THE ADAS-COG NAME ITEM: MORE TROUBLE THAN IT IS WORTH?

Selam Negash, PhD, MSc[1], Christopher Weber, PhD[1], Lori Garzio, MS[1], Christopher Randolph, PhD[1,2]
[1]MedAvante, Inc., [2]Loyola University Medical Center

INTRODUCTION

- The Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-Cog), the most widely used primary endpoint in mild-moderate Alzheimer's disease (AD) trials, is marked by high error rates in administration as well as scoring[1,2].
- This has led to the increased use of centralized oversight, including recording and review of these assessments.
- The quality control practice, however, is complicated by the 'Name' item on the Orientation subtest, which requires the subject to provide his/her own name.
  - This has implications with respect to release of personal health information, which can occur even in the absence of recording, if the rater mistakenly writes down the name on source documentation.

The goal of this study was to examine error rates on the 'Name' item of the ADAS-Cog, and the extent to which a score on this item contributes to the orientation score and also the total score.

METHODS

The C-Path Online Data Repository (CODR)

- The CODR was launched by Coalition Against Major Diseases (CAMD) at Critical Path (C-Path) in an effort to accelerate advances in AD therapeutic development[3].
- The database contains data from placebo arm of over 20 clinical trials of AD and MCI.
- Of these, there were four mild-moderate AD trials with scores on the 'Name' item of Orientation subtest. They generated a total of 6,185 responses to the 'Name' item.

MedAvante Central Review

- ADAS-Cog assessments from two double-blind, placebo-controlled mild-moderate AD clinical trials that were reviewed by MedAvante clinicians were also evaluated.
- This generated a total of 6,669 responses to the 'Name' item.

For both cohorts, the percentage of responses on the 'Name' item that were scored as "incorrect" was calculated. The correlations between the 'Name' item score and the total score were also examined.

Finally, internal consistency for the Orientation subtest was calculated with and without the 'Name' item by Cronbach's alpha.

RESULTS

- Table 1 shows the proportion of responses that were scored as "incorrect" out of the total Orientation 'Name' items for each cohort.
- For both cohorts, the percentages of errors on this item were very low (less than 1.5%).

Table 1
Incorrect Responses to the Orientation 'Name' item on ADAS-Cog

COHORT	Total Orientation 'Name' Items	"Incorrect" Orientation 'Name' Items
CODR	6,185	28 (0.45%)
MedAvante	6,669	83 (1.20%)

- Figure 1 shows the scatterplots for the 'Name' item and the Total Score for the CODR database (*1a*) and MedAvante cohort (*1b*).

Figure 1a
Correlation between Orientation 'Name' item and Total Score (CODR database)

0 = Correct
1 = Incorrect

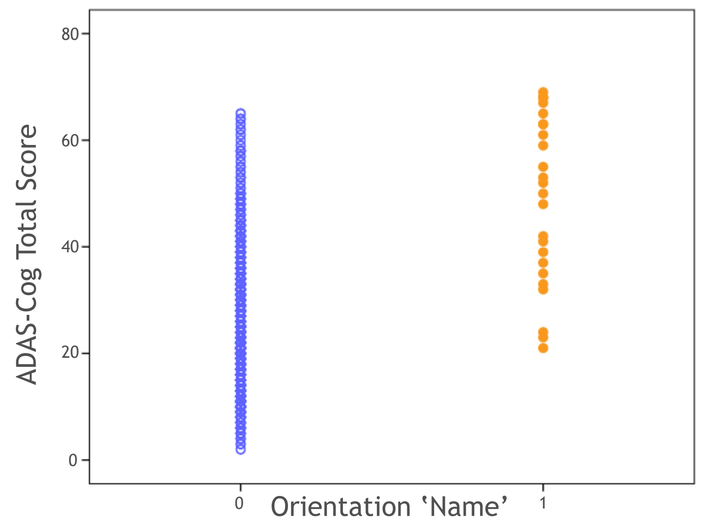
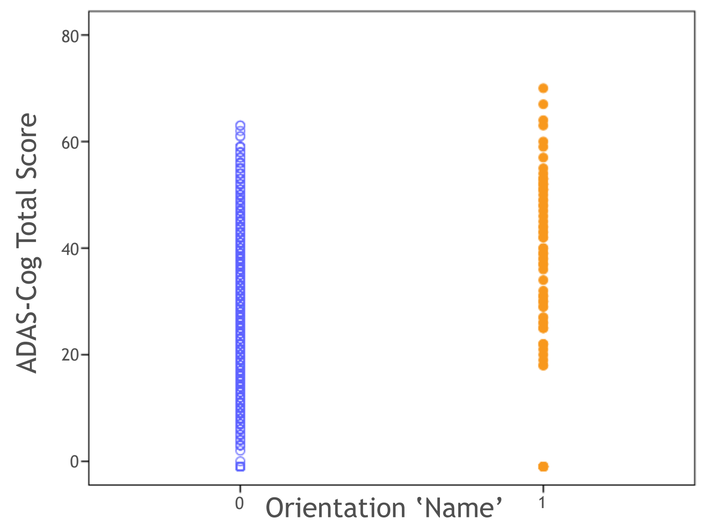


Figure 1b
Correlation between Orientation 'Name' item and Total Score (MedAvante cohort)

0 = Correct
1 = Incorrect



- The 'Name' item showed weak correlations with the total score for both CODR (r = 0.215) and MedAvante (r = 0.138) cohorts.
- Chronbach's alpha for the eight orientation items combined across the two cohorts was 0.934. Further, removing the 'Name' item did not affect the alpha value, indicating that it has weak internal consistency with the other orientation items.

CONCLUSION

- The 'Name' item in the ADAS-Cog has a very low error rate; as a result, it does not contribute to the variance in the total score.
- It also creates central oversight issues, conflicting with protected health information disclosure.
- **We recommend that the ADAS-Cog instrument be modified to eliminate the 'Name' item from the orientation subscale, and simply provide credit for that item in calculation of the total score.**
- **This will enable centralized oversight of the administration of this scale without the potential exposure of personal health information.**

References:
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