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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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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