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Rapid serological tests ineffectively screen for HIV exposure in HIV-positive infants

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Abstract

Background—Data on the performance and utility of rapid serological tests in infants to determine HIV exposure are unclear and in some instances contradictory. This study sought to understand the performance of rapid serological tests in high HIV burden, high Option B+ coverage settings to be used as an HIV exposure screening tool.

Methods—A total of 3,600 infants up to 24 months of age at four regional hospitals in Uganda were systematically enrolled and tested simultaneously using both HIV rapid serological and nucleic acid-based tests.

Results—Only 58 of the 94 HIV-positive infants who received both rapid serological and nucleic acid-based tests were positive with the rapid serological test (sensitivity: 61.7%; 95% CI: 51.1 – 71.5). Using rapid serological tests to screen infants for exposure to HIV and follow-up nucleic acid-based testing would have missed 38.3% (36 of 94) of HIV-positive infants. Finally, several HIV-positive infants who were negative by rapid serological test presented to well child entry points and considered healthy. All three HIV-positive infants presenting to outreach and immunization were negative by rapid serological testing and 73% (8 of 11) presenting to outpatient.

Conclusions—These data suggest that the use of rapid serological tests may have inadequate performance as an indicator of exposure and potential HIV infection amongst infants presenting at both well child (immunization and community outreach) and sick-infant (nutrition and inpatient) entry points. In order to improve the identification of HIV-positive infants, nucleic acid-based testing should instead be considered in infants under 18 months of age.

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Keywords

EID; rapid serological tests; infants

INTRODUCTION

Achieving elimination of mother-to-child transmission (EMTCT) of HIV is a priority within the global HIV/AIDS community. Significant progress has been made in increasing access to antiretroviral therapy (ART) for pregnant women living with HIV as a critical step toward realizing this goal. In 2016, approximately 75% of HIV-positive pregnant women accessed antiretroviral treatment across 21 high-burden countries in sub-Saharan Africa¹. However, global EMTCT targets are far from being met, and tens of thousands of children are newly infected annually¹. Outcomes for HIV-positive children are substantially worse than those for HIV-positive women, as only 51% of children living with HIV are on ART¹.

Access to timely diagnosis for the estimated 1.2 million HIV-exposed infants in these 21-high burden countries remains a huge bottleneck to improving health outcomes for those who become infected¹. Early infant diagnosis of HIV (EID) and immediate linkage to care is critical to survival. Without treatment, peak mortality for infants infected *in utero* or *intrapartum* occurs between two and three months of age², and an estimated 50% of infected infants die by age two years³. Further, data from sub-Saharan Africa demonstrated that early initiation on ART for HIV-positive infants significantly reduced mortality^{4, 5}. In 2015, only 51% of HIV-exposed infants received a first nucleic acid-based test by two months of age¹. Thus, a large proportion of HIV-exposed infants received a first nucleic acid-based test either too late or not at all. These statistics suggest that more deliberate and conscientious efforts are needed to identify HIV-exposed and –infected infants for expedited linkage to care and treatment.

Provider-initiated testing and counseling (PITC) is a mechanism to identify those HIV-positive children who are not retained in, or never enter, the prevention of mother-to-child transmission (PMTCT) cascade of care but present at other pediatric entry points within health care facilities. In 2010 and 2016, the WHO recommended that HIV serological assays, including rapid serological tests (RDT), can be used to determine HIV exposure in an infant less than four months of age, to determine HIV exposure in infants with signs or symptoms suggestive of HIV infection, to exclude infection in HIV-exposed, asymptomatic infants at nine months of age, to identify HIV-exposed infants at nine months of age in need of referral nucleic acid-based testing, or to ascertain HIV diagnosis in infants older than 18 months of age^{6, 7}.

Prior to 2010, access to nucleic acid-based testing and early infant diagnosis was poor^{8, 9}. Rapid serological tests, already on the market and in widespread use for diagnosis of adults, were considered to support identification of HIV exposure in infants and in some settings as an aid to infant diagnosis due to easy access, decentralization of testing, and low costs. Rapid serological tests at that time were considered better than no test at all even if it was well understood that the performance for determining exposure and/or infection was sub-optimal, particularly as serological tests are unable to distinguish between maternal and

infant antibodies. However, as access to nucleic acid-based testing and early infant diagnosis continue to expand, are of good quality, and now reasonably priced, the utility and performance of rapid serological tests in infants has come into question^{1, 7, 10, 11}.

