



Meeting Report

Regional consultation on algorithms for the diagnosis of syphilis in Latin America and the Caribbean

Summary¹

¹ For the complete meeting report please refer to the Spanish version

Executive Summary

As part of the support to countries of the Latin American and Caribbean Region (LAC), regarding the implementation of the Strategy and Action Plan for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis and care and treatment for key populations, the Pan-American Health Organization (PAHO) with support from the Centers for Disease Control and Prevention (CDC) convened a regional consultation on algorithms for syphilis diagnosis.

Among the main elements for the elimination of congenital syphilis are systematic and timely detection of infection and treatment of positives. Since there are new diagnostic tests which enable up-dating diagnostic algorithms of syphilis, this meeting reviewed diagnostic algorithms and scenarios in which these can be applied. A Regional and country LAC focus was considered so as to facilitate countries to establish the most appropriate diagnostic tools to their specific setting/s as well as promote identification of syphilis diagnosis and treatment strategies for pregnant women and key populations.

During the meeting discussions, it was established that there is a need for countries of the Region to up-date their syphilis screening, diagnosis and treatment strategies. Among the topics discussed was the role of national and regional reference laboratories, diagnostic capacities at different levels of care, the strengthening of a regional network of diagnostic laboratories, the use of rapid tests and point of care testing procedures (refer to the agenda of the meeting).

Another area of discussion was countries' needs in supporting national reference laboratories to ensure quality of syphilis testing all levels, and ensuring quality of syphilis testing at all levels. Additionally, discussions about the importance of integrating syphilis and HIV testing within program and laboratory settings was discussed, given that in the context of mother-to-child transmission program aims are closely aligned (this close alignment of HIV and syphilis testing/treatment goals may also be true for some other programs, such as outreach for certain vulnerable populations).

The principal results of this meeting were:

- A consensus on the benefits of adopting several diagnostic algorithms for syphilis testing depending upon clinical setting. Implementation of such algorithms in different scenarios would be promoted for the purpose of improving coverage of syphilis testing and prompt treatment for pregnant women as well as different risk populations in the LAC Region.
- A consensus on the importance of ongoing quality assurance of syphilis laboratory testing, ideally under the leadership of a national reference laboratory.
- A consensus on requesting PAHO provide assistance in providing data on quality of specific syphilis test (using CDC or other ministry of health reference laboratories), and on identifying reliable data for procurement of commodities needed to ensure

quality and accuracy of syphilis testing (e.g., specialized slides, reagents, equipment needed for certain tests).

- The establishment of an expert group committee for the guidance of specific topics related to syphilis diagnosis and treatment.
- A joint PAHO/CDC work plan for the strengthening of the capacities in countries and the improvement in the implementation of the strategy of the elimination of congenital syphilis.

Background

In 2009, the Pan American Health Organization (PAHO) and the United Nations Children's Fund (UNICEF) launched the Regional Initiative for the Elimination of the Maternal and Child Transmission of HIV and of the congenital syphilis and in September 2010, the Member States of PAHO approved the Strategy and Plan of Action for the elimination of the transmission maternal and child of HIV and of the congenital syphilis in 2015 through resolution CD50.R12².

Through this resolution, the region commits to the following targets by the year 2015:

- Reduction of the incidence of transmission of HIV from HIV-positive mothers to their infants to 2% or less.
- Reduction of the incidence of mother-to-child transmission of HIV to 0.3 cases or less per 1,000 live births.
- Reduction of the incidence of congenital syphilis to 0.5 cases or less (including stillbirths) per 1,000 live births.

HIV and syphilis testing of all women early in pregnancy, and prompt treatment of infected women, are essential to achieve these targets.

The syphilis component of this dual elimination initiative builds on an existing commitment from the region for elimination of congenital syphilis, adopted in 1995, when the Latin America and Caribbean (LAC) region adopted the Plan of Action for the Elimination of Congenital Syphilis (Resolution CE116.R3)³. Key elements of the cascade for elimination of congenital syphilis are: 1) prevention of syphilis infection in the general population, 2) routine timely syphilis screening and treatment of pregnant women; and 3) prompt treatment of syphilis seropositive pregnant women and their sexual contacts.

Most countries in the region have policies for universal syphilis screening in pregnant women. However, uptake of screening is often less than optimal because screening policies are not applied in a systematic way, or due to lack of standardized syphilis testing algorithms that are practical and appropriate for different clinical settings. In 2011, 22 countries reported on ANC syphilis testing, of which none reported the target coverage of 95%. Eleven countries reported coverage rates of over 90%, and the remaining eleven reported coverage levels ranging from close to 90% to less than 20%⁴.

