Improving Administration and Scoring in CAPS-5

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THE METHODOLOGICAL ISSUE BEING ADDRESSED

The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) is recognized as the gold standard for clinical trial outcomes and is typically implemented using a structured pencil and paper clinical interview[1]. However, the scale's intricate administration and scoring processes have been noted to introduce the potential for increased error and variability among raters that may adversely impact data quality and signal detection.

INTRODUCTION (AIMS)

In an effort to reduce administration and scoring errors, an electronic (eCOA) version of the CAPS-5 was built by expert clinicians to provide administration and scoring guidance throughout the form[2]. Most importantly, this electronic version of the form automates the severity score at the item, symptom cluster, and total symptom severity levels, components often miscalculated and misinterpreted in the paper form.

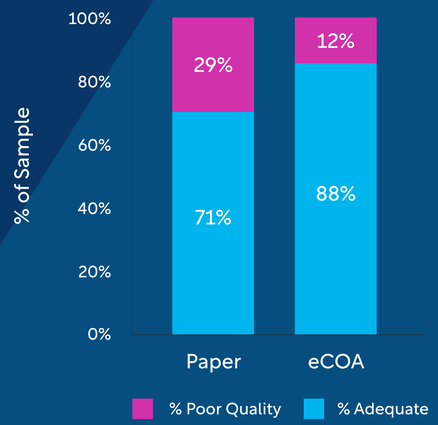
METHODS

Among clinical trial participants, CAPS-5 paper-based assessments (n=195) were compared to those administered on eCOA (n=356) by a team of calibrated reviewers using audio recordings and source data. The proportion of assessments with quality issues, such as scoring and administration errors, was calculated in both groups. To control for potential differences in disease severity between assessments with quality issues and those without, the predictive impact of severity on review outcome was also investigated.

Training for both groups of raters (paper and electronic) administering the CAPS-5 was identical and encompassed a didactic tutorial on the CAPS-5, covering development, principles of use, interview techniques, and scoring approaches. A post-test, mandating a minimum score of 80%, ensured comprehension. Trainees below this threshold underwent remediation and a subsequent retest. Following this, inter-rater reliability was evaluated through a videotaped CAPS-5 interview, compared against gold-standard scores. Attaining 80% agreement in this reliability exercise was required; those who did not meet these criteria underwent remediation and retesting. A final applied training session, led by scale experts, evaluated assessment techniques, adherence to scoring guidelines, administration protocols, and general knowledge about the indication and scale.

FIGURE 1

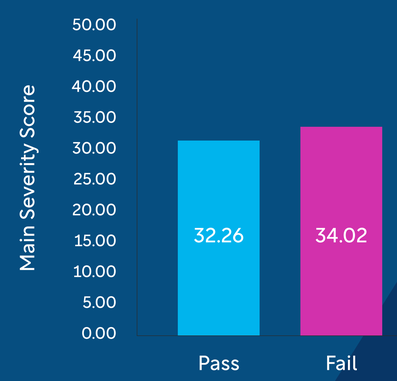
% Failures by Administration Type



Side-by-side comparison of % pass/fail rates between paper and electronic versions

FIGURE 2

Mean Severity Score by Review Outcome



Analysis of participants' severity scores aimed to assess the potential impact on raters' administration performance. The mean severity scores for both raters who passed and those who failed the administration were found to be similar, suggesting that severity scores did not significantly influence rater performance.

TABLE 1

	Fail	Pass	Total
eCOA	42	320	362
Paper	57	138	195
Total	99	458	557

Side-by-side comparison of raw data pass/fail rates was conducted between the paper and electronic versions

TABLE 2

Administration	Education	% of Raters
eCOA	MD or equivalent	33%
eCOA	PhD or equivalent	33%
eCOA	Master's Degree or equivalent	33%
Paper	Associates Degree or equivalent	1%
Paper	Bachelor's Degree or equivalent	2%
Paper	Master's Degree or equivalent	33%
Paper	MD or equivalent	43%
Paper	PhD (Doctorate) and Medical Degree (MD/DO)	6%
Paper	PhD or equivalent	15%

The analysis of raters' education demographics was conducted to assess potential impacts on scale administration performance. All raters in both studies held a minimum education level of a Master's degree or better in clinical psychology or a related field, coupled with at least one year of experience working with the population of patients with trauma disorders. The only exception to this criterion was for raters who received waivers

RESULTS

Paper administrations of the CAPS-5 evidenced over twice the rate of quality issues (29%) versus eCOA (12%) This difference was statistically significant ($X^2 = 26.948$, df = 1, p = 0.000000209). A binary logistic regression predicting review outcome from CAPS-5 severity score was not statistically significant (p = 0.432), providing no evidence that the patient's disease severity had an impact on whether or not an assessment had quality issues.

CONCLUSIONS

In PTSD clinical trials, rater error in CAPS-5 assessments is a source of variability, reducing power and increasing the risk of trial failure. The present study was intended to help evaluate the impact of utilizing an electronic adaptation of the scale in reducing rater error compared to traditional paper and pencil administrations. The use of an electronic platform, with real-time clinical guidance, automated scoring, and other features, can help standardize scale administration and scoring, substantially reducing error variance and improving signal detection.

DISCLOSURES

All authors are fulltime employees of WCG Clinical Endpoint Solutions.

REFERENCES

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2. Kobak KA, Feiger AD, Lipsitz JD. Interview quality and signal detection in clinical trials. Am J Psychiatry. 2005 Mar;162(3):628. doi: 10.1176/appi.ajp.162.3.628. PMID: 15741493.