430

and disability, issues often already assessed in trials and which may not be of direct concern to the respondent. Such assessments fail to account for interactions between health status and other influences on QoL, such as economic, social and environmental factors. The needs-based model argues that QoL is the extent to which individuals are able to meet their needs. Specific diseases influence different needs and interventions are effective where they allow more needs to be met. Relevant needs are identified from qualitative interviews with patients. The approach has been applied in the development of QoL instruments specific to depression, adult growth hormone deficiency, genital herpes, migraine, incontinence, urogenital atrophy, male erectile difficulties, rheumatoid arthritis, care givers of Alzheimer patients, ankylosing spondylitis, atopic dermatitis, psoriasis, lupus and psoriatic arthritis. All language versions of these instruments have excellent psychometric properties, are sensitive to clinical improvements and several are now the QoL instruments of choice for clinical trials.

CONCLUSIONS: The needs-based model provides a true "QoL" measurement that complements clinical assessments of health status.

THE RELATION OF DISTRIBUTION- AND ANCHOR-BASED APPROACHES ON INTERPRETATION OF CHANGES IN HEALTH-RELATED QUALITY OF LIFE Norman GR, Gwadry-Sridhar FH, Guyatt GH, Walter SD

Morman GR, <u>Gwadry-Sridhar FH</u>, Guyatt GH, Walter SD McMaster University, Hamilton, ON, Canada

BACKGROUND: Approaches to interpretation of quality of life changes in clinical trials have fallen into two camps: those that rely on the distribution of changes and the Effect Size (ES), and those that use some external anchor, such as patient judgements of change, which is then used to compute a Minimally Important Difference (MID), the proportion benefiting from treatment, p(B), and the number needed to treat (NNT).

OBJECTIVE: To examine the relationship between the ES and p(B), and the impact of the MID on this relationship.

METHODS: We used a simulation based on a normal distribution to compute the proportion of patients benefiting in both parallel group and crossover designs, for various values of the ES and the MID. We assessed the agreement of the simulation with empirical data from four studies of asthma and respiratory disease. We also examined the effect of skewness in the distribution of change scores on the relationship between ES and p(B).

RESULTS: The simulation showed a near-linear relationship between ES and p(B), which was nearly independent of the value of the MID. Agreement of the simulation with the empirical data was excellent. While the curves differed for crossover and parallel group designs, the general form was similar. Introducing moderate skew into the distributions had minimal impact on the relationship.

Abstracts

CONCLUSIONS: The proportion of patients who will benefit from treatment can be directly estimated from the effect size, and is nearly independent of the choice of MID. Effect size and anchor-based approaches provide equivalent information in this situation.

PMI26

ASSESSMENT OF RESPONDENT ACCEPTABILITY OF UTILITY MEASURES: DISCRIMINATORY POWER OF GRAPHIC POSITIONING SCALE VERSUS TRADITIONAL SCALING MEASURES

Franic DM¹, Pathak DS²

PMI25

¹The University of Georgia, Athens, GA, USA; ²The Ohio State University, Columbus, OH, USA

OBJECTIVE: To compare the discriminatory power of two different measures—graphic positioning scale (GPS) and traditional scale (TS)—in assessing respondent acceptability of three utility measures: standard gamble (SG), visual analogue scale (VAS) and willingness to pay (WTP).

METHODS: Two face-to-face interviews were conducted at least one week apart in a convenience sample of women aged 22 to 50 years with no history of breast cancer or cancer requiring chemotherapy. Study participation required completion of two surveys: one evaluating utility for an acute condition (post chemotherapy nausea and vomiting: PCNV), and the other, for a chronic condition (breast cancer). Data were collected between March 2000 and June 2000 at a University in the Midwest US. Respondents were randomized to either GPS or TA. A four-way, mixed-design analysis of variance (ANOVA)-2x(2x3x4)—was conducted, i.e., assessment (GPS/TS), condition (acute and chronic), utility (VAS, SG, WTP) and acceptability (difficulty, clarity, reasonableness and comfort). Each of the four levels of acceptability was measured on a nine-point Likert scale.

RESULTS: Analysis of 119 useable respondent surveys showed that condition, utility, and acceptability were significant main effects. Furthermore, ANOVA results suggested three significant interactions: condition and assessment; condition and acceptability; utility and acceptability. **CONCLUSION:** Results of this study support Narayana's (1977) findings in the marketing literature and indicate that GPS has higher discriminatory power than TS in assessing respondent acceptability of utility measures. These results can be explained by direct versus indirect comparisons made with GPS and TS methods respectively.

PMI 27

FACTORS INFLUENCING COMPLETION OF THE EUROQOL EQ-5D GENERIC QOL QUESTIONNAIRE

Hazell ML, Cropper JA, Frank TL, Frank PI North West Lung Research Centre, Manchester, UK