Data on the performance and utility of rapid serological tests in infants to determine HIV exposure and HIV infection are confusing and sometimes conflicting¹². Furthermore, it has been suggested that the performance could be different depending on the health of the infant^{6, 7}. We, therefore, sought to understand the performance of rapid serological tests to be used as a screening tool to accurately determine HIV exposure in infants presenting across the health care facility outside of PMTCT and the subsequent need for referral nucleic acid-based testing.

METHODS

This was a cross-sectional prospective study of infants below the age of two years presenting at primary health facility entry points at four hospitals in Uganda. The four hospitals included were: Mulago National Referral Hospital, St. Mary's Hospital Lacor Hospital, Mbali Regional Referral Hospital, and Mbarara Regional Referral Hospital. Infants were recruited from six facility entry points at each health care facility: Immunization (Expanded Program on Immunization)/well-child clinic, pediatric outpatient, pediatric inpatient, nutrition ward, outreach, and PMTCT, which was the traditional early infant diagnosis testing setting. A statistically determined sample size total of 3,600 infants less than two years of age were included in the study. One hundred and fifty infants were enrolled at each of the six entry points per hospital. Data collection occurred between September 2014 and August 2015.

Patients were systematically sampled and enrolled at each entry point. Due to low daily volumes (< 16 infants/day), consecutive enrollment was employed at the nutrition and PMTCT entry points. Systematic sampling across all attending patients was used within the immunization, pediatric outpatient, pediatric inpatient, and outreach settings due to high patient volume, to ensure unbiased patient selection. It was predicted that each entry point could enroll 15 infants per day per study nurse; therefore, if an entry point typically had 16–30, 31–45, or 46–60 eligible infants per day each study nurse would enroll every other, third, or fourth infant, respectively. Study systems were put in place to ensure no infant was enrolled at multiple entry points. The study objectives and study enrollment processes, including pre-HIV test counseling, were explained to the mother or guardian of each infant invited to participate in the study at non-PMTCT entry points before they signed a letter of informed consent.

Demographic and clinical data were collected for each infant and mother (if present) using standardized study-specific forms and study-specific identification numbers. All enrolled infants underwent both serological and nucleic acid-based testing to determine HIV exposure and HIV infection status, respectively. Dried blood spot specimens (DBS) were collected for nucleic acid-based testing and rapid serological tests using fresh capillary blood were conducted simultaneously for each patient. Both tests were conducted on each enrolled infant regardless of the respective results, except for infants at the PMTCT entry

point who did not receive serological screening as their exposure status was already known. Health care facility staff and laboratory technicians were blinded to the test results of the other. Health care facility staff, including nurses, clinical officers, and laboratory technicians, were trained on study procedures, how to conduct DBS specimen collection and rapid serological testing, and demonstrated proficiency before study commencement.

Rapid serological testing was performed using the Alere Determine™ HIV-1/2 (Waltham, MA, USA). One drop of whole blood was collected using a lancet heel stick, applied to the test strip, and tested per manufacturer's instructions. Either that same lancet heel stick or a fresh draw was used to collect an additional 3 – 5 drops of whole blood that were applied to a filter paper card (Whatman 903, GE Healthcare Biosciences, Pittsburgh, PA). Specimens were dried for four hours or overnight at room temperature and shipped weekly for testing to the Central Public Health Laboratories in Kampala, Uganda. Dried blood spot specimens were processed and tested with the Roche COBAS AmpliPrep/COBAS TaqMan (CAP/CTM 96) HIV-1 Qualitative Test (Roche Molecular Serologicals, Branchburg, NJ, USA) according to the manufacturer's instructions.

Any infant with positive rapid serological test or nucleic acid-based test result were referred to PMTCT for post-test counseling of their mothers and inclusion in care and treatment per the national standard of care guidelines.

