CUAs has accelerated in recent years. Use of recommended methods has increased, although a sizeable number of analyses still do not adhere to best practice. Continued monitoring of these trends is crucial to enhancing the quality of the field.

**MC2**

**15DS—A NEW DYNAMIC QUALITY OF LIFE TOOL WITH INCREASED SENSITIVITY AND IMPROVED COMPOSITE STRUCTURE FOR RECALL BIAS AND RESPONSE SIFT ADJUSTMENTS**

Soini EI, Rymanen OP

1 Department of Health Policy and Management, Department of Social Pharmacy, University of Kuopio, Kuopio, Finland. 2 General Practice, Department of Public Health and Clinical Nutrition, University of Kuopio, Kuopio, Finland

**OBJECTIVES:** Response sift (RS) and recall bias (RB) cause problems in patient-reported outcomes (PRO). RS refers to the change of meaning in health-related quality of life (HRQoL) in pretest-posttest design. RB is the result of variation in the recall of earlier HRQoL states, satisfaction and symptoms. To present a new composite HRQoL tool for integrating contemporaneous items with recall/response items. The innovative aim of the generic 15Ds tool is the adjustment of RB/RS. METHODS: The widely utilized 1SD tool yields both 15-dimensional health profiles and an overall HRQoL index. The 1SD was promoted by the WHO health definition and the additive valuation of multi-attribute utility theory (MAU) to produce quality-adjusted life years (QALY). The 15Ds was innovated by the literature and pragmatic experience with the 1SD. RESULTS: The 15Ds contains 15 contemporary dimensions with five states (i.e. the conventional 1SD), 15 recall/response dimensions with six states for transitions, and three validation dimensions. The recall/response dimensions adjust subjects’ contemporary states for RB/RS. The validation dimensions contain a comparison of the subject’s general health state to the health of a same-age population (5 states), RB/RS comparison for health transitions (6 states), and comparison for the level of healing (illness conceptualization, 5 states). A preliminary analysis revealed that patients have more sensitivity for changes measured as the recall/response items than for changes in the contemporary items over time. The 15Ds gives slightly better outcomes in the index changes and offers higher discrimination for the changes of HRQoL when compared with the conventional 1SD. CONCLUSIONS: The 15Ds can produce 15-dimensional contemporary health profiles, 15-dimensional recall/response health profiles, overall HRQoL index for both 15Ds and 1SD, and approximations for the validation of transitions, health and illness. The 15Ds is recommended for recall (e.g. acute conditions when no baseline HRQoL is obtainable) and RB/RS adjustment.

**MC3**

**USING SIMULATIONS TO EXPLORE THE INFLUENCE OF COMPETING RISK ON TREATMENT-EFFECT**

Kent DM1, Hayward RA2

1 Tufts-New England Medical Center, Boston, MA, USA. 2 University of Michigan, Ann Arbor, MI, USA

**OBJECTIVES:** In previous work, we explored through computer-aided simulated clinical trials how heterogeneity of baseline risk can lead to heterogeneity of treatment-effect under a variety of assumptions. We now explore how heterogeneity of competing risks affects treatment-effect heterogeneity under a variety of assumptions. METHODS: Using simulated clinical trials in which the intervention has a constant effect on disease-specific risk (odds ratio = 0.7) but no effect on competing risk and in which outcomes in individuals are determined by varying 2 parameters: (1) the overall risk of the outcome of interest and (2) the ratio between the competing risk and the disease-specific (i.e. treatment-responsive) risk. RESULTS: Under conditions in the simulations, the odds ratio of the treatment-effect on the overall outcome is highly dependent on the ratio of the competing and disease-specific risk, decreasing as this ratio increases. Although the absolute treatment-effect increases with increasing overall risk, the odds ratio for the treatment decreases as the overall risk increases (holding constant the ratio between disease-specific and competing risk). When disease-specific outcomes are measured, a similar relationship between treatment-effect and overall risk is observed, although the decrease in the odds ratio with increasing risk is greatly attenuated. Detecting significant treatment-effect heterogeneity (on the odds ratio scale) based on competing risk is likely to occur only when competing risk is very high or when patients can be sub-grouped by variables which distinguish between disease-specific and competing risk. CONCLUSION: The ratio of competing risk to disease-specific risk in a population can have an important impact on the measured treatment-effect, even when disease-specific outcomes are measured. Detection of competing-risk-based treatment-effect heterogeneity may depend on the identification of risk factors that differentiate disease-specific from competing risk. Simulations can be useful to anticipate the magnitude of these effects when planning a clinical trial.

**MC4**

**BREAKING THE SILENCE: THE EFFECTS OF EXPLICIT INSTRUCTIONS ON INCORPORATING INCOME IN TTO EXERCISES**

Krol M1, Brouwer W1, Sendi P2

1 The institute for Medical Technology Assessment, Rotterdam, The Netherlands. 2 Institute for Clinical Epidemiology, Basel, Switzerland

**OBJECTIVES:** The recommendation of the US Panel to incorporate productivity costs in terms of health effects (QALYs) in a cost-effectiveness analysis aroused quite some debate. A crucial yet under-explored question in this debate is whether people include effects of ill-health on income in health state valuations (HSV). The same holds for the actual inclusion in HSV of the effects of ill-health on leisure. This study aims to test whether respondents to health-state valuations using TTO questions include the effects of ill-health on income and leisure when the measure is silent on both. Moreover, it tests the consequences of explicit instructions to either include or exclude the income-effects in HSV. METHODS: Three questionnaires were developed and administered among the general public. Respondents were asked to value three distinct EQ-5D health-states using TTO. In version 1 respondents did not receive instructions on including or excluding income-effects in their valuations, but inclusion was assessed afterwards. In versions 2 and 3 respondents were instructed upfront to incorporate income-effects or to assume that income would not change. They were furthermore asked whether they included the effects of ill-health on leisure-time in their HSV. RESULTS: In version 1 64% of the respondents spontaneously included income-effects in their HSV. In version 2 and 3 88% included leisure-time. There were no differences in the valuations of respondents including or excluding income-effects, also in case of explicit instruction. Inclusion of leisure-time resulted in a significantly lower TTO-value in only one of the three health-states. CONCLUSIONS: Respondents do not consistently include income- and leisure-effects in their valuations. Including income-effects (spontaneously or instructed) does not seem to affect TTO-valuations and may therefore best be placed on the cost-side of the cost-effectiveness ratio. Leisure-