Assessment of the impact of rapid syphilis tests on syphilis screening and treatment of pregnant women in Zambia

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Abstract

Objective: To evaluate the impact of rapid syphilis tests (RSTs) on syphilis testing and treatment in pregnant women in Kalomo District, Zambia.

Methods: In March 2012, health workers at all 35 health facilities in Kalomo Distract were trained in RST use and penicillin treatment. In March 2013, data were retrospectively abstracted from 18 randomly selected health facilities and stratified into three time intervals: baseline (6 months prior to RST introduction), midline (0–6 months after RST introduction), and endline (7–12 months after RST introduction).

Results: Data collected on 4154 pregnant women showed a syphilis-reactive seroprevalence of 2.7%. The proportion of women screened improved from baseline (140/1365, 10.6%) to midline (976/1446, 67.5%), finally decreasing at endline (752/1337, 56.3%) ($P < 0.001$). There was no significant difference in the proportion of syphilis-seroreactive pregnant women who received 1 dose of penicillin before (1/2, 50%) or after (5/48, 10.4%; $P = 0.199$) RST introduction with low treatment rates throughout.

Conclusion: With RST scale-up in Zambia and other resource-limited settings, same-day test and treatment with penicillin should be prioritized to achieve the goal of eliminating congenital syphilis.

Keywords

Antenatal care; Congenital syphilis; Penicillin; Rapid syphilis tests

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1. Background

Globally, it is estimated that approximately 1.4 million annual cases of syphilis occur during pregnancy [1]. A recent meta-analysis demonstrated that, among asymptomatic, untreated pregnant women with syphilis, fetal loss and stillbirth, neonatal deaths, and prematurity/low birth weight were 21%, 9.3%, and 5.8%, respectively, more frequent when compared with women without syphilis [2]. Treatment of syphilis-seroreactive pregnant women with 1 dose of intramuscular penicillin at least 30 days prior to delivery reduces the risk of adverse pregnancy outcomes to that of a non-infected mother, although full treatment of latent maternal syphilis requires three doses of intramuscular penicillin [3-5]. However, modeling data suggest that less than 10% of women with syphilis during pregnancy are screened and appropriately treated [1], despite the 2007 World Health Organization's Global Elimination of Congenital Syphilis initiative goals of testing more than 90% of pregnant women and of treating more than 90% of those who are seroreactive by 2015 [6].

Recently-developed rapid syphilis tests (RST; BIOLINE, Korea) have a high sensitivity (85.7% to 100%) and specificity (96% to 100%), and do not require the traditional laboratory infrastructure used for rapid plasma reagin (RPR) tests [7-9]. Previous studies have suggested increased syphilis screening post-RST implementation, but longer-term evaluation of screening rates after initial training is needed [10]. In March 2012, the Elizabeth Glaser Pediatric Aids Foundation completed RST training and implementation in accordance with the Zambian Ministry of Health (MOH) guidelines [11,12] for antenatal care (ANC) staff in Kalomo District, Zambia. The present study evaluates the performance of RSTs and treatment of seropositive women in ANC facilities 12 months after RST implementation and describes the impact of RST use on ANC and prevention of mother-to-child transmission (PMTCT) services.

2. Methods

2.1. Study site selection and standard of care

Kalomo is a rural district with a population of 254 211 (2010 census) in an area of approximately 15 000 km^2 with one main tarmac road [13]. Prior to March 2012, RPR tests were used during ANC to screen for syphilis. In March 2012, 35 MOH staff from all 35 facilities in Kalomo received off-site training for RST and syphilis treatment, with intermittent on-site supervision at some facilities afterwards. Of these 35 facilities, 18 were selected by random-number generator, and included 1 urban district hospital, 2 urban health centers, and 15 rural health centers. All facilities provide antenatal PMTCT of HIV services, which at the time of the study included HIV testing, partner testing, and referral to antiretroviral therapy services, as well as under-five pediatric services, free of charge. The selected facilities had a mean of 39.3 first ANC visits per month (range, 8.5—70.3). The study population discussed herein included a random sample of pregnant women attending their first ANC visits at any of these 18 facilities.

2.2. Study design

The study followed a quasi-experimental evaluation design with baseline, midline, and endline comparisons. Data on pregnant women were retrospectively abstracted using facility registers from September 2011 to March 2013 and stratified into three intervals, namely baseline (6 months prior to introduction of RSTs), midline (0 to 6 months after introduction of RSTs), and endline (7 to 12 months after introduction of RSTs). The primary outcome was the proportion of pregnant women screened for syphilis at the first ANC visit. Secondary outcomes were: (1) the proportion of syphilis-seroreactive women treated with penicillin; (2) the proportion of women seroreactive for HIV and syphilis; and (3) the proportion of syphilis-seroreactive women with poor pregnancy outcomes (i.e. low birth weight (<2500 g), premature delivery (<37 weeks), stillbirth). For the purposes of the present study, stillbirth was defined as any birth outcome recorded by health facility staff as a stillbirth (fresh or macerated) in the Labor and Delivery register. The Zambian MOH training defines stillbirth as any fetus born at more than 28 weeks of gestation without a heartbeat [11].