This study was approved by the Mildmay Uganda Research Ethics Committee, Uganda National Council for Science and Technology, Mulago Hospital Research and Ethics Committee, Institutional Review Committee at St. Mary's Hospital, Lacor, and the Chesapeake Institutional Review Board in the USA.

Statistical analysis was performed with the R statistical software (Version 3.3.2, Free Software Foundation, Boston, MA, USA) and GraphPad Prism (Version 6.0, La Jolla, CA, USA). Infants from like entry points were pooled across hospitals for primary analyses. Additionally, infants presenting to the PMTCT entry point did not receive a serological screen as their exposure status was already known and thus were excluded from the analyses observing the performance of rapid serological tests to detect HIV exposure. Two-sample comparisons were done using the nonparametric rank-based Wilcoxon-Mann-Whitney and Fisher's exact test for continuous and binary outcome, respectively. Binomial probability confidence interval was computed using the Wilson method¹³.

RESULTS

A total of 3,000 infants were enrolled at non-PMTCT facility entry points (46% female) (Table 1). Approximately half of the infants included were eight months of age or younger (49%) and 70% of infants were 12 months of age or younger. The median age at study inclusion was nine months (IQR: 4 – 14 months). In the HIV-positive study population, 35% of infants were eight months of age or younger, and 51% were 12 months of age or younger. The median age at study inclusion for HIV-positive infants was 12 months (IQR: 6 – 17 months). Most (78%) infants were breastfeeding at the time of testing; however, less than half (43%) of the HIV-positive infants were breastfeeding at the time of testing. Fifty-eight

percent of infants had attended a health care facility at some point within the previous year for any health care services including immunization in all study groups.

Ninety-four HIV-positive infants and children were identified at the non-PMTCT facility entry points combined. Infants presenting to the PMTCT entry point did not receive a serological screen as their exposure status was already known and thus were not included in analyses. One infant was excluded due to an error in the nucleic acid-based early infant test that could not be repeated resulting in a total of 2,999 infants with both rapid serological and nucleic acid-based test results. The sensitivity of the rapid serological test to accurately detect HIV exposure was 61.7% (95% confidence interval: 51.1 – 71.5), while the specificity was 97.3% (95% CI: 96.6 – 97.8) (Table 2). The positive predictive value in this population was 42.3% (95% CI: 34.0 – 51.1). Of the 137 infants with a positive rapid serological test, 79 (57.7%) were HIV-negative by nucleic acid-based testing. The negative predictive value in this population was 98.7% (95% CI: 98.3 – 99.1). Of the 2,862 infants with a negative rapid serological test, 36 (1.3%) were HIV-positive by nucleic acid-based testing. Additionally, 58% (79 of 137) infants with a positive rapid serological test were negative by nucleic acid-based testing.

We next analyzed the sensitivity of rapid serological tests to detect HIV exposure across several age ranges (Table 3). Under one year of age, the sensitivity remained less than 50%. The sensitivity increased to approximately 75 – 85% between the ages of 12 – 24 months. Similarly, the positive predictive value of rapid serological tests was below 35% in infants less than eight months of age and increased to above 90% only at one year of age.

The median age of HIV-positive infants with a negative rapid serological test was 8.5 months, while the median age of HIV-positive infants with a positive rapid serological test was 14 months (Figure 1) (Wilcoxon p-value = 0.0067). Though HIV-positive infants with a negative rapid serological test were significantly younger than HIV-positive infants with a positive rapid serological test, over a third (36.1%) of rapid serological test-negative, HIV-positive infants were one year of age or older. Further, 38% of rapid serological test-positive, HIV-positive infants were one year of age or younger. Finally, there were no significant differences between HIV-positive infants with a positive rapid serological test and negative rapid serological test when comparing gender, breastfeeding status, or facility attendance.

Finally, though it was expected that most rapid serological test-negative HIV-positive infants would have been from entry points providing care to sick infants^{6, 7}, several were identified in healthy populations (Table 4). A third (25 of 80) of HIV-positive infants who presented to health care facilities sick (nutrition and inpatient entry points) had a negative rapid serological test. Twenty-five percent of HIV-positive infants tested at the nutrition entry point were negative by rapid serological test (15 of 59), while 48% of HIV-positive infants tested at the inpatient entry points were negative by rapid serological test (10 of 21). Interestingly, 100% of HIV-positive infants tested at the outreach and immunization entry points were negative by rapid serological test (3 of 3). Lastly, 73% of HIV-positive infants tested at the outpatient entry point were negative by rapid serological test (8 of 11).

