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 inconsistency at individual clinical trials visits with measures of same-visit clinician 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 9 countries. As part of the quality 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, integrating earlier subject comments, and refraining from comments about drug about drug (vs placebo) assignment. Independently, numeric scores data from the visit were uploaded and subjected to daily scale-specific computerized error checks including predefined within-scale logical inconsistencies, unexpected cross-scale patterns, pre-set discrepancies from independent expert scorers, and overly similar or overly variable cross-visit patterns (2). 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 via two-tailed Fisher Exact Test analyses within and across the three trials.

Results: In total, 7% (N=143) of the visits had an interview quality concern and 16% (N=326) had a data quality concern. Both within and across the 3 studies, the presence of an interview quality concern at a visit was significantly (positively) associated with the presence of a data quality concern at the visit (combined and individual p's < .0016). Overall, 52% of visits with an interview quality concern versus 13% without an interview quality concern had a data quality concern.

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. The findings serve to cross-validate the computerized data flags and interview skills assessment methodology. The findings have implications for surveillance, training, and risk-based models of monitoring, and raise the question whether data quality would be improved by interview skills remedial interventions provided during the course of a trial.

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 inconsistency at individual clinical trials visits with measures of same-visit clinician interview skill as assessed by independent experts via audiotape review using standardized interview proficiency criteria

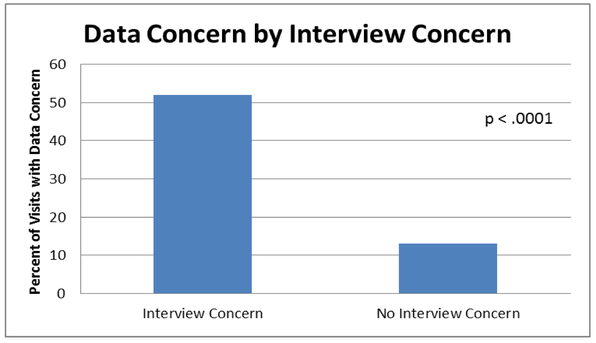
METHODS

- 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 9 countries
- As part of the quality 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, integrating earlier subject comments, and refraining from comments about drug (vs placebo) assignment
- Independently, numeric scores data from the visit were uploaded and subjected to daily scale-specific computerized error checks including predefined within-scale logical inconsistencies, unexpected cross-scale patterns, pre-set discrepancies from independent expert scorers, and overly similar or overly variable cross-visit patterns (2)
- 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 via two-tailed Fisher Exact Test analyses within and across the three trials

RESULTS

- In total, 7% (N=143) of the visits had an interview quality concern and 16% (N=326) had a data quality concern
- Both within and across the 3 studies, the presence of an interview quality concern at a visit was significantly (positively) associated with the presence of a data quality concern at the visit (combined and individual p's < .0016)
- Overall, 52% of visits with an interview quality concern versus 13% without an interview quality concern had a data quality concern (See Figure 1)

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
- The findings serve to cross-validate the computerized data flags and interview skills assessment methodology
- The findings have implications for surveillance, training, and risk-based models of monitoring, and raise the question whether data quality would be improved by interview skills remedial interventions provided during the course of a trial

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