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Impact of Shifts to Birth Testing on Early Infant Diagnosis Program Outcomes in KwaZulu-Natal, South Africa

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Abstract

Background: South African early infant diagnosis (EID) guidelines shifted to recommending an initial HIV nucleic acid-based test (NAT) test at birth in 2015. Prior to this, initial NAT was recommended at 6 weeks of age. Here we examine parameters of EID performance in KwaZulu-Natal before and after this change.

Methods: Data on all HIV diagnostic NAT conducted for the province between January 2013 and April 2016 were assembled and analyzed. Laboratory barcodes allowed identification of repeat tests on the same child. We evaluated coverage, positivity rates, age at testing and frequency of repeat tests across birth cohorts.

Results: In birth cohorts 2013 and 2014, 62.1% and 61.8%, respectively, of tests <16 weeks were done in children 6 to 8 weeks of age. In birth cohort 2015, 41.3% of tests <16 weeks were done earlier at less than 2 weeks of age. The percentage of children with a positive result who had at least one follow-up test increased from 11.5% and 13.1% in birth cohorts 2013 and 2014 to 24.8% in 2015. The percentage of infants with an initial non-positive result who received at least one follow-up test did not appreciably change from 15.0% and 14.4% in 2013 and 2014 to 14.7% in 2015.

Conclusion: Birth testing allows for earlier identification of HIV-infected infants who need urgent antiretroviral treatment initiation. Although follow-up testing rates may be under-estimated in this data source, repeat testing rates remained low. More effort is needed to ensure infants tested at birth continue to be engaged in care and undergo follow-up testing.

Keywords

early infant diagnosis; testing coverage; pediatric HIV; PMTCT program evaluation; South Africa

Introduction

UNAIDS reported 7,800 AIDS-related deaths in South African children in 2015 [1]. The Children with HIV Early Antiretroviral Therapy (CHER) study established that early initiation of antiretroviral therapy (ART) could reduce mortality in HIV-infected infants by 76% [2]. A study in Johannesburg found that ART initiation was associated with a 71% decrease in risk of death [3]. This underscores the importance of early infant diagnosis (EID) as an opportunity to diagnose infants sooner and begin ART earlier.

South Africa's Ministry of Health HIV guidelines in KwaZulu-Natal began to include birth testing in April 2015. Prior to this, the testing guidelines recommended infants be first tested at age 6 weeks and 6 weeks after breastfeeding cessation. In 2015, the testing protocol was changed to HIV-testing at birth followed by a second test at age 10 weeks for all HIV-exposed infants and at age 16 weeks if the infant received 12 weeks of nevirapine prophylaxis. This schedule aimed to improve early identification of in-utero infected infants so they could initiate ART as soon as possible [4].

In 2016, the World Health Organization (WHO) consolidated HIV guidelines made a conditional recommendation to add an HIV nucleic acid-based test (NAT) at birth as part of the EID strategy. Prior to this, the recommended initial test was at 4–6 weeks [5].

We conducted a retrospective evaluation of the EID program in KwaZulu-Natal, South Africa. Cohorts born in 2013, 2014 and 2015 were evaluated for uptake of the program, age at testing, proportion testing HIV NAT positive and proportion of positive and non-positive infants who had at least one follow up test.

METHODS

Study Design and Data Collection:

All dried blood spot (DBS) specimens collected for HIV NAT testing from all infants in the KwaZulu-Natal public health sector are tested at the National Health Laboratory Services (NHLS) at Inkosi Albert Luthuli Central Hospital in Durban, South Africa. Qualitative HIV-1 total nucleic acid (TNA) PCR testing is done using the COBAS® AmpliPrep/COBAS® TaqMan® (CAP/CTM) HIV-1 Qualitative test Version 2 (Roche® Molecular Systems, Inc., Branchburg, New Jersey, United States). Results of all HIV NATs performed in KwaZulu-Natal for infants born after January 1, 2013 and before April 30, 2016 were retrospectively retrieved from NHLS for this study. HIV NATs performed between 2013 and 2014 should have followed the 6 week testing guidelines. HIV NATs performed in 2015 and 2016 should have followed the birth testing guidelines with a 10 week follow up test. Variables of interest from the dataset included laboratory barcode, date of blood specimen collection, NAT result, date of birth, sex, district and facility type where the specimen was collected. The laboratory barcode allows identification of repeat tests in the same infant. A subset of the database was checked through the TrakCare electronic medical record database to ensure individual infants were correctly linked. Of 20,000 records checked, 85% of infants were correctly linked based on their barcode. Unique children NAT-tested is the

number of total children tested regardless of how many individual NATs they may have received.