For elimination of congenital syphilis and control of syphilis in key affected groups, it is essential to both have access to practical and well performing diagnostics for the detection

² Organización Panamericana de la Salud (OPS). Estrategia y Plan de acción para la eliminación de la transmisión materno-infantil del VIH y de la sífilis congénita. 50.º Consejo Directivo, 62.ª sesión del Comité Regional. Resolución CD50.R12. OPS, Washington, D.C.; 2010. <http://new.paho.org/hq/dmdocuments/2010/CD50.R12-e.pdf>

³ Ibid

⁴ Pan American Health Organization. 2012 Progress Report: Elimination of mother-to-child transmission of HIV and congenital syphilis in the Americas. Washington, D.C.: PAHO; 2013.

of syphilis infection, and to use them in effective ways appropriate to the clinical setting. Syphilis diagnostic technologies have been available for decades, but have required basic laboratory capacity that is not often available at the clinical setting. Drawing blood and sending specimens for testing and results leads to loss to follow up of many syphilis-infected pregnant women, especially those coming to antenatal care late in pregnancy or for only one visit. However, in recent years simple, point-of-care (POC) technologies have been developed that can be applied by non-laboratory personnel in environments other than traditional laboratory settings. Rapid diagnostics that allow testing and treatment to be done in clinical settings with limited laboratory capacity have made these this intervention cost-effective and feasible in essentially every nation⁵. In addition, implementation of POC tests for syphilis has been shown to be feasible and acceptable for patients and health providers, and has led to improvement in several aspects of health services⁶. To ensure the quality of syphilis testing, both laboratory-based and POC testing, essential elements are the use of standardized procedures for quality assurance (QA), quality control, and proficiency testing.

Challenges exist in the region in ensuring appropriate integration of the more traditional and newer syphilis diagnostic technologies, appropriate protocols for testing QA, and arrive at appropriate and effective adaptation of the service delivery environment to achieve optimal benefit of the available technologies.

Aim of the meeting: The aim of the meeting is to arrive to a consensus on strategies that can be applied in the LAC region to achieve broader access to quality syphilis testing based on global guidance, country experiences and expert opinion,

Objectives

1. Review of current policies and practices to identify issues hindering or supporting optimal syphilis screening and diagnosis, with focus on regional efforts for elimination of congenital syphilis, syphilis control in key populations, and syphilis surveillance.
2. Reach a consensus on recommendations for syphilis screening/diagnosis algorithms for specific settings for the Region taking into account emerging diagnostic technologies, program and cost- effectiveness, and the regional epidemiological context.
3. Identify key actions for follow-up on regional and country level for policy and program implementation and scale up of effective syphilis screening and diagnosis

Methods

⁵ Kahn JG, Jiwani A, Gomez GB, Hawkes SJ, Chesson HW, Broutet N, Kamb ML, Newman LM. The Cost and Cost-Effectiveness of Scaling up Screening and Treatment of Syphilis in Pregnancy: A Model. *PLoS One*. 2014; 9(1).

⁶ García PJ, Cárcamo CP, Chiappe M, Valderrama M, La Rosa S, Holmes KK, Mabey DC, Peeling RW. Rapid Syphilis Tests as Catalysts for Health Systems Strengthening: A Case Study from Peru. *PLoS One*. 2013;8(6)

This meeting brought together regional and global experts, as well as laboratory and program representatives from countries throughout Latin American and the Caribbean to discuss and build a common understanding of the issues, and propose strategies that countries can use to move forward the agenda of quality syphilis screening and diagnosis.

It was envisioned that a background paper will be developed summarizing the current situation. The background paper will draw from a survey that has been administered to countries (web-based and paper-based) as well as relevant other documents such as technical cooperation reports.

Main Conclusions

1. The meeting provided consensus on a series of diagnostic algorithms considering different target populations and settings.
2. Among the proposed algorithms, the group agreed on the need to include a specific algorithm of testing and treatment when only rapid tested are available.
3. Some countries of the Region such as Brazil have adopted national strategies for the prevention of congenital syphilis, including diagnosis and treatment. There is need to use this example in the Region.
4. The participants recognized the need to implement the up-dated algorithms and promote and strengthen activities related to the elimination of congenital Syphilis.
5. The implementation of the up-dated algorithms will require continuous training programs and the evaluation of competencies of staff who carry out syphilis diagnosis in the countries of the Region.

A major output of this meeting will be the launch of the document: *'Regional Guidance on Syphilis testing in Latin America and the Caribbean: Improving Uptake, Interpretation, and Quality of Testing in Different Clinical Settings'* in the fourth trimester of 2014 which then be promoted and implemented in countries of LAC.

6. PAHO in collaboration with CDC and Regional partners have agreed to work on a list of syphilis diagnostic tests, outlining test qualities and characteristics, and to work on a list of essential commodities needed for certain types of syphilis tests. These will be presented to the procurement unit of PAHO: The Strategic Fund".

The participants also