



POSTER PRESENTATION

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# A mixed-methods assessment of understanding (AoU) tool for AIDS vaccine trials in sub-Saharan Africa: results from a pilot study

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## Background

Assessments of understanding (AoUs) in clinical trials are often composed of true/false multiple choice questions, however, these tools can be difficult for volunteers with limited education or without prior testing experience.

## Methods

35 adults were recruited at two research centers in Southern Africa. A within-subjects, repeated measures design was used, whereby each volunteer served as his/her own control. An AoU tool with closed- and open-ended questions was administered within a hypothetical AIDS vaccine trial setting. Performance on closed- and open-ended questions was compared using correlations and repeated-measure t-tests, limited to 4 complex concepts: false sense of security, risk of false positive test, need for contraception, and potentially enhanced susceptibility.

## Results

Mean scores of understanding for each concept assessed by closed-ended questions ranged from 0.73 (need for contraception) to 0.84 (risk of false positive test); and by open-ended questions from 0.4 (risk of false positive test) – 0.6 (need for contraception). Scores for the open-ended measure were all lower than the equivalent closed-ended measure. Correlations between the closed- and open-ended measures were generally low, achieving significance for false sense of security ( $r=0.377$ ), potentially enhanced susceptibility ( $r=0.393$ ), and total score across concepts ( $r=0.617$ ). Volunteers' understanding as

assessed by the closed- and open-ended methods differed significantly: false sense of security = -3.862; risk of false positive test = -7.210; need for contraception = -2.303; and potentially enhanced susceptibility = -8.007. The correlation with years of education was consistently and significantly higher for the open-ended measure than the true/false questionnaire with the exception of need for contraception.

## Conclusion

The results suggest the qualitative measure better assesses understanding than the quantitative measure. The scores from the two assessment methods have limited interchangeability. The standard closed-ended questions appear to provide an inflated measure of volunteers' understanding. An assessment tool with closed- and open-ended questions is better suited to determine genuine understanding.

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