Study Sample:

Three separate datasets were received with HIV NATs completed in 2012–2013, 2014–2015 and January to April of 2016. There were 399,163 HIV NATs in total in these three datasets and 345,260 unique infants. The datasets were concatenated and all tests for infants who were born before January 1, 2013 (26,446) or after December 31, 2015 (30,468), had a NAT done outside of KwaZulu Natal (73), had an unknown birthdate (7,226), and were older than 18 months at the time of the NAT (939) were excluded. A total of 65,152 NATs were removed (Figure 1). The final database included 334,011 HIV NATs on 266,653 unique children.

Analysis

The data were imported into SAS 9.4 (SAS Institute Inc., Cary, NC) and were analyzed using frequency distributions over the 2013, 2014 and 2015 twelve-month birth cohorts. The age of first test was defined as the day the first NAT blood specimen was collected. If the initial test was non-positive (negative, indeterminate or rejected tests) and the follow up test was positive, the earliest positive test was used to calculate age of HIV diagnosis. Infant age at testing was calculated based on date of birth and date of testing. In some analyses, data were restricted to tests done before sixteen weeks because infants born December 31, 2015 could only have a maximum follow-up of 4 months until April 30, 2016.

Testing coverage was estimated by the ratio of the number of infants who were tested divided by the expected number of HIV-exposed births. The expected number of HIV-exposed births was calculated by applying the HIV seroprevalence rate among women of childbearing age 15–49 years in the Province to the number of live births registered [6,7].

Finally, we examined how follow-up testing changed across the three birth cohorts. Follow up testing was defined as an infant returning for any repeat testing that required a second DBS specimen. We examined rates of any follow-up NAT, rates of follow-up based on initial result, and consistency of results in the follow-up test if it occurred.

Lastly, chi-squared test for linear trend was used to evaluate the changes in program coverage, uptake and follow up across the three birth cohorts.

RESULTS

Early Infant Diagnosis Testing Coverage

Between 2013 and 2015, 266,653 infants received an HIV NAT. The total number of NAT-tested infants increased from 78,453 in birth cohort 2013 and 75,667 in birth cohort 2014 to 112,533 in birth cohort 2015 (Table 1). Between 2013 and 2015, there was a 43.44% increase in the number of infants tested.

The expected number of HIV-exposed births in KwaZulu-Natal declined over the three-year period. Restricting the analysis to unique infants tested less than 16 weeks of age, the

estimated coverage improved from 71.3% and 62.9% in birth cohorts 2013 and 2014, to testing more than the expected number of HIV-exposed infants in birth cohort 2015 (Table 1).

Testing Age and Test Result

Table 2 shows the frequency distribution for all tests by year of birth and includes age at test, test result and facility type. The proportion of infants with a positive NAT decreased from 2.73% to 1.42% ($p < .0001$) and the proportion of rejected tests declined from 5.08% in 2013 to 2.66% in 2015 ($p < .0001$). The overall proportion of infants with indeterminate NATs fluctuated across the years and there was a 41.67% increase in the number of test-indeterminate infants between 2013 and 2014 and a 38.24% increase in the number of test-indeterminate infants between 2014 and 2015 ($p < .0001$).

In 2013, 53,341 (67.99%) infants received a NAT between ages 4 and 8 weeks. In 2014, 49,262 (65.10%) tests were done between ages 4 and 8 weeks ($p < .0001$). There were 1,519 (1.94%) infants tested at < 2 weeks of age in 2013 and by 2015, 46,025 (40.90%) HIV NATs were done on infants < 2 weeks old ($p = 0$) (Table 2). The number of infants tested at an age older than 16 weeks decreased from 10,772 (13.73%) to 9,235 (8.21%) in 2015 ($p < 0.0001$).

In 2013, 12,002 (15.30%) infants were tested on specimens collected at a hospital and 66,451 (84.70%) infants received tests at clinics. By 2015, 40,313 (35.82%) infants were tested on specimens collected at hospitals and 72,223 (64.18%) infants were tested at clinics ($p < 0.0001$).

