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COMPARABILITY OF INTERVIEW AND SELF-ADMINISTRATION OF THE FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-TUBERCULOSIS (FACIT-TB) INSTRUMENT IN IRAQI PULMONARY TUBERCULOSIS PATIENTS

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OBJECTIVES: To investigate the extent to which two different modes of administration (interview by a trained interviewer versus self-administration) yielded a comparable estimate of health-related quality of life (HRQL) in pulmonary tuberculosis (PTB) patients. **METHODS:** The study was conducted between September 1st 2012 and July 31st 2013, among consecutive PTB patients treated at Thoracic and Respiratory Disease Specialist Centre in Baghdad, Iraq. The mode of administration of the Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB); a new tuberculosis (TB) -specific instrument, at baseline was registered in 305 subjects. **RESULTS:** Although the FACIT-TB was designed for self-administration, most patients in our sample (N = 193, 63.278%) requested some help from the interviewer to fill out the questionnaire. Mann Whitney U test showed that those patients capable of self-administration were younger (38.16 ± 12.93 versus 43.58 ± 16.41 years, P = 0.005) and required less time to complete the questionnaire compared to those who interviewed by a trained interviewer (14.64 ± 3.24 versus 17.22 ± 2.61 minutes, P < 0.001), while Chi-Square statistics showed that this group of patients had a higher education level (P < 0.001). No differences in gender were observed. HRQL score across all domains for those who interviewed by a trained investigator was slightly lower than those who answered the questionnaire by self-administration. However, the results did not reach statistical significance (P > 0.05). **CONCLUSIONS:** Technical equivalence has been demonstrated in the sample of PTB patients in Iraq. FACIT-TB instrument is flexible and it is able to accommodate the needs of patients with diverse social, educational, and functional skills. Technical equivalence across different modes of administration of questionnaire permits unbiased assessment of the impact of the disease and its treatments on patients' HRQL.

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HEALTH RELATED QUALITY OF LIFE IN CANCER PATIENTS: EVALUATION WITH A SELF-ADMINISTERED IPAD APPLICATION

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OBJECTIVES: Cancer has the second highest mortality rates after cardiovascular diseases in the world. Advances in treatment options caused significant enhancements in survival of cancer patients. However, the major parameter affecting treatment success and treatment adherence in these patients is the quality of life (QoL). We aimed to develop a self-administered iPad application for evaluation of QoL in a short questionnaire. **METHODS:** As part of routine practice in Preventive Oncology Department EORTC QLQ-C30 was administered to 1549 cancer patients treated in Hacettepe University Oncology Hospital. We determined 10 questions that explains most of the variation in QoL using factor analysis, and designed a new application for iPad, where patients can record responses themselves. **RESULTS:** The 10 factors that described by the factor analysis had the power of 74.2% explaining QoL variances. The reliability analysis of these factors showed a Cronbach alpha coefficient of 0.75. The new self-administered iPad application was tested in a pilot study that conducted in 127 patients taking chemotherapy regimens in the outpatient setting. The validity and reliability analyses revealed that the new application can be effectively used in Turkish cancer patients. **CONCLUSIONS:** Our results revealed that our software application will be useful and efficient for monitoring of the changes in QoL during their treatment course. Furthermore, this kind of mobile applications may be practical for health professionals in daily routine clinical assessments of patients. Also, the audio and visual enhancements in electronic applications provide increased accessibility for the cancer patients.

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THE SELECTION OF APPROPRIATE HEALTH STATE UTILITY VALUES (HSUVs) FOR HEALTH TECHNOLOGY ASSESSMENT (HTA): LESSONS TO BE LEARNT

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OBJECTIVES: Incorporation of health-related quality of life (HRQoL) evidence into economic models is a requirement of many countries for the purposes of Health Technology Assessment (HTA), and therefore appropriate health state utility values (HSUVs) are often sought. The objective of this review was to: (i) identify and summarise the principal limitations of HSUVs used in recent submissions appraised by the National Institute for Health and Care Excellence (NICE) and (ii) produce a categorical checklist that can be used by manufacturers to reduce uncertainty when selecting HSUVs for HTA. **METHODS:** Evidence appraisal documents for the 50 most recently published technologies assessed by NICE were retrieved in June 2014. Economic models were assessed and utility inputs reviewed. Critiques of the utilities reported by the evidence review group or final appraisal committee were extracted, reviewed and categorised. **RESULTS:** Of the appraisals reviewed (43 single technology appraisals (TAs) and 7 multiple TAs), utility inputs were either sourced from the literature (n=27), published mapping algorithms (n=11), de novo mapping algorithms (n=2), or derived from clinical trials (n=10). The concerns expressed by review groups can be categorised into four categories: (i) generalisability – relevance of HSUVs to UK clinical practice, deviation from NICE scope, and the use of other countries' valuations for health states; (ii) HSUV selection – inadequate justification of HSUVs, and lack of consideration for covariates and disutilities; (iii) mapping algorithms – use of non-validated or non-peer-reviewed publications, incomplete reporting of key model information, and ambiguity regarding selection and justification of mapping function; (iv) risk of bias – sample size, instrument response rates, and general study quality identified as factors affecting HSUV validity. **CONCLUSIONS:** The selection of appropriate HSUVs is critical to reduce uncertainty in economic

models. A checklist based on critiques of recent HTAs will be a useful tool for manufacturers when selecting relevant HRQoL parameters.

