RECOMMENDATIONS ON HRQL/UTILITY DATA IN 14 EUROPEAN PHARMACOECONOMIC GUIDELINES

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OBJECTIVES: Health care decision-making processes, including public reimbursement of pharmaceuticals, fall under the responsibility of individual European states, with each country developing its own pharmaco-economic evaluation recommendations. Each guideline addresses HRQL and utility assessment issues but vary in content and approach. The objective of this study was to provide an understanding of these differences. METHODS: MEDLINE and government agency searches were performed to identify pharmaco-economic guidelines published in Europe. Recommendations on HRQL and utility evaluation were extracted and compared across guidelines. RESULTS: Guidelines on conducting health economic evaluation studies were found in 14 European countries. Ten were directly or closely related to the reimbursement authorities, while 4 had academic origin. Four different recommendations were proposed for evaluating HRQL outcomes: 1) Disease-specific and generic instruments should be used together (France, The Netherlands, Poland, Portugal); 2) Either specific and/or generic instruments should be used depending on the objectives of the health economic study (Belgium, Hungary); 3) Only generic HRQL measures should be used only (Denmark, Spain); and 4) Three types of HRQL instruments should be used simultaneously in health economic evaluations: generic, disease-specific and utility-based HRQL instruments (Italy). Four countries did not recommend preferred methods for HRQL evaluation in their guidelines (Germany, Finland, Norway, UK). With respect to utility assessment, there appeared to be some consensus across guidelines: the EQ-5D and the HUI are acceptable instruments for estimating utilities indirectly, while the time-trade-off and the standard gamble methods are the most accepted methods for the direct measurement of utilities. CONCLUSIONS: Although there appears to be agreement on the preferred choice of utility-based instruments, recommendations for psychometrically-based HRQL evaluation vary substantially across guidelines published in various European countries.

MEASURING POPULATION HEALTH FOR 191 COUNTRIES: WHO METHODS AND RESULTS

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OBJECTIVES: To measure average levels of population health for 191 WHO Member States in the year 2000 and for each subsequent year. WHO has recognized the fundamental need for cross-population comparable data on health and various other categories of evidence for health policy. This paper outlines the conceptual basis for the description and measurement of health embodied in recent WHO work. METHODS: WHO has developed new methods to improve the comparability of self-report data across countries, and used these in the WHO Multi-country Household Survey Study to obtain comparable measures of health state prevalences for 58 countries. For measurement purposes, health is operationalized in terms of levels on a core set of health domains, each characterized by a single cardinal scale of capacity. Healthy life expectancy (HALE) estimates are based on analysis of mortality for 191 countries, disability for 130 causes for 17 regions of the world, and an analysis of 63 health surveys in 55 countries. RESULTS: HALE at birth ranges from a low of 39 years for African women to a high of 72 years in developed countries. The equivalent “lost” healthy years range from 20% of total life expectancy at birth in Africa to 11–12% in the European and Western Pacific regions. The sex gap is highest for Eastern Europe and lowest in North Africa and the Middle East. CONCLUSIONS: The new methods used in the WHO Multi-country Household Survey Study have increased the comparability of self-report data across countries, a major step forward in the use of self-reported data on health. Health is conceptualized as a set of health domain capacities, rather than of quality of life, well-being or utility. Building on this experience, WHO is developing improved health status measurement techniques for a World Health Survey to be carried out in 2002.

PATIENT-DERIVED UTILITY ESTIMATES OF CHRONIC HEPATITIS C BASED ON EQ-5D AND RS SCORES

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OBJECTIVE: The objective of this study was to assess patient-derived utility estimates for clinical and histological health states representing variation in chronic hepatitis C (CHC) associated disease severity. METHODS: A total of 428 patients with CHC participated in a cross-sectional interview-based study using the utility measurement methods rating scale (RS) and EuroQol (EQ-5D). Current clinical and histological health status was...
assessed and assigned to an ordinal scale representing ascending severity of disease. Rating scale was transformed by the Torrance transformation. Multivariate stepwise regression with a log-transformed outcome was used to calculate utilities for the health states adjusted for age, gender, viral status, co-morbidity, and short-term effect of current antiviral medication. RESULTS: Quality-of-life values based on RS ($r = 0.24; p < 0.001$) and EQ-5D ($r = 0.13; p < 0.019$) showed significant correlation with the severity of disease scale. Overall, RS resulted in higher utilities than EQ-5D. Depending on health state and instrument, utilities ranged from 0.92 (mild hepatitis, RS) to 0.72 (hepatocellular carcinoma, EQ-5D). Short-term relative utility reduction during the time of treatment with combination therapy was 15% for RS ($p < 0.001$) and 14% for EQ-5D ($p < 0.001$). RS and EQ-5D were highly and significantly correlated ($r = 0.64, p < 0.001$) suggesting that the results are robust. CONCLUSION: Patients with CHC appear to experience a lower quality of life compared to the general population. This study suggests that the Torrance transformation of the rating scale or EuroQoL from patient reports are feasible and robust instruments for assessing patient preferences regarding quality of life. These results can be used in cost-effectiveness analyses in studies of patients with chronic hepatitis C.

