INTRODUCTION

Blinded data analytics seeks to unobtrusively identify patterns of clinical trials ratings associated with poor quality data. Measures of function, such as the CGI, are particularly vulnerable to error because of their subjectivity and the requirement that the current rating period be compared to an earlier point in time (CGI-I and CGI-C). In schizophrenia trials, the problem is compounded by the multidimensional nature of schizophrenia symptoms. We have previously demonstrated that error rates in rating in clinical trials may be reduced in association with monitoring and intervention. The current analysis sought to determine the frequency and regional distribution of errors in usage of the CGI in a database derived from 10 global schizophrenia studies.

METHODS

Utilizing centralized, blinded data quality monitoring of CGI assessments in ten international schizophrenia clinical trials (79,500 visits), pre-defined patterns were utilized to detect inconsistencies in the relationship between the CGI-I and changes from baseline in the PANSS and CGI-S scores, respectively. Sites with unusually high error rates were subsequently subjected to more intensive scrutiny. Chi-2 analysis was used to compare error rates by region.

RESULTS I

For the CGI-I vs. PANSS total score change from baseline comparison the predetermined error criteria were flagged in 8.4% of visits. The association of geographic region on the error rate was statistically significant (chi-2 = 346, df = 4, p<0.001). Among the regions, Eastern Europe had the lowest error rate (5.7%, SE=0.183). The association between a change in rater across visits and the error rate was not statistically significant.

RESULTS II

For the CGI-I vs. CGI-S change from baseline comparison, the predetermined error criteria were flagged in 5.5% of visits. The association of geographic region on the error rate was statistically significant (chi-2 = 261.3, df=4, p<0.001). Again, among the regions Eastern Europe performed best (3.8%, SE=0.129). Errors were statistically significantly more frequent (by 17%) when there was a change in rater across visits (chi-2 = 8.05, df=1, p<0.01)

CONCLUSIONS

Blinded data monitoring can unobtrusively detect markers of poor data quality, identifying sites that may benefit from intervention. Errors in scoring the CGI are relatively common and vary in frequency by geographical region. The etiology of the regional effect is unclear. However, regional effects on data quality and clinical trial success have been reported by others.

REFERENCES