Abstract #20

The Accuracy of a HIV Rapid Assay Based Testing Algorithm Using Whole Blood Specimens; a Field Experience

Abstract Category:	Point of Care Algorithms Using Combinations of Rapid Tests
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OBJECTIVE

To assess the sensitivity and specificity of a serial testing algorithm based on rapid HIV assays, performed on EDTA blood obtained by finger prick for the identification of possible HIV infection, used in a multi-centre phase III clinical trial.

METHODS

Quality assurance measures such as training sessions on the collection of whole blood by finger prick, the use and performance of HIV rapid tests, a bimonthly internal quality control testing program, batch control and supervision were implemented at all participating sites (Uganda, Benin, South Africa and India) before starting the trial. At follow up of HIV negative women whole blood was tested in a serial procedure using three different rapid tests (Determine HIV 1/2 (Abbott), SD Bioline HIV 1/2 3.0 (STANDARD DIAGNOSTICS), Uni-Gold HIV (Trinity Biotech)). When there was a discordant result between the Determine and SD Bioline tests, the third assay (i.e. Uni-Gold) determined the final outcome. The participant was only informed on her HIV status if the first positive algorithm was confirmed on a second whole blood specimen tested with the same rapid test algorithm. From all participants a final visit plasma sample was obtained and tested with the qualitative HIV RNA-PCR which was defined as gold standard.

RESULTS

On a total of 4297 specimens tested, the algorithm showed an initial sensitivity of 100% (95% CL: 90.0%-100%) and an initial specificity of 99.91% (95% CL: 99.8%-100%). Two out of 4 initial false positives tested negative on a second whole blood specimen. The two other tested twice false positive on different whole blood specimens taken the same day and negative on a plasma sample collected later. Conclusions: This serial rapid test based testing algorithm using whole blood obtained by finger prick is suitable for the identification of possible HIV infection in remote areas. Quality assurance measures should be implemented to guarantee good performance of HIV rapid test using whole blood.

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