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POLICY AND PRACTICE

Syphilis testing in antenatal care: Policies and practices among laboratories in the Americas

Minh Luu [a], Cal Ham [a], Mary L. Kamb [a], Sonja Caffe [b], Karen W. Hoover [a], Freddy Perez [b,*]

[a] Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA
[b] Communicable Diseases and Health Analysis Department, HIV, Hepatitis, Tuberculosis and Sexually Transmitted Infections Unit, Pan American Health Organization, Washington DC, USA

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ABSTRACT

Objective: To asses laboratory syphilis testing policies and practices among laboratories in the Americas. *Methods:* Laboratory directors or designees from PAHO member countries were invited to participate in a structured, electronically-delivered survey between March and August, 2014. Data on syphilis tests, algorithms, and quality control (QC) practices were analyzed, focusing on laboratories receiving specimens from antenatal clinics (ANCs). *Results:* Surveys were completed by 69 laboratories representing 30 (86%) countries. Participating laboratories included 36 (52%) national or regional reference labs and 33 (48%) lower-level laboratories. Most (94%) were public sector facilities and 71% reported existence of a national algorithm for syphilis testing in pregnancy, usually involving both treponemal and non-treponemal testing (72%). Less than half (41%) used rapid syphilis tests (RSTs); and only seven laboratories representing five countries reported RSTs were included in the national algorithm for pregnant women. Most (83%) laboratories serving ANCs reported using some type of QC system; 68% of laboratories reported participation in external QC. Only 36% of laboratories reported data to national/local surveillance. Half of all laboratories serving ANC settings reported a stockout of one or more essential supplies during the previous year (median duration, 30 days). *Conclusion:* Updating laboratory algorithms, improving testing standards, integrating data into existing surveillance, and improved procurement and distribution of commodities may be needed to ensure elimination of MTCT of syphilis in the Americas.
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1. Background

Syphilis infection during pregnancy is often devastating, resulting in severe adverse pregnancy outcomes in more than half of untreated cases [1]. Adverse perinatal outcomes caused by maternal syphilis infection can be prevented through the screening of pregnant women and by providing prompt treatment for those testing positive [2,3]. Furthermore, syphilis screening and treatment is recognized as one of the most highly cost-effective public health interventions [4], recommended as part of essential antenatal care (ANC) globally [5]. Despite this, preventable congenital syphilis infections continue to occur because pregnant women—especially those who are poor or living in rural settings—are often not screened according to national guidelines [6–8]. The most commonly used serologic screening tests for syphilis require specialized reagents and equipment and trained technicians—a laboratory capacity typically unavailable outside larger hospital or reference laboratories in most low- and middle-income countries [9]. However, globally, many pregnant women receive ANC at lower-level facilities without such laboratory capacity [6–8]. To date, little has been reported in the Americas region regarding the current state of laboratory-based syphilis testing, including the types of tests available, algorithms used, or testing quality.

Mother-to-child transmission (MTCT) of syphilis is a significant public health concern worldwide, including in Latin America and the Caribbean (LAC). In 2008, WHO estimated that, globally, 250 000 infants were born with congenital syphilis [10]. In the same year, more than one-third of the estimated 106 500 pregnant women infected with syphilis in LAC countries were not appropriately treated, resulting in approximately 33 000 adverse pregnancy outcomes [10,11]. In 2010, the Pan American Health Organization (PAHO) member countries approved the Strategy and Plan for Action for this first regional initiative supporting dual elimination, including country-level commitment to reducing incidence of congenital syphilis to 0.5 cases or less (including stillbirths) per 1000 live births [12]. Reaching the congenital syphilis elimination goals requires countries to achieve programmatic targets

* Corresponding author at: HIV, Hepatitis, Tuberculosis and STI Unit – CHA//HT, Pan American Health Organization, 525 23rd St NW, Washington, DC 20037, USA. Tel.: +1 202 974 3486.
E-mail address: perezf@paho.org (F. Perez).

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of routine syphilis screening (target, 95% of all pregnancies) and treatment (target, 95% treatment of women testing positive) [11,13]. Regional PAHO progress reports have documented consistent increases in regional syphilis testing coverage: by 2014, at least nine of the 35 PAHO member states had reported data suggesting achievement of program elimination targets for both syphilis and HIV [14]. Nonetheless, several countries have continued to lag on coverage of syphilis screening during pregnancy [14], indicating that reaching the ANC testing coverage targets continues to be difficult for many countries. New diagnostics, such as point-of-care (treponemal) rapid syphilis tests (RSTs), may be more practical and effective than traditional diagnostics in ANC settings where rapid treatment is critical [6,15].

The aim of the present survey study was to assess the syphilis testing practices of laboratories in PAHO member countries to understand the syphilis testing algorithms, types of diagnostic tests, and testing practices and standards currently applied by laboratories in countries within the region of the Americas.

2. Material and methods

2.1. Survey recruitment, design, and administration

A descriptive, cross-sectional study was conducted among countries in the Americas to explore syphilis laboratory testing practices in reference centers and clinical settings where syphilis testing typically occurs. Laboratory directors were contacted by e-mail and invited to participate in the survey based on an established contact list with PAHO support. The sampling goal of the study was to at least include the national or regional reference laboratory for each country and, if possible, lower-level laboratories that conducted syphilis testing. There was no limit to the number of participating laboratories per country.

