in micturition diary variables. **CONCLUSIONS:** Multiple methodologies provide strong justification for recommendation of a 10-point MID for all OAB-q subscales. This MID may be conservative for some subscales, however a uniform MID is recommended to facilitate instrument use and interpretation.

QL2

TESTING THE CROSS-WALK: SALVAGING CANCER SPECIFIC MEASURES FOR USE IN ECONOMIC EVALUATION

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OBJECTIVES: Clinical trials often include condition-specific measures that lack the attributes required for economic evaluation. This study reports on the investigation of models for estimating EQ-5D$_{index}$ (a generic, utility-weighted index of health status) from FACT-G and QLQ-C30 (two widely used cancer-specific measures.) **METHODS:** As part of an observational study in colorectal cancer FACT-G, QLQ-C30 and EQ-5D were administered to 223 patients in an NHS hospital one week after discharge following surgery. Alternative models for estimating EQ-5D$_{index}$ from the items of both cancer-specific questionnaires were evaluated. Items were treated as both continuous data or were dichotomised. These were entered as independent variables in a series of stepwise linear regression analyses with EQ-5D$_{index}$ as the dependent variable. Criteria for comparing model performance were pre-specified and included explained variance (r^2), Pearson correlation co-efficient (r) and mean absolute difference. **RESULTS:** More than 55% of the variance was explained by the model which employed continuous items and the estimated EQ-5D$_{index}$ correlated well with actual scores ($r > 0.65$). Items from FACT-G and QLQ-C30 performed equally well in this model. Less variance was explained by the model using dichotomised items ($r^2 > 0.40$) and the correlation between estimated and actual EQ-5D$_{index}$ was less pronounced ($r > 0.45$). Items from QLQ-C30 performed better than those from FACT-G in this model, but altering the cut-point to dichotomise the items had an appreciable effect on explained variance. Despite moderate to good correlation between actual and estimated EQ-5D$_{index}$ in both models, the mean absolute difference between these scores gave some cause for concern. **CONCLUSIONS:** Despite differences in item content, both QLQ-C30 and FACT-G generate viable estimates of EQ-5D. This is an important finding that allows for the conversion of data from studies where direct comparison is otherwise impossible. However, the technique requires further refinement so as to improve its performance.

QL3

"FAMIDIAL STUDY": ANALYSIS OF THE DIFFERENCES BETWEEN DIALYSIS PATIENTS AND THEIR CAREGIVERS (FAMILY CARERS, NURSES AND DOCTORS) ON DIALYSIS PATIENTS' HRQOL, AND OF THE FAMILY CARERS' HRQOL AND BURDEN

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OBJECTIVE: To assess the agreement between patients and careers (Familiar-FAM, Nurse-NUR and Physician-PH) on patients' HRQoL and to evaluate HRQoL and burden of FAM. **METHODS:** 221 patient-carrier pairs stratified by age and gender were randomly selected from 14 dialysis units: 152 hemodialysis-69 peritoneal dialysis. Patients' HRQoL was evaluated by patient and FAM, NUR and PH using EQ-5D (dimensions and Visual Analogue Scale-VAS). Patients and FAM answered the SF-36 (PCS-MCS) and Duke-UNK Functional Social Support (FSS). FAM also answered Caregiver Burden Interview of Zarit (ZS); PH, the co-morbidity Index of patients; and NUR, patient's dependence in daily activities using the Barthel Scale (BS). **RESULTS:** The correlation coefficients between the VAS of the patients and their carriers were 0.42 (FAM), 0.49 (NUR) and 0.30 (PH); NUR and PH scored VAS higher than patients (p < 0.01). The agreement (Kappa) between EQ-5D dimension scores varied between moderate for Mobility (0.56-FAM; 0.55-NUR; 0.47-PH) and Self-Care (0.48-FAM;