**UT5**

**COMPARISON OF THE SF6D AND THE EQ5D IN PATIENTS REQUIRING CORONARY REVASCULARISATION**

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OBJECTIVES: Recently, a new index score to measure health status has been developed based on items from the SF36, the so-called SF6D. To assess its merits and validity we compared baseline and change statistics of the SF6D and the EQ5D in a group of patients undergoing coronary revascularisation. METHODS: A consecutive cohort of 535 patients enrolled in a randomised controlled trial comparing off-pump coronary artery bypass surgery (CABG) with on-pump CABG and percutaneous transluminal coronary angioplasty (PTCA) was administered the SF-36 and the EQ-5D questionnaires pre- and post-intervention. The SF6D “utility” was computed according to the scoring system that recently became available. RESULTS: We observed no differences in change score across the arms of trials. Therefore, data on all patients were analysed together. There were more missing in the SF6D than in the EQ5D: 12.7% versus 4.7%. All baseline and change variables had non-normal distributions. Although baseline mean values were comparable (SF6D 0.625; EQ5D 0.645, t-test: $p = 0.09$) median values differed significantly (SF6D 0.603; EQ5D 0.691, Wilcoxon matched pairs test: $p = 0.0009$). Median change from baseline as measured with the SF6D was significantly lower than change as measured with the EQ5D (0.024 versus 0.052, $p = 0.00002$). CONCLUSIONS: The SF6D and the EQ5D appear to result in similar baseline scores using the recommended mean values. However, both the median baseline values and change scores differed significantly. This indicates that the SF6D and the EQ5D measure different concepts of health status and cannot be used as equivalents.

**UT6**

**IMPROVEMENT IN HEALTH UTILITY AMONG RHEUMATOID ARTHRITIS (RA) PATIENTS TREATED WITH ADALIMUMAB (D2E7), A FULLY HUMAN ANTI-TNF MONOCLONAL ANTIBODY**

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OBJECTIVES: To establish whether treatment with adalimumab (D2E7, Abbott) improves health utility in patients with moderate/severe RA. METHODS: A total of 544 active RA patients from 10 European countries, Canada and Australia were randomized to receive adalimumab or placebo (other disease modifying anti-rheumatic drugs were discontinued). For 474 patients, the Health Utilities Index-Mark 3 (HUI3) measured health utility at baseline, month 3 and 6. An HUI3 score of 1 represents perfect health and 0 represents death. HUI3 change from baseline was estimated for each treatment group in a linear regression controlling for age, sex, country, and baseline disease severity (measured by the Disease Activity Score-28). This analysis includes the 430 patients with non-missing values for these variables. RESULTS: At baseline, HUI3 scores were comparable across treatment groups, but mean HUI3 (0.266) was far below population norms (patients with mild RA typically score above 0.70). Older patients and patients with more severe arthritis had lower HUI3 ($p = 0.034$ and $p < 0.001$, respectively). U.K. patients had lower HUI3 than patients from Australia ($p = 0.002$), Canada ($p = 0.011$) or Germany ($p = 0.016$). Sex was not a significant predictor of baseline HUI3 scores. At month 3, least squares mean HUI3 scores (controlling for age, sex, country and baseline disease severity) improved by 0.160 for the 40mg every other week adalimumab group, a statistically significant and clinically meaningful change compared to the placebo group’s 0.064 improvement ($p = 0.011$). At month 6, the improvement was 0.166 for the 40mg every other week adalimumab group compared to 0.078 for the placebo group ($p = 0.029$). Patients with more severe RA improved more than others ($p < 0.001$). Age, sex, and country were not predictors of improvement. CONCLUSIONS: Adalimumab monotherapy improves patients’ health utility by statistically and clinically meaningful amounts within three months of treatment initiation and sustains health utility at month 6.