A structured questionnaire was developed by a panel of technical laboratory and program experts from PAHO Headquarters and the US Centers for Disease Control and Prevention (CDC), and was pilot tested by three laboratory directors in charge of syphilis testing to assure its utility, validity, and reliability. The final questionnaire consisted of the following sections: respondents' positions; type of laboratory; syphilis testing practices, including use of RSTs; barriers to implementation of RSTs; syphilis testing algorithms used; test volume and turn-around times; number of staff available to perform syphilis testing; training of staff; procurement, distribution, stockouts, and funding; other quality assurance (QA) and quality control (QC) procedures, including external QA; participation in national, regional, or local surveillance systems; and perceived needs to improve syphilis testing. In this survey, an RST was defined as a finger-prick, whole blood syphilis test that could be performed onsite at a clinical encounter by a trained health provider who may not be a trained laboratory technician and/or specialist. Respondents were informed that the rapid plasma reagin (RPR) should not be considered an RST. Laboratory-based tests discussed included non-treponemal tests (RPR and venereal disease research laboratory (VDRL) test) and treponemal tests (chemiluminescence immunoassays, enzyme immunoassay [EIA], fluorescent treponemal antibody absorption [FTA-ABS], *Treponema pallidum* hemagglutination assay, *Treponema pallidum* particle agglutination assay [TPPA]). Classification of LAC subregions (Central America, Caribbean, Andean, and Southern Cone) was made in the manner of previous PAHO reports [16].

2.2. Survey administration and statistical analysis

The survey was administered electronically between March and August, 2014, using SurveyMonkey (Palo Alto, CA, USA) via an online web link. Data were analyzed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). Descriptive analyses were performed to determine proportions and percentage of responses between national or regional reference laboratories and local, municipal, district, or hospital laboratories (i.e. lower-level laboratories) overall and by subregions. Frequencies of laboratory characteristics, syphilis test types, and testing algorithms were calculated for all laboratories and by laboratory type (national/regional or lower-level laboratory). Subanalyses of barriers to RST implementation and stockouts of testing supplies were conducted only for laboratories receiving specimens from ANC settings and/or pregnant women.

3. Results

A total of 69 laboratorians from 30 (86%) of the 35 PAHO member states completed the survey (Table 1). Participating institutions were fairly equally distributed between larger national or regional reference laboratories (n = 36, 52%) and lower-level or local laboratories (n = 33, 48%) comprised of maternity hospital laboratories, private or public hospitals, and other primary or local health clinics. Most (94%) participating laboratories were public. Of the participating laboratories, 54 (78%) reported receiving specimens for syphilis testing from ANCs.

3.1. Types and use of syphilis tests and testing algorithms applied

The most common non-treponemal test used was the RPR, reported by 62% of laboratories (Table 2); 25 (39%) laboratories (46% of national/regional; 32% of lower-level) reported using only the RPR for non-treponemal testing, 20 (31%) used only the VDRL test for non-treponemal testing (30% of national/regional; 32% of lower-level laboratories), and 14 (22%) performed both RPR and VDRL. Four (6%) did not conduct any non-treponemal syphilis testing. For treponemal serological tests, FTA-ABS was the most commonly used single test by both national/regional (47%) and lower-level (33%) laboratories. Twenty-two laboratories (32%; 25% of national/regional and 39% of lower-level) reported that they used no laboratory-based treponemal test, although four of these reported using an RST.

Of the 69 reporting laboratories, less than half (41%) reported using an RST. This was marginally lower compared with laboratories providing testing for ANCs, of which 46% reported using an RST. Use of RSTs was slightly less common among lower-level laboratories (36%) than national/regional laboratories (44%). Among the subregions, the Caribbean had the lowest use of RSTs (13%) and the Southern Cone had the highest (57%). The reported reasons for laboratories not using RSTs varied (Fig. 1), with approximately one-fourth (26%) of the respondents indicating that this was because RSTs were not included in their national algorithm. Other reasons reported were that the tests were not included in the procurement system (13%) and that the institutions were national/reference laboratories that did not provide direct services to patients (13%). When asked about acceptable settings for RST implementation, the majority (59%) of respondents thought mobile outreach programs for at-risk populations was an acceptable setting, followed by ANCs (46%), HIV clinics (49%), sexually transmitted infection (STI) clinics (51%), and primary healthcare clinics (46%). All of the 25 laboratories conducting RSTs in ANC clinics reported that the test was conducted by trained laboratory personnel; however, only 3% of lower-level facilities using RSTs reported that the test was also performed by trained health providers.

Overall, 71% (49) of respondents, representing laboratories from all 30 participating countries reported the existence of a recommended national algorithm for syphilis testing in pregnant women (Table 3). For 13% of laboratories, respondents reported that there was no such national algorithm; for the remaining 16%, respondents were unaware of whether a national algorithm existed for pregnant women. Only seven laboratories representing five countries reported their syphilis testing algorithm for ANC clinics included an RST (five laboratories used only an RST, one used an RST with reactive tests confirmed by a non-treponemal test, and one used a treponemal test confirmed by an RST).

When asked which types of clinical programs their laboratory supported, 78% (81% of national/regional; 76% of lower-level) reported receiving samples from ANC programs. Additionally, 77% received

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