

of *Psychiatric Research* has been purchased by Elsevier, and a corporation has been formed to license MMSE commercial rights: MiniMental LLC of Massachusetts. MiniMental offers examination forms, guides, and software through Psychological Assessment Resources, Inc., of Florida for about \$1 per test. (Hardly exorbitant: \$1 per test represents less than 1% of the cost of a psychiatric evaluation and, probably, less than 1% of the cost of a day of psychiatric training.)

Computer professionals worry about stealth patents—patents held quietly until there is a market to control. Has psychiatry fallen afoul of a stealth copyright? For years, we taught trainees to use a copyrighted examination. Must they purchase examinations from Psychological Assessment Resources in order to conduct interviews without risk of a lawsuit?

Some might argue that this copyright was lost through lack of enforcement. Are MiniMental and Psychological Assessment Resources unaware that psychiatric centers have freely reproduced MMSE forms for years? Internet searches for “MMSE” yield many sites, even complete forms without mention of copyright. This makes for an interesting legal argument but one that is not certain to prevail in court.

Computer programmers established the Open Source Initiative to avoid copyright battles. Software contributed to Open Source Initiative is free for copying, with an understanding that refinements will be contributed back (5). Psychiatrists have *assumed* this model for years, openly publishing their techniques and technical improvements.

Psychiatrists need tests such as the MMSE and, like psychologists (6), should respect intellectual property rights. For teaching, we need consensus—teach any effective interview technique, even a commercial one, or teach only *open*, freely available techniques.

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Interview Quality and Signal Detection in Clinical Trials

TO THE EDITOR: The quality of assessments in clinical trials is an important methodological variable that is often overlooked. Few trials examine raters’ applied clinical skills, and no studies, to our knowledge, have examined the impact of interview quality on signal detection. Thus, the question as to

whether patients who receive high-quality clinical interviews are more or less likely to separate active drug from placebo has not been empirically examined.

Data were obtained from all raters (N=34) conducting outcome assessments in a phase II multicenter (N=20) antidepressant trial. All baseline Hamilton Depression Rating Scale interviews were audiotaped as part of an ongoing quality-control effort. A random sample of 25% (N=56) of the baseline audiotapes was reviewed by one of four external reviewers. Interviews were evaluated for interview quality along four dimensions with the Rater Applied Performance Scale (1): adherence to interview guidelines, use of appropriate follow-up questions, use of questions to clarify ambiguous information, and neutrality, i.e., avoiding leading questions that direct the patient toward specific responses. Each dimension was rated “unsatisfactory,” “fair,” “good,” or “excellent.” To protect the confidentiality of the study sponsor, only the active comparator (paroxetine) (N=109) and placebo (N=107) cells of the trial were made available for analysis.

Overall, paroxetine failed to distinguish itself from placebo (change in paroxetine: mean=9.72, change in placebo: mean=9.22, difference: mean=0.5) ($t=0.51$, $df=214$, $p=0.61$). However, subjects whose interviews were rated “good” or “excellent” did achieve significant drug-placebo separation (change in paroxetine: mean=11.61, change in placebo: mean=4.78, difference: mean=6.83) ($t=2.61$, $df=20$, $p<0.02$). The subjects with a mean baseline Rater Applied Performance Scale interview of “fair” or “unsatisfactory” failed to distinguish themselves from placebo (change in paroxetine: mean=7.56, change in placebo: mean=10.44, difference: mean=-2.88) ($t=-1.13$, $df=32$, $p=0.27$). The difference in drug-placebo separation for good ratings (6.84) was significantly greater than the drug-placebo separation for bad ratings (-2.88) ($F=6.46$, $df=1, 52$, $p<0.02$).

Interview quality had a profound impact on signal detection in this study. This points to the need for increased attention to the rater’s applied clinical skills in clinical trials. Training programs targeting applied clinical skills can be effective if sufficient time is devoted to this endeavor. Use of new technologies to train raters remotely using videoconferencing has been empirically shown to improve both didactic and applied skills (2). Rater training and rater certification (including applied skills), in addition to ongoing monitoring for rater quality, need to become standardized parts of clinical trial methodology (3).

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