Age at first positive result

In 2013, 776 (36.19%) infants tested HIV positive between ages 4 and 8 weeks. In 2014, 592 (30.50%) infants tested HIV positive between ages 4 and 8 weeks. In 2015, 407 (25.45%) infants were diagnosed at < 2 weeks and 356 (22.26%) HIV-infected infants were diagnosed between 4 and 8 weeks ($p < .0001$) (Table 2). In all birth cohorts, a significant proportion of infants received a first positive HIV NAT older than age 16 weeks although this declined from 814 (37.97%) in birth cohort 2013 and 877 (45.18%) in birth cohort 2014 to 402 (25.14%) in birth cohort 2015 ($p < .0001$).

Follow Up Testing

Over three years, about 16% of infants age less than 16 weeks in each birth cohort year were retested with a second NAT using a separate blood specimen. The percentage of first test positive infants who return for a confirmatory positive tests increased from 15.63% to 31.16% between 2013 and 2015 ($p < .0001$).

Over three years the percentage of first test positive infants who had a confirmatory positive test result increased from 74.04% to 83.64%. The percentage of first-test negative infants who had a positive follow-up test result decreased from 1.50% to 0.74%. The percentage of first-test negative infants who had a negative follow-up test result increased from 93.94% to 97.04%. The percentage of first-test indeterminate infants who had a follow-up positive test

result decreased from 18.45% to 9.56%. The number of first-test rejected infants who had a positive follow-up test result increased from 1.20% to 2.37% between 2013 and 2014. However, this percentage decreased to 1.00% by 2015 (see Tables, Supplemental Digital Content 1A–C).

DISCUSSION

We evaluated the EID program for HIV-exposed infants born between 2013 and 2015 in KwaZulu-Natal, South Africa and found the estimated HIV NAT coverage of infants tested before age 16 weeks increased from 71.3% in 2013 to exceeding the expected number of HIV-exposed births in 2015. We estimated testing coverage based on the expected numbers of HIV-exposed infants. However, high-risk infants born to HIV-uninfected mothers may also have been tested. High risk included low birth weight, premature infants or infants who were symptomatic at birth [8]. In addition, repeat testing with a different barcode may have occurred. Hence our testing coverage estimates are likely to be overestimations.

Nevertheless, these data suggest the recent introduction of birth NAT in the EID program has improved the coverage of infant testing, and is similar to the high coverage rates achieved elsewhere [9]. The decrease in positive infant HIV NAT results may be attributed to the success of the PMTCT program, with 93% of HIV-infected women receiving ART during the antenatal period [10].

Overall there has been higher coverage of HIV NAT in the Province following introduction of birth NAT. High rates of facility delivery in the Province may explain the high testing coverage achieved. The move from clinic-referred specimens to hospital-referred specimens fits with an expectation that birth NAT would occur in a labor or post-delivery ward. The delivery may be an opportunity to link the infant to further care before mother and her infant are lost to follow up, which has been shown to significantly increase after delivery [10].

The positivity rate for infants has decreased from 2.73% to 1.42% for infants tested at any age and 1.97% to 1.16% for infants tested before age 16 weeks. Although birth testing required infants to return for a follow up confirmatory test, repeat testing rates in both test-positive and test-negative infants were consistently low, at around 16% over three years.

One of the primary challenges of birth testing is ensuring infants receive a follow up test to confirm the diagnosis. Although the testing guidelines changed in April of 2015, some hospitals and clinics may have been slow to initiate birth testing. A study conducted in 2010 found that clinics were still following guidelines from 2008 despite a guidelines update in 2010 [12]. The low percentage of infants returning for a follow up test could be attributed to a lag in updated guideline implementation.

Despite testing guidelines, our data show that many tests occurred outside the designated time window indicated by cohort. Although the guidelines stipulated a 6 week test, 2,136 infants in 2013 and 2,289 infants in 2014 were tested before 4 weeks of age. In 2013, 56 (2.62%) of those tests returned positive and in 2014 56 (2.44%) tests returned positive. The 2013 testing guidelines recommended targeted birth test during this period for high-risk infants [8]. Further, the birth testing guidelines were implemented in April of 2015. After

taking into account a potential delay in implementation across hospitals and clinics, 40.9% of infants being tested at less than 2 weeks of age was appropriate. Infants born in the earlier part of the year would have received their testing under the older protocol, which accounts for the 28.99% of tests done between 4 and 8 weeks. Limited access could account for the number of infants tested at 16 weeks or older and the test could have coincided with an immunization appointment.