DISCUSSION

The WHO recommends that rapid serological tests can be used to determine HIV exposure in an infant less than four months of age, to determine HIV exposure in infants with signs or symptoms suggestive of HIV infection, to exclude infection in HIV-exposed, asymptomatic infants at nine months of age, to identify HIV-exposed infants at nine months of age in need of referral nucleic acid-based testing^{6, 7}. Infants with a reactive rapid serological test should then undergo nucleic acid-based PCR testing. Our results, however, found that this approach had an unexpectedly low sensitivity (61.7%) and positive predictive value (42.3%). Though the population included in this study was of unknown HIV exposure, using rapid serological tests as a referral test to nucleic acid-based testing for this population per WHO guidelines would have resulted in missing approximately 38% (36 of 94) of HIV-positive infants due to having a negative rapid serological test. Interestingly, this population of rapid serological test-negative, HIV-positive infants had a median age lower than the rapid serological test-positive, HIV-positive infants indicating that perhaps they had not yet developed their own anti-HIV antibodies. Age alone, however, could not explain the poor performance of the rapid serological tests or lack of anti-HIV antibodies, as the box plots were significantly overlapping. The sensitivity of rapid serological tests to determine which infants required referral nucleic acid-based testing improved by age; however, the sensitivity remained at or below 80% up to two years of age. These results were likely due to the time the infants were infected, which could not be determined within this study.

A recent systematic review and meta-analysis observed better performance of rapid serological tests to determine exposure and HIV infection; however, it is important to note that all studies on this topic were conducted prior to 2008¹². Significant progress has been made in the last ten years in PMTCT, namely the significant increase in mothers receiving lifelong antiretroviral therapy for their own health and to reduce transmission (Option B+)¹. Expanded access to better drugs may have accounted for differences between these findings as it is possible that antiretroviral therapy, especially when provided soon after infection, can lower viral loads and thus antigen required to generate a robust antibody response and passive maternal antibody transfer^{14–17}. Likewise, the presence of antiretroviral prophylaxis in HIV-positive infants may similarly delay autologous antibody production. Maternal infections occurring late in the third trimester or during breastfeeding could also affect infant rapid serological test performance as infection would have occurred too late to allow for passive maternal antibody transfer. In contrast, however, a recent study in Kenya saw similar results to those presented here¹⁸. Twenty-three percent (11 of 48) of HIV-positive infants under eight months of age had a negative rapid serological test.

Interestingly, while it was expected that most, if not all, rapid serological test-negative, HIV-positive infants would have been sick, several healthy yet HIV-positive infants had a negative rapid serological test. Our results as well as those from the Kenya study, however, suggest that serological testing should not be performed in symptomatic or asymptomatic infants to determine who is in need of referral nucleic acid-based testing. Doing so would unfortunately likely result in 25 – 40% of HIV-positive infants being rapid serological test-negative and thus missed for receiving a critical nucleic acid-based diagnosis and follow-up linkage to antiretroviral therapy and care¹⁸. Alternatively, maternal testing should be

emphasized and prioritized as a more reliable mechanism to identify HIV exposure in infants less than 18 months of age. Known HIV-exposed infants or, on the rare occasion, infants whose exposure status cannot be ascertained through maternal testing should directly receive nucleic acid-based testing for diagnosis.

Though concerns have been raised about the cost of introducing nucleic acid-based testing at nine or 12 months of age instead of serological testing, there have been recent significant decreases in the cost per test for early infant diagnosis¹⁰. When considering the proportion of HIV-positive infants who would be missed for nucleic acid-based testing and thus potentially resulting in loss or death, the cost-effectiveness of implementing nucleic acid-based testing for all infants under 18 months of age may be high^{19, 20}. This is generally due to the testing intervention having a significant impact on life expectancy of such a young population. For example, adding an additional test in the algorithm (at birth) was cost-effective^{19, 20}. Furthermore, significant investments have been made to expand access to viral load testing of patients on antiretroviral therapy essentially dwarfing the small volumes and relatively low costs required to test all HIV-exposed, sick, or suspected infants using nucleic acid-based testing instead of serological testing.

