AuSCR Research Task Group approved projects

Title	Construct validation of the EQ-5D-3L questionnaire for identifying anxiety or depression in patients with stroke
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Summary	Many survivors of stroke have long-term psychological consequences that impact on their
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Many survivors of stroke have long-term psychological consequences that impact on their quality of life. The prevalence of anxiety and depression following stroke is nearly 50%, and it is associated with impaired function, distress, and poor overall quality of life in survivors of stroke.

The development and validation of instruments to identify anxiety and depression has become an important area of research. However, to demonstrate their validity, these instruments require evaluation in different disease populations. Eligible registrants of the Australian Stroke Clinical Registry are followed-up at 3-6 months following stroke and questionnaire data are collected including information on survival, living situation, perceived general health, and quality of life. Anxiety or depression measures using diseasespecific questionnaires, such as the Hospital and Anxiety Depression Scale (HADS), are not collected at the AuSCR follow-up. Instead, self-reported anxiety or depression is measured using the EQ-5D-3L questionnaire. EQ-5D-3L is increasingly being used in large populationbased studies and clinical registries to assess health-related quality of life as a measure of population health status to inform public health and health care policy. The EQ-5D-3L quality of life measure has been shown to have good internal consistency when applied to a general population and in groups of patients with chronic diseases, including stroke. However, to our knowledge there is no information on the validity of the EQ-5D-3L anxiety or depression domain as an indicator of anxiety or depression following stroke. The overall objective of the present study is to assess the construct validity of EQ-5D-3L anxiety or depression domain as a measure of self-reported mood disturbance in patients with stroke.

Our aim: To assess the construct validity of the EQ-5D-3L instrument as a measure of self-reported anxiety and depression following stroke.

In order to do this, the HADS questionnaire will be administered along with the EQ-5D-3L during the AuSCR 90-180 day follow-up procedure. The HADS is a sensitive 14 item questionnaire on anxiety and depression that is well validated in stroke and other chronic illness populations. It was originally developed to indicate the possible presence of anxiety and depressive states in the setting of a medical out-patient clinic. The HADS contains two 7- item scales: one for anxiety and one for depression. Each scale contains seven items, with each item rated from 0 (best) to 3 (worst). The scale scores are calculated by summing the responses to the items up to a maximum score of 21 points (severe case) per scale. A subscale score higher than 7 indicates a possible anxiety disorder or a depression.(18) Scale scores of between 8 and 10 identify mild, 11–15 moderate, and 16 or above severe cases of anxiety/depression. Good reliability and validity, and excellent screening properties have been reported for the use of the HADS in the general population and various clinical populations.

Sample size: 200

Construct validation is the extent to which a test measures what it is intended to measure. Construct validity will be investigated by determining the correlations between the EQ-5D-

3L anxiety/depression dimension and HADS. Spearman's Rank-Order Correlation or other appropriate measures of pairwise associations will be used to measure the correlations between questionnaire responses. We will consider correlation values of <0.20 to be a very poor correlation; 0.20-0.39 to be poor, 0.40-0.59 to be moderate, 0.60-0.79 to be good and >0.80 to be an excellent correlation.

The feasibility and acceptability of EQ-5D-3L will be investigated by calculating the percentage of missing values and inappropriate responses on each domain and VAS score. All analyses will be conducted using Stata version 12 (StataCorp LP, College Station, TX, USA) and statistical significance will be set at a p-value of 0.05.