INTRODUCTION

To validate OraQuick ADVANCE Rapid HIV-1/2 saliva based antibody test (SBT) against blood based rapid testing (BBT) in children aged 18 months to 18 years in Kenya and Zimbabwe.

METHODS

Antiretroviral therapy (ART)-naïve children were tested for HIV using a series of rapid BBT and SBT.

BBT followed Kenyan and Zimbabwean national algorithms

Determine (3rd and 4th generation in Kenya and Zimbabwe respectively), followed by First Response if Determine was reactive

SBT samples collected and interpreted by research staff

BBT performed and interpreted by clinic or research staff

Sensitivity and specificity calculated using BBT national algorithms as gold standard; secondary analysis excluded 2 cases where SBT was positive but national algorithm was initially falsely negative

Binomial distribution used for 95% confidence intervals [95%CI]

RESULTS

Excluding children where BBT was incorrect

- 2 truly positive children tested SBT positive and BBT negative
  - 9 year old, mom positive, confirmed positive by ELISA 1 week after initial BBT
  - 2 year old child was confirmed positive by First Response and INSTI

Excluding the 2 children

| Sensitivity: 100% (97.5% CI 94-100) |
| Specificity: 99.9% (97.5% CI 99.8-100) |

Stability of results (Kenyan sites)

- Among 43 children with positive SBT at 20 minutes
  - 43 (100%) had positive SBT at 40 minutes

- Among the 163 children with negative SBT at 20 minutes
  - 163 (100%) had a negative SBT at 40 minutes

Strength of test results from manufacturer reading cards (Kenya sites)

- Among 43 positive SBT results:
  - Strongly positive results:
    - 26 (60%) at 20 minutes
    - 29 (67%) at 40 minutes

- Weakly positive results:
  - 3 weakly positive at 20 minutes, all strongly positive at 40 minutes

CONCLUSIONS

- SBT tests have high sensitivity and specificity in ART-naïve children and adolescents
- Considerations to expand use of SBT in children are warranted
- As in adults, recommendations should include a warning not to use SBT in children on ART
- The ease and safety of SBT may allow HIV testing at outpatient triage or allow task shifting from HCW to caregivers
- Future research will explore the acceptability and uptake in diverse settings (in and out of facilities) as well as by diverse users (caregivers and HCW)

ACKNOWLEDGEMENTS

Global WACH, Kizazi, Kenya Research & Training Center (KRTC)
Study team and participants
Funding provided by University of Washington Center for AIDS Research and Thrasher Pediatric Research Foundation

BGAP study team
Funding provided by: Duke Global Health Institute, the UK Medical Research Council (MRC) and the UK Department for International Development (DFID) under the MRC/DFID Concordat agreement and is also part of the EDCTP programme supported by the European Union (MRP011268/1)