

Title: Psychometric data monitoring in clinical trials: Can disparities between patient and clinician reported outcomes predict measurement error?

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Methodological question being addressed: Can disparities between patient and clinician reported outcomes in depression be used to predict measurement error?

Background: Ongoing psychometric data monitoring was applied to a randomized, placebo-controlled trial of a compound used to treat patients with Major Depressive Disorder. Data monitoring identifies potentially discrepant items in psychometric measures and targets those visits for discussion with the clinician. In particular, we reviewed data generated by a patient self-report HAMD using Interactive Voice Response (IVR) and the clinician administered MADRS. In this study we used the correlation between the MADRS administered by a clinician and the patient-rated HAMD using IVR as a proxy for risk of assessment error.

Methods: Data from 575 patient visits was analyzed using SAS 9.3 and correlations obtained across visits and between MADRS and IVR HAMD scores. The change in individual item scores across visits was also calculated to examine similarity and magnitude of change captured across scales.

Results: There was very weak correlation with poor significance between MADRS item Reported Sadness and HAMD item Depressed Mood (Spearman's $r = 0.055$, $p = 0.590$) at the baseline visit. MADRS Inner Tension and HAMD Psychic Anxiety had similarly weak correlations at baseline and visit 2 though the items across scales assessing both sleep and appetite had moderate to strong correlations across all visits.

Conclusions: We found that the two scales under consideration did not agree strongly and individual item correlations thought to measure similar constructs across scales had very weak or no correlation. Based on the results of interactions with raters that were targeted based on the discrepancies across scales, we found that the primary source of error was located with the rater.

Keywords: Treatment resistant depression, data-monitoring

Conflicts of interest: All employees are employees of Cronos CCS in Lambertville, NJ