A mathematical model conducted in 2016 estimated that infants who receive birth testing are 54% less likely to return for a follow up test compared to those who receive a 6 week test [13]. The follow up testing data demonstrated a variation in whether an infant returned for a follow up test based on the initial test result. Lack of repeat testing in test-positive infants bodes poorly for the likelihood of early initiation of ART for infected infants. In 2013 and 2014, infants were tested at 6 weeks to detect all intrauterine and intrapartum infections. Infants who tested positive during this period would have received a confirmatory positive test at 16 weeks or 6 weeks post breastfeeding cessation [8].

Although 2015 guidelines dictated that infants return at ten weeks for a follow up test, approximately 70% of infants whose first tests were positive did not return for a follow up test in 2015. Infants who did return were tested much earlier than birth testing guidelines recommends. It is possible that infants who return for a vaccination appointment may receive a second HIV NAT during the same clinical visit. Alternatively, this may be seen as a marker of the return for initiation of ART, at which time the confirmation NAT is done. This further suggests improved linkage to care with the new EID approach.

Lack of repeat testing in test-negative infants raises concerns about missed intrapartum and early postnatal infections in those who tested negative initially [14]. In 2013 and 2014, infants who tested negative may have been required to return if there were clinical symptoms of HIV infection [8]. Still, in 2015 only 15% of infants who tested negative at birth returned for negative follow up testing. A study conducted in Western Cape, South Africa found that 49% of infants with a negative NAT returned for a follow up test within the first 182 days of life [14]. Our data showed that infants with first test negative results can take up to two or three times the amount of time to return for a confirmatory test when compared to their positive counterparts.

Indeterminate and rejected tests can be classified as missed diagnostic opportunities and are a problem for clinicians because they delay diagnosis [12]. The number of indeterminate tests increased from 240 (0.36%) to 596 (0.58%) for infants tested at less than 16 weeks of age. An indeterminate test may mean a very low viral load signal that makes it difficult for the test to detect. Additionally, if a mother becomes infected late into the pregnancy, the infant might have a lower viral load at birth leading to an indeterminate diagnosis. However, further investigation would need to be done to see why the proportion of indeterminates increased over the three years.

In 2013 our data showed that 59.43% of first test indeterminate infants and 52.03% of first test rejected infants returned for a follow up test. In 2015 this number had decreased to 46.30% and 31.87% respectively. By 2015 there was a 52% increase in the number of

infants being tested at less than 16 weeks. The implementation of birth testing meant a higher proportion of tests would need to be linked to their subsequent test result. This produced challenges of linking an unnamed infant to their subsequent test result and the introduction of a new barcode system, which health care workers were still unaccustomed to, resulting in an artefactual reduction in rates of follow up testing.

Limitations

Repeat testing in the same infant was detected via laboratory barcode but correct assignment of the unique barcode relied on health care workers being fully effective in implementing the system employed by the laboratory. Verification of correct linking via the electronic laboratory database revealed that 15% of infants may have been assigned new bar code due to clerical error. Hence our estimate of repeat testing is most likely an underestimation of infants who return for follow up testing. Despite this limitation, the low repeat testing rates are concerning and need further investigation and intervention.

Other limitations of the study include that the data we used provided information on when the infant was tested and the test result but did not provide details on whether the infant began ART which is a crucial component in the cascade of care. There was no information on the mother and whether she was diagnosed at an antenatal appointment or during delivery. This may influence the likelihood of returning for a follow up test. There was also no information on breastfeeding practices to evaluate whether transmission occurred through breastmilk. Lastly, the high sample sizes across each birth cohort most will likely show significance even with minor differences.

Strengths

Our data was representative of the entire province of KwaZulu-Natal with test results available from both hospital and clinic sites. Each patient record was complete because of mandatory fields on the laboratory information system. Therefore, the data should be representative of outcomes throughout each district in KwaZulu-Natal. Future research can look at patient outcomes for those infants who are diagnosed as HIV positive and if they are properly linked to care.