Several limitations exist within this study. This study was not designed to determine the performance of serological testing to identify infants in need of referral nucleic acid-based testing in both well, asymptomatic infants compared to sick, symptomatic infants. Due to this, the sample size to observe this phenomenon in well, asymptomatic infants (those presenting at outreach and immunization entry points) was small. It is notable, however, that there were proportionally more false negative rapid test results in healthy infants compared to those who presented sick. Additionally, because we expected serological testing to successfully and consistently identify HIV exposure in infants, we did not conduct rapid serological testing for those presenting to the PMTCT entry point. Further, again because we expected serological testing to successfully and consistently identify HIV exposure in infants, though we provided maternal testing services within the study, maternal test results were not recorded. We were unable, therefore, to determine how many HIV-exposed yet uninfected infants were negative by rapid serological test.

These data suggest that the use of rapid serological tests and serological testing should be carefully considered before being used to determine either HIV exposure and infection in infants. As recommended by the WHO, serological assays should not be used in infants between 4 – 18 months of age to determine HIV exposure and instead should be determined through maternal HIV testing whenever possible⁷. Though rapid serological tests are significantly cheaper than nucleic acid-based testing, the focus of PMTCT and EID programs are generally to identify HIV-positive infants in need of antiretroviral treatment. By using rapid serological tests to identify infants in need of a referral nucleic acid-based test would result in a large proportion of significantly vulnerable HIV-positive infants to be missed and sent home without the necessary care and treatment. In order to improve identification and linkage of HIV-positive infants, nucleic acid-based testing should instead be considered in infants under 18 months of age.

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Figure 1.
Comparison of age by all and rapid serological test outcome among HIV-positive infants.

TABLE 1

Demographic characteristics of study participants

	Total, N = 3,000	Total, N = 2,905	Total, N = 94
	All infants	HIV-negative infants	HIV-positive infants
Gender, n (%)			
Female	1,390 (46)	1,347 (46)	42 (45)
Male	1,610 (54)	1,558 (54)	52 (55)
Age group, n (%)			
0–4 months	847 (28)	830 (29)	16 (17)
4–8 months	626 (21)	609 (21)	17 (18)
8–12 months	621 (21)	606 (21)	15 (16)
12–16 months	420 (14)	399 (14)	21 (22)
16–20 months	282 (9)	270 (9)	12 (13)
20–24 months	204 (7)	191 (7)	13 (14)
Median age, months (IQR)	9 (4–14)	9 (4–14)	12 (6–17)
Breastfeeding status, n (%)			
Currently breastfeeding	2,349 (78)	2,308 (79)	40 (43)
Not breastfeeding	635 (21)	582 (20)	53 (56)
Unknown	16 (1)	15 (1)	1 (1)
Facility attendance within 1 yr, n (%)			
Attended	1,741 (58)	1,676 (58)	64 (68)
Did not attend	1,227 (41)	1,197 (41)	30 (32)
Unknown	32 (1)	32 (1)	0 (0)

Performance of rapid diagnostic tests compared with reference laboratory virological/EID testing using the Roche CAP/CTM Qualitative HIV-1 Assay

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TABLE 3

Sensitivity of rapid diagnostic tests by age range

Age range (months)	0 – 4	4 – 8	8 – 12	12 – 18	18 – 24
Sample Size	7/16	8/17	7/15	25/31	11/15
Sensitivity	43.8%	47.1%	46.7%	80.6%	73.3%
Sample Size	7/62	8/24	7/13	25/26	11/12
Positive Predictive Value	11.3%	33.3%	53.8%	96.2%	91.7%

TABLE 4

The number and proportion of true positives and false negatives by entry point.

	True positives	False negatives	Total positives	Proportion of false negatives
Nutrition	44	15	59	25.4%
Inpatient	11	10	21	47.6%
Outpatient	3	8	11	72.7%
Outreach	0	2	2	100%
Immunization	0	1	1	100%