DIAGNOSTIC ACCURACY OF HIV ORAL RAPID TESTS VERSUS BLOOD BASED RAPID TESTS AMONG CHILDREN

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Introduction

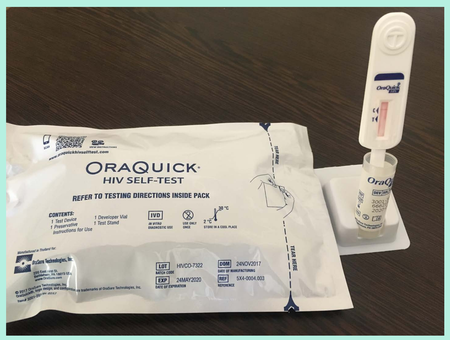
- Gaps persist in HIV testing globally for children who missed testing as part of prevention of mother to child transmission (PMTCT) programs
- Saliva based tests (SBT) have high sensitivity and specificity (98.0% and 99.7%) in adults but performance has not been established in children (18 months to 12 years)
- SBT may be less traumatic, easy to perform at triage, and pose less risk to health care workers than blood-based tests (BBT)

Objective

- 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

Table 1: Baseline characteristics

	BBT HIV positive n=71	BBT HIV negative n=1705
Child characteristics	n (%) or median (IQR)	n (%) or median (IQR)
Age (years)	6.8 (4.2, 11.0)	7.4 (4.7, 11.6)
18-<24 months	1 (1)	1 (0.1)
2-5 years	21 (30)	491 (29)
>5-12 years	34 (48)	811 (48)
>12-18 years	15 (21)	402 (24)
Female	46 (65)	872 (51)
Recruitment		
Zimbabwe	28 (39)	1542 (90)
Kenya	43 (61)	163 (10)

Table 2: Performance of SBT vs BBT

		BBT		
		Positive	Negative	Total
SBT	Positive	71	2	73
	Negative	0	1703	1703
	Total	71	1705	1776

Sensitivity: 100% (97.5% CI 94-100)
Specificity: 99.9% (95% CI 99.5-100)

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)

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BGAP study team

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