Conclusion

The introduction of birth testing increased the coverage of HIV testing in HIV-exposed infants in KwaZulu-Natal and reduced the age of HIV diagnosis. The benefit of early infant diagnosis can significantly reduce infant morbidity and mortality by allowing infants to begin treatment sooner. While more infants were tested earlier, the lack of confirmatory tests for most infants points to the need of increased education about the birth testing protocol and the necessity of the second test. Programmatic components that include adequate counseling of families about the importance of follow-up and active tracing of those in urgent need of care need to be strengthened.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1:
Exclusion Criteria, Total HIV PCR Tests and Total Number of Infants by Birth Cohort

Table 1:

Estimated HIV PCR testing coverage across birth cohorts 2013, 2014 and 2015 in KwaZulu-Natal, South Africa

	2013 Birth Cohort n or (%)	2014 Birth Cohort n or (%)	2015 Birth Cohort n or (%)	P value
Testing Coverage				
Number of births in the province	236,499	231,722	213,992	
HIV prevalence (%)	40.1	42.4	44.4	
Expected Number of HIV-exposed births	94,836	98,250	95,012	
Number of Infants Tested by < 16 weeks Tested <16 weeks	67,681	61,851	103,298	
Estimated coverage by < 16 weeks (%)	71.3%	62.9%	100%	P=.0003
Number of infants tested at any age	78,453	75,667	112,533	
Estimated coverage of testing (%)	92%	90.46%	100%	<.0001

Table 2:

Total number of HIV PCR tests by test result, age of test and facility type across birth cohorts 2013, 2014 and 2015 in KwaZulu-Natal, South Africa

	2013 Birth Cohort n (%)	2014 Birth Cohort n (%)	2015 Birth Cohort n (%)	P Value
Total Infants	78453	75667	112533	
Tests Result				
Indeterminate	336 (.43)	476 (.63)	658 (0.58)	<.0001 p<.0001
Negative	71,989 (91.76)	70,785 (93.55)	107,278 (95.33)	<.0001
Positive	2,144 (2.73)	1,941 (2.57)	1,599 (1.42)	<.0001
Rejected	3,984 (5.08)	2,465 (3.26)	2,998 (2.66)	<.0001
Total Infants Tested < 16 weeks	67,681	61,851	103,298	
Indeterminate	240 (.36)	329 (.53)	596 (.58)	<.0001 p<.0001
Negative	62,721 (92.67)	58,483 (94.55)	98,694 (95.54)	<.0001
Positive	1,330 (1.97)	1,064 (1.72)	1,197 (1.16)	<.0001
Rejected	3,390 (5.0)	1,975 (3.2)	2,811 (2.72)	<.0001
Age at First Test				
< 2 weeks	1,519 (1.94)	1,611 (2.13)	46,025 (40.90)	P=0 p<.0001
2 weeks > 4 weeks	617 (.79)	678 (0.90)	1,681 (1.49)	<.0001
4 weeks > 8 weeks	53,341 (67.99)	49,262 (65.10)	32,627 (28.99)	<.0001
8 weeks > 10 weeks	4,329 (5.52)	3,537 (4.67)	3,679 (3.27)	<.0001
10 weeks > 12 weeks	4,497 (5.73)	3,729 (4.93)	12,764 (11.34)	<.0001
12 weeks > 14 weeks	1,610 (2.05)	1,429 (1.89)	2,732 (2.43)	<.0001
14 weeks > 16 weeks	1,768 (2.25)	1,605 (2.12)	3,790 (3.37)	<.0001
Older than 16 weeks	10,772 (13.73)	13,816 (18.26)	9,235 (8.21)	<.0001
Age At First Positive Test^a				
< 2 weeks	38 (1.77)	37(1.91)	407 (25.45)	<.0001 p<.0001
2 weeks > 4 weeks	18 (0.84)	19 (.98)	44 (2.75)	.18
4 weeks > 8 weeks	776 (36.19)	592 (30.50)	356 (22.26)	<.0001
8 weeks > 10 weeks	133 (6.20)	117 (6.03)	88 (5.50)	<.0001
10 weeks > 12 weeks	154 (7.18)	135 (6.96)	141 (8.82)	<.0001
12 weeks > 14 weeks	123 (5.74)	81 (4.17)	74 (4.63)	<.0001
14 weeks > 16 weeks	88 (4.10)	83 (4.28)	87 (5.44)	.0026
Older than 16 weeks weeks	814 (37.97)	877 (45.18)	402 (25.14)	<.0001
Facility Type				
Clinic	66,451 (84.70)	62,516 (82.62)	72,223 (64.18)	P=0
Hospital	12,002 (15.30)	13,151 (17.38)	40,313 (35.82)	P=0

^a An infant may be diagnosed as positive on the 1st PCR test or a Follow Up Test. This includes the positive regardless of when it was taken.