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 OoL, 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

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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. **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

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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

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PMI25

OBJECTIVE: Postal surveys only investigate HRQOL in those who return questionnaires and also complete enough information for analysis. Calculation of a single index of HRQoL (EQ-5D index) is impossible where data are missing. This study investigates completion of EQ-5D and the factors associated with non-completion.

METHOD: A postal questionnaire was sent to 10,471 adults registered to two general practices in Manchester. Non-responders received reminders after four and eight weeks. Demographic information for non-responders was obtained from general practitioner records. Indicators of social deprivation were obtained from the Regional Health Authority. EQ-5D rates 5 HRQOL domains on three levels with overall health state marked on a visual analogue scale (VAS) between 0 (worst) and 100 (best).

RESULTS: In total, 6838 (65.3%) questionnaires were returned; 5954 (56.9%) were complete. The self-care domain was missed most often (5.6% of responders) followed by anxiety/depression (4.4%), usual-activities (4.3%), pain/discomfort (4.1%), and mobility (3.9%). There was a significant difference in proportions between self-care and anxiety/depression (4.4% vs 5.6%, difference =-0.121, 95% CI of difference -0.195 to -0.0481). Four hundred thirty one people missed the VAS. Women were more likely to miss domain questions (10.2% vs 7.7%, chi² 12.67, p < .001) as were older respondents (mean age 47.6 vs 57.7 t -12.16, p < .001). Missing data were less common in those with further education or a degree $(10.3\% \text{ vs } 5.5\% \text{ and } 5.3\% \text{ respectively, chi}^2 46.4, p <$ 0.001). Social deprivation was more common in those who missed a question but this was not statistically significant.

CONCLUSION: Low levels of non-completion were found, although respondents were significantly less willing to answer about self-care than about other domains, possibly not wishing to appear dependent on others. The importance of analyzing the degree of non-completion of a questionnaire and possible associated factors should be noted. Future work is needed to investigate HRQoL in those who do not respond to or complete questionnaires.

CANCER

PCN 1

BASELINE ANEMIA AND RISK OF POOR RESPONSE TO CHEMOTHERAPY IN INTERMEDIATE GRADE NON-HODGKIN'S LYMPHOMA (IGNHL) PATIENTS

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Anemia at diagnosis (baseline) is a potential adverse prognostic factor for no response to chemotherapy in addition to the standard risk factors.

OBJECTIVE: The purpose of this study was to identify factors associated with baseline anemia and to determine risk factors associated with no response to CHOP chemotherapy in IGNHL patients.

METHODS: A historical case series sample of 591 patients diagnosed between 1993 and 1999, and treated in 12 practice sites with CHOP chemotherapy was used. Baseline anemia was defined as a hemoglobin (Hb) value <12 g/dl at baseline. Multiple logistic regression was used to determine factors associated with baseline anemia and model its relationship with response [no response (NR) versus partial response (PR) and complete response (CR)].

RESULTS: Anemia was present in 193/546 (35.3%) patients. Baseline Hb values were not available for 45 patients. Multiple logistic regression showed that baseline anemia was significantly associated with elevated LDH (OR; 95%CI) (OR = 2.74; 1.66–4.50), presence of B symptoms (OR = 2.16; 1.22-3.83), stage III-IV (OR = 1.81: 1.10-2.93), male gender (0.42: 0.25-0.69), and large cell diffuse (OR = 2.05; 1.19-3.54) or immunoblast (3.99; 1.78-9.02) histologic types. No significant interactions existed between any of the variables included in this model. Multiple logistic regression (predicting NR versus CR/PR) showed that the presence of baseline anemia (OR = 2.29; 1.10-4.74) controlling for elevated LDH, advanced Stage III-IV, and age greater than or equal to 60, was a significant risk factor for NR to CHOP chemotherapy.

CONCLUSION: The results support previous findings of the high prevalence of, and risk factors associated with, baseline anemia prior to CHOP chemotherapy. Baseline anemia was a significant risk factor for NR to CHOP chemotherapy, even after controlling for age, stage, and LDH. We conclude that additional studies with a comprehensive set of known risk factors validating this relationship between baseline anemia and response to CHOP chemotherapy are warranted.

PCN 2

COST OF TREATMENT AND FOLLOW UP OF BREAST CANCER. A RETROSPECTIVE EVALUATION IN A COMPREHENSIVE CANCER CENTRE

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OBJECTIVE: Breast cancer is one of the major causes of premature death for women. The management of its cost is important for both the national health insurance and the individual health-care providers. The objective of this study was to assess the global medical cost of breast cancer, from diagnosis to follow up, in a French medical centre.

METHODS: Our evaluation was based on a retrospective cohort of 120 patients followed from January 1995 to February 2000 at Centre René Huguenin (Saint-Cloud). Comprehensive treatment schemes and clinical events were reported from patients' medical files. Detailed medical consumptions and mean duration of staff occupation were obtained primarily from direct observa-