2.3. Data collection

Ten data collectors from Kalomo District were trained and tested in research ethics, standardized data extraction, and management techniques prior to data collection. Data capture was done using TeleForms (Hewlett-Packard, Palo Alto, CA, USA) [14]. Pregnant women attending their first ANC visit during the observation period were randomly selected from the MOH-approved Safe Motherhood (SMH) register using a sequential skip pattern dependent on ANC volume at the facility. Facilities with less than 12 first ANC visits per month randomly sampled every other woman in the SMH register; all other facilities (with a range of 16—70 first ANC visits per month) randomly sampled every fourth woman in the SMH register across all three time periods. Women were identified by a unique SMH number and tracked across other MOH-approved, standardized registers, including the Integrated PMTCT register, the Labor and Delivery register, and facility RST logs. Abstracted data for analysis included information on (1) syphilis testing, (2) syphilis treatment, (3) HIV testing, and (4) delivery for mother/infant pairs. All women randomly selected from the SMH register were included in the analysis, even if they could not be traced to delivery. Stockout data for testing materials and penicillin were abstracted from facility pharmaceutical and supply logs. Baseline testing values were calculated using data from the 6 (33.3%) facilities that had RPR testing materials in stock. Twelve facilities (66.7%) were not performing antenatal syphilis screening prior to the introduction of RST and thus baseline data were not available for analysis. There was no documentation of any confirmatory RPR tests performed for any positive RSTs at the facility level. Verification and completeness of forms was done in the field by data supervisors. Forms were then sent to the central data processing office and scanned using TeleForm software, allowing for double-data entry compiled into a password-protected Microsoft Access (Microsoft, Redmond, WA, USA) database.

2.4. Data analysis

Differences in patient outcomes between index (baseline) and comparison groups (midline and endline) were calculated using Pearson's χ^2 test or Fisher exact test. A *P* value of less than 0.05 was considered statistically significant. SAS version 9.3 (SAS Institute Inc., Cary, NC, USA) was used for all analyses.

2.5. Ethics

The protocol for the study was reviewed and approved by the Boston University Institutional Review Board, the ERES Converge Zambian Institutional Review Board, and the Centers for Disease Control and Prevention's Associate Director for Science.

3. Results

3.1. Demographic and ANC characteristics

ANC data from 4154 pregnant women presenting to any of the 18 selected ANC facilities during the observation period were collected and analyzed (Table 1). ANC demographic data were missing for 19 women across all three time periods. Median gestational age at first ANC visit was 22 weeks (range, 7—39) across the three time intervals. The median number of visits for the study population was 1 ANC visit across all time periods (median, 1; range, 1—6).

3.2. Performance of syphilis screening

At baseline, 10.3% (140/1365) of women were screened for syphilis at their first ANC visit by RPR testing (Table 2). Within the first 6 months following the introduction of RSTs, testing increased to 67.5% (976/1446) of women across all 18 facilities, finally dropping to 56.3% (752/1337) at endline (*P*<0.001 for both midline and endline compared with baseline).

3.3. Syphilis and HIV seropositivity

Syphilis seroreactivity prevalence in the study population was 2.7% (50/1868), with no significant differences across the three time periods. HIV seropositivity was 4.5%, with no significant differences across the three time periods. HIV testing data was available for all 4154 women included in the study.

3.4. Treatment and birth outcomes of syphilis-seroreactive women

In the baseline group, 1 of 2 syphilis-seroreactive women was treated with 1 dose of penicillin. During the first 6 months following RST introduction, only 13% (3/23) of seroreactive women received 1 dose of penicillin, and 7—12 months after RST introduction, 8% (2/25) of seroreactive women received 1 dose of penicillin (Table 2). Timing of treatment was not reliably recorded. Birth outcome data from Labor and Delivery registers were available for 19.3% (802/4154) of women in the study population, 1.5% (12) of whom had tested syphilis seroreactive at their first ANC visit; these 12 women had documented live births, but birth weight and gestational age data were not available in the Labor and Delivery register. Treatment with at least 1 dose of penicillin was documented for three

women, but there was no documentation of treatment for the remaining nine seroreactive women or for infants for whom we had delivery data.

