Do Interview Skills Matter? Assessing the Relationship of Rater Interview Quality and Clinical Trials Data Quality in 3 Psychiatric Trials

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ABSTRACT

Introduction (Aims): It seems intuitive that the quality of data acquired from clinician-administered research scales should be closely linked to the quality of the patient interview. Although a post-hoc analysis of an MDD trial suggested better drug/placebo separation for patients whose baseline raters had been deemed to be good interviewers (1), we are aware of no systematic assessment of the relationship between interview skill and data quality during the course of a psychiatric clinical trial. We assessed the relationship between interview skills and data quality by comparing algorithm-driven measures of data consistency at individual clinical trials visits with measures of inter-rater interview skill as assessed by independent experts via audiotape review using standardized interview proficiency criteria.

METHODS

2029 study visits were examined from three IRB/Ethics Committee-approved separately-sponsored international adult psychiatric clinical trials comprising 3 indications (ADHD, schizophrenia, bipolar), 143 sites, and nine countries. As part of the monitoring program for each trial, site clinician rating-scale interviews with study subjects at study visits were audiotaped and uploaded daily for review of interview quality by external experts using a standardized, validated research interview skills measure that assessed proficiencies such as asking questions neutrally, probing when subject responses were unclear, and over- or under-similar cross-visit patterns. For each site, independent raters scored data from the visit (n=143) and uploaded daily study-specific computerized error flags and interview skills assessment methodology. Independently, numeric scores data from the visit were uploaded and subjected to daily scale-specific computerized error flags including within-scale logical inconsistencies, unexpected cross-scale patterns, and overly similar or overly variable cross-visit patterns. To examine the relationship, if any, of interview quality and data quality, we compared dichotomized per visit quality concern occurrence (yes/no) for the interviews and the scores data for each visit against Exact Test analyses within and across the three trials.

RESULTS

In general, 52% of visits with an interview quality concern versus 13% without an interview quality concern had a data quality concern (See Figure 1).

CONCLUSION

In three separate studies, across three patient indications, with three sets of efficacy scales, deficiencies in site clinician interview skill at the per-visit level were significantly associated with poor data quality.

DISCLOSURES

1) Kobak, K.A., Feiger, A.D., Lipsitz, J.D. Letter to the Editor: Interview Quality and Signal Detection in Clinical Trials. American Journal of Psychiatry, Published online: March 01, 2005 http://dx.doi.org/10.1176/appi.ajp.162.3.628

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1) J0764; 2016; 10th Annual Scientific Meeting, 21-22 February 2017 – The Fairmont, Washington DC, USA

Poster presentation at the 2017 International Society for Clinical Trials Methodology; POSTER-108; No author information disclosed.