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Error Rates and Data Integrity: eCOA versus Paper Administration of the PANSS

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The Methodological Question Being Addressed

Does the use of electronic clinical outcomes assessment (eCOA) impact rates of scoring errors as evaluated with the ISCTM Working Group Consensus method for PANSS data?

Introduction (Aims)

Clinical trials of schizophrenia are prone to high rates of failure, in part due to noise in endpoint data from several factors including rater error. Scoring inconsistencies are associated with low inter-rater reliability and low internal consistency. In this study, the utility of an electronic platform with built-in consistency checks in improving data quality in clinical trials is compared to paper-based administration in combination with other methods for improving data quality.

The Positive and Negative Syndrome Scale (PANSS) is a widely used, complex scale that has a very specific set of logical relationships and rules. Traditional paper-based administrations, which require manual data entry and source data verification, contribute to poor interrater reliability and inaccurate clinical trial results. The use of electronic COA (eCOA) has several advantages from operational and clinical standpoint, including eliminating calculation errors, reducing site burden, and standardizing measurements to improve data quality. The present study examined the utility of consistency checks in minimizing scoring errors in eCOA versus paper-based administrations.

Methods

eCOA administrations of the PANSS were identified from recent schizophrenia trials and compared against paper-based administrations of the same scale in a separate trial. All studies were randomized, double-blind, multisite clinical trials. Consistency/inconsistency flags assembled from the International Society for CNS Clinical Trials and Methodology (ISCTM) working-group were applied to both paper and eCOA administrations. The working-group had identified twenty-four flags, which ranged from within-visit scoring inconsistencies (e.g., a difference of more than two points between related items) to between-visit alerts (e.g., same response on all items from previous visit). The flags were divided based on extent to which they represented an error (Possibly, Probably, Very probably/Definitely). The proportions of flags that constituted an error were compared between paper-based and eCOA administrations.

Results

There were 4,714 paper-based and 4,231 eCOA PANSS assessments. The proportion of flags that represented highly probable/definite error was significantly higher in paper-based (13%) compared to eCOA (2%) administrations. The flags triggered with most frequency in paper administrations included tension (G4) should not be greater than anxiety (G2)

and same response on all items from previous visit. Overall, the inconsistency flags in paper administrations were comparable to those reported in the ISCTM working group, NEWMEDS (14.9%), which were both higher than those triggered in eCOA (2%) (as constituting an error).

Conclusion

Overall, eCOA PANSS administrations are less susceptible to scoring inconsistencies and error compared to those administered on paper. Clinical trials that utilize consistency checks in conjunction with an eCOA platform can benefit from standardized measurement and flags that alert to errors over the course of a trial. The continual data quality monitoring in this setting, coupled with rater training and remediation, can improve data quality and reliability of trials.