3.5. HIV and syphilis

At baseline, 28% (16/57) of HIV-positive women were tested for syphilis by RPR; at midline and endline, 86.8% (59/68) and 66.1% (39/59) of HIV-positive women were tested for syphilis, respectively. HIV-positive women were more likely than the general population to receive syphilis testing, regardless of the time period ($P < 0.001$; Table 3). Of the 114 women testing HIV-positive at their first ANC visit, 5.3% (n = 6) were also seropositive for syphilis, but only 1 (16.7%) woman positive for both syphilis and HIV was treated with penicillin. HIV testing rates were not affected by RST testing; across all periods, 81.2% (3374/4154) of women presenting to their first ANC visit received an HIV test, with no significant differences in HIV testing between time periods (Table 3).

3.6. Stockouts

Analysis of stockouts affecting testing uptake was performed for 15 of the 18 facilities evaluated in the study since three facilities did not have pharmaceutical and laboratory supply logs. During the baseline period, of the facilities that had RPR tests available, 33.3% (2/6) had documented periods of RPR stockouts, ranging from 8—20 weeks. During the midline period, 33% (5/15) of the facilities had documented stockouts of RSTs, ranging from 4—12 weeks, with a median stockout period of 6 weeks. During the endline period, 60% (9/15) of the facilities had stockouts, ranging from 1—16 weeks, with a median stockout period of 5.5 weeks. However, throughout the entire observation period there were no documented stockouts of penicillin at any health facilities according to the facility pharmaceutical logs.

4. Discussion

The present evaluation demonstrated that introduction of RSTs significantly improved syphilis testing uptake in the six months immediately after introduction; however, testing decreased to some degree in the 6—12 months following. These findings are similar to a prior study performed in Zambia [10], which demonstrated an increase in screening uptake from 17.1% to 95.6% (urban areas) and 36.9% to 96% (rural areas) with RST use, but only up to five months after RST introduction. However, there was no evaluation up to 12 months or assessment of potential drop-off after initial staff training. Recently, a Kenyan evaluation demonstrated increased testing uptake at 12 months following initial RST training, but did not provide data regarding initial use of RST immediately after training [15].

Stockouts of testing supplies occurred frequently, likely affecting screening coverage and performance after RST introduction. Analysis of stockout patterns demonstrated an increased number of facilities with RST test kit stockouts during the endline period, although the median length of stockout time was similar to that in the midline period. Nevertheless, the increase in number of ANC facilities experiencing stockouts during the endline period does not fully explain the lower rates of RST observed in the endline period compared with the midline period. Shifts in trained staff members and lack of sustained

on-site supervision may help explain the lower rates of RST use in the endline compared with the midline. Regardless, however, supply chain management remains a crucial aspect of implementing RSTs.

The syphilis seropositivity rate of 2.7% was comparable to values reported in other Sub-Saharan African countries [16]. The availability of treatment was extremely limited, with only 12% of seropositive women across all three time periods having received at least 1 dose of penicillin. Taking into account the missed testing opportunities, a smaller prevalence of syphilis was found in this district using RPR tests and RST (2.7%) compared with estimates from prior national survey data, which used RPR testing alone (4% to 7%) [17]. Prior studies in Zambia using RPR tests have demonstrated a wide variability, with syphilis seroprevalence rates of 12% being reported in pregnant women in Mongu, a rural district, and rates of 3.5% being reported in Lusaka [10]; a different study found a 6% seroprevalence rate among ANC attendees in Lusaka [18]. Variations in test positivity may be explained by differences in test technology, where the RPR test identifies a nonspecific antibody that can be present in the absence of syphilis, while RST assesses syphilis-specific antibodies [19,20].

Documentation of treatment was available for only a few women testing positive for syphilis. While significant differences between treatment rates were not observed, the sample size was too small to conclude any substantive change in treatment rates following introduction of RST. Further, it can be concluded that poor treatment rates were never a result of penicillin stockouts since these were not observed. Thus, the poor treatment rates observed are either due to the actual lack of provision of treatment or the dearth of treatment documentation. With the scale-up of RST implementation in Zambia and elsewhere, a focus on the treatment of seroreactive women is essential to ensure the intended impact of this investment. A recent article described similar results in Kenya, where no treatment data were recorded for any woman tested following the introduction of RSTs [15].

Women who were HIV positive were more likely to be tested for syphilis; indeed, 5.3% of HIV-positive women tested seroreactive for syphilis. However, co-infected women were not more likely to be treated with penicillin. Though there was a small sample size and low prevalence of syphilis documented in the study population, the proportion of women seen to be co-infected is larger than other estimates from Sub-Saharan Africa, with syphilis and HIV co-infection rates of 0.9% and 1.4% being recently observed in Tanzania [21,22]. Introduction of RST testing did not affect facility-level rates of HIV testing uptake for pregnant women, which remained above 77% at all time periods compared. Since 2007, all MOH facilities in Kalomo have had on-site monthly mentorship of PMTCT services, including HIV testing. This, coupled with the considerable length of time during which HIV testing has been a routine part of ANC care, may help explain the higher, consistent rates of rapid HIV testing compared with those of the similarly-performed RST.

