Translational and Cultural Adaptation of Key Outcome Measures in International CNS Trials

Discussant

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Translational Adaptation of Outcome Measures

Use of diagnostic psychiatric, cognitive, or functional ability instruments outside of the settings they were developed for, is fraught with significant issues. This may arise from:

- User of instrument may not be from a discipline that is trained in use of psychological tests
- Subjects tested may differ on cultural and linguistic grounds from original development and standardisation groups
- Abnormal scores may be attributed to pathological processes rather than to factors such as education level, literacy, cultural differences in cognitive and perceptual information processing

This may result in diagnostic error of over-diagnosis of significant morbidity and unnecessary prescription, or under diagnosing and not treating underlying condition

Cognitive and Perceptual Processing Across Cultures

- Extent of potential distortion of psychometric properties of a test/scale/instrument that is translated from one cultural group to another is not well-appreciated
- Item Response Theory (IRT) posits that properties of a test can be described against the abilities in the population
- Cut-off scores used to “pass” or “fail” a test are based on the proportion of the population that can “pass” or “fail” the test
  - Assessment that an individual meets criteria for a diagnosis means an assessment that incorporates the position of the test within the overall range of the population
- Three psychometric properties of a test may be affected by language translation and by transfer across cultures
  - Difficulty of the test
  - Range of abilities/behaviours that it is able to discriminate
  - Ability to guess the correct answer

Each of the above may be altered in two ways: lowering or increasing the test difficulty

Cultural and Social Factors Affecting use of Translated/Transferred Scales (i)

- Issue is complicated by different cognitive and perceptual development in populations with different cultural and physical environment
- Different cultures are exposed to different perceptual and cognitive problems in daily life
  - "practice" means that certain cognitive processes may produce their outputs more automatically without need for conscious monitoring, i.e. different cultural groups are more "efficient" processing different problems

Cultural and Social Factors Affecting use of Translated/Transferred Scales (ii)

- Aboriginies posses superior ability in spatial localisation compared to European counterparts
- Oral spelling in some groups is more difficult in some languages due to clear phonetic forms used
- Written language may not have syllabic structure but relies on figure recognition and rote learning
- Sexual practices, taboos in one culture, may be normal in another
- Daily alcohol/cannabis/stimulant use, socially acceptable in some cultures is considered “illness” in another

Thus, test materials not validated for a cultural group may carry different psychometric properties, normative behaviour cut-offs, compared to the original group

What to do in International Clinical Trials or when using Translational Instruments (i)

- Gold standard: conceptualise, develop, test, validate instruments in actual population. Cut-off scores may differ
- Silver standard: translate with cultural adaptation, perform reconciliation, checking for linguistic distortion. Perform validation during study to support results
- Iron standard: translate/back translate/reconcile

What to do in International Clinical Trials or when using Translational Instruments (ii)

Different rules may apply to different measures

- Diagnostics instruments: require far greater standardisation
  - Diagnosis should not be made with translated instruments
  - Symptom presence/absence can be reliably assessed
  - Cultural factors will influence scores
- Outcome instruments: change is less affected
  - Impact of change may not be same in different cultures, as pathology ratings are impaired by cultural bias