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TRANSLATION AND LINGUISTIC VALIDATION OF THE ELECTRONIC COLOMBIA SUICIDE SEVERITY RATING SCALE IN ASIA-PAC

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OBJECTIVES: The Columbia Suicide Severity Rating Scale (C-SSRS) has been developed into an electronic self-rated version (the e-CSSRS) in order to facilitate compliance with regulatory requirements for prospective monitoring of suicidal ideation and behaviours. The e-CSSRS v2.0 for IVRS has been translated and linguistically validated for use in over 60 countries. Whilst translating and linguistically validating the scale it was noted that particularly in the Asia-Pacific region there were some challenging issues around the concept of suicide from a linguistic and cultural perspective. This study aimed to determine what these issues were and highlight how they were resolved. **METHODS:** Eighteen reports were reviewed from the Asia-Pacific region. The languages were: China-Mandarin, India-English, India-Gujarati, India-Hindi, India-Kannada, India-Malayalam, India-Marathi, India-Tamil, India-Telugu, Korea-Korean, Malaysia-English, Malaysia-Malay, Malaysia-Mandarin, Philippines-English, Philippines-Tagalog, Singapore-English, Singapore-Malay, and Singapore-Mandarin. Each report was reviewed for challenges relating to translation and cultural adaptation. **RESULTS:** Across all reports specific homonymic confusions were encountered within two target languages: in Indian Hindi the same word is used for "pill" and "bullet"; in Singapore Malay the words for "end" and "saving" sound similar, occasioning confusion in prompts about attempts to end life. Translations were adapted to avoid these confusions. In two cases the use of a gun in suicide attempts was found to be rare or unknown: in Singapore English the relevant prompt was clarified to minimise confusion; for Malayalam for Kerala, where shooting is rare and hanging is common, "getting a gun" was changed to "getting a rope" wherever it appeared and for similar reasons "collecting pills" was changed to "collecting a poison." **CONCLUSIONS:** The e-CSSRS v2.0 IVRS is now available in for use in over 60 countries. Some issues were identified relating to translation and the methods of suicide in a small number of languages but these were resolved throughout the linguistic validation process.

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FROM CLINICALLY RELEVANT OUTCOME MEASURES TO QUALITY OF LIFE IN EPILEPSY

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OBJECTIVES: Utilities can be easily derived using generic quality of life (QoL) instruments. However, problems in collecting utility scores may occur because clinical evaluations still favor disease specific instruments over generic quality of life instruments for reasons of sensitivity and reliability. Especially in case of the fluctuating nature of seizures in epilepsy, generic QoL-instruments are often found to be unsuitable for outcome research. A proposed method to bridge the gap between clinically relevant outcome measures and QoL is to derive utility scores for epilepsy health states. The aim of this study is to develop a scoring algorithm to transform epilepsy health states into utility scores. **METHODS:** The proposed scoring algorithm was based on valuations of health states generated by the Time Trade-Off (TTO) method. The TTO was based on clinically important attributes (seizure frequency, seizure severity and treatment related side-effects). A full factorial design was used which resulted in 78 scenarios. Besides standard demographics, every participant was asked to value 10 or 11 different health states. A multilevel regression analysis was performed to account for the nested structure of the data. The TTO was conducted using online survey software. **RESULTS:** In total 531 subjects of the general population, with an average age of 42 years, have participated in the TTO study. Preliminary results show that the best health state (no seizures and no side-effects) is estimated at 0.89 utility and the worst state (seizures twice a day, many side-effects, type 5 seizure) is estimated at 0.16. **CONCLUSIONS:** This study provides a scoring algorithm for transforming clinically relevant outcome measures of epilepsy into utility estimates which can be incorporated into economic evaluations. Although seizure frequency is the most commonly reported primary outcome measure in epilepsy research, this study suggest that the impact of seizure severity alone should not be underestimated.

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AN ANALYSIS OF THE HEALTH TECHNOLOGY ASSESSMENT RECOMMENDATION AND GUIDANCE ON USE OF EQ-5D-5L IN COST-EFFECTIVENESS MODELING

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OBJECTIVES: Several national health technology assessment (HTA) bodies including the National Institute for Health and Care Excellence (NICE) for England and Wales recommend EQ-5D as the preferred health-related quality of life (HRQL) measure for use in cost-effectiveness analyses. This study aims to evaluate the recommendation and impact of using EQ-5D-5L versus EQ-5D-3L for cost-effectiveness modeling in HTA submission guidelines and subsequent reimbursement decisions. **METHODS:** A targeted review of national HTA submission modeling guidelines since the introduction of the EQ-5D-5L measure was carried out for the UK and France. The cost-effectiveness modeling guidelines were assessed for the requirements for EQ-5D at either level. The impact of guideline requirements on submissions were analysed by examining the presence of EQ-5D-5L in the 20 most recent technical appraisal manufacturer submissions for each HTA body. **RESULTS:** While all HTA bodies recommended the use of EQ-5D as a generic measure of HRQL, only NICE specifically recommended EQ-5D-5L. However, it was not a requirement. Of the latest published guidance only NICE and the Scottish Medicines Consortium had one EQ-5D-5L submission each. Despite evidence suggesting increased sensitivity and reduced ceiling