In Kalomo, infant delivery rates at health facilities are generally low; 2007 data showed a 47% facility delivery rate [17] and unpublished data from a recent cluster-randomized control trial with active follow-up demonstrated a 51.3% facility delivery rate [Zambia Chlorhexidine Application Trial, in preparation; 2014]. The limitations of retrospective data

collection likely account for the much lower facility delivery rate of 19.3% seen in the present study. Poor documentation at the facilities limited our ability to trace women from antenatal records to delivery records, and to trace women delivering at a different facility than where they received ANC. Given the lack of documentation on infant data, it is impossible to draw any conclusions regarding infant outcomes.

Additional limitations to this retrospective study include its lack of generalizability, since it was performed in a single district, and its reliance on retrospective data from facility-based registers, making it impossible to distinguish between poor documentation and poor clinical practice. Reliable records of current facility staff previously trained in RSTs were difficult to obtain, thus making it challenging to determine whether the observed decrease in testing was due to untrained staff. Qualitative studies are needed to help identify factors affecting testing uptake at the facility level.

This evaluation demonstrates the adoption of new diagnostics in resource-limited settings after an initial training period; however, contrary to previously published studies [10], it demonstrates a drop-off in testing with time. The highest increase in testing uptake was observed during the first six months following RST introduction (including the introductory phase of RSTs). The initial increase in testing uptake then fell over the subsequent six months, albeit maintaining a significant increase from baseline. However, assessment of RST sustainability may be best conducted at a time point longer than 12 months following initial adoption of RSTs. Stockouts of RSTs impacted testing rates, but do not fully account for the drop-off in testing rates from midline to endline time periods. Trained staff shifts and lack of sustained RST supervision may also have contributed to this decline in testing rates.

Most importantly, the lack of impact that increased screening had on the treatment of syphilis-seroreactive women needs to be urgently addressed. All staff trained in RST should be trained in penicillin administration to optimize the benefits of RST, aiming to provide simultaneous same-day testing and treatment with a single dose of penicillin. Additionally, the dismal lack of information about infants born to syphilis-seroreactive women represents a dismal gap in care for these mothers and infants.

5. Conclusions

While the promise of point-of-care testing for treatable conditions such as syphilis is great, the challenge of sustaining new point-of-care technologies is considerable. Variables affecting testing performance include stockouts, trained staff turn-over, lack of sustained supervision after training, and overburdening of staff. Emphasis on sustained staff training, commodity management, and adequate data collection is required during RST scale-up in resource-limited settings. Further, through the RST scale-up in Zambia and elsewhere, appropriate treatment for women identified to be syphilis-seroreactive is essential for the elimination of mother-to-child transmission of syphilis.

Acknowledgments

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Table 1

Characteristics of pregnant women presenting to first antenatal care (ANC) visit.

	Baseline	Midline	Endline	Total	P value
Total no.	1361	1441	1333	4135	
Median gestational age, weeks (range)	22 (8–38)	21 (7–38)	21 (7–39)	22 (7–39)	
Median number of ANC visits (range)	1 (1–6)	1 (1–6)	1 (1–6)	1 (1–6)	
Number of HIV-positive women (%)	57 (4.2)	70 (4.9)	60 (4.5)	187 (4.5)	0.72

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Table 2

Proportion of pregnant women tested and treated. [a]

	Baseline (n = 1365)	Midline (n = 1446)	Endline (n = 1337)	Total (n = 4148)	P value
Received RPR as first test	140 (10.3)	0	0	140 (33.8)	
Received RST as first test	0	976 (67.5)	752 (56.3)	1728 (41.7)	<0.001
Positive first test	2 (1.4)	23 (2.4)	25 (3.3)	50 (2.7)	0.015
Received 1 penicillin dose	1 (50)	3 (13)	2 (8)	6 (12)	0.1992

Abbreviation: RPR, rapid plasma reagin; RST, rapid syphilis tests.

[a] Values are given as number (percentage) unless otherwise indicated.

Table 3

HIV and syphilis seroprevalence at first antenatal care visit. [a]

	Baseline (n = 1366)	Midline (n = 1449)	Endline (n = 1339)	Total (n = 4154)	P value
Women tested for HIV	1,121 (82.1)	1,225 (84.5)	1,028 (76.8)	3,374 (81.2)	0.33
Number of HIV-positive women	57 (4.2)	68 (4.7)	59 (4.4)	187 (4.5)	0.72
Number of HIV-positive women tested for syphilis	16 (28)	59 (86.8)	39 (66.1)	114 (60.9)	<0.001
Number of women positive for HIV and syphilis	0 (0)	1 (1.6)	5 (12.8)	6 (5.3)	<0.001

[a]Values are given as number (percentage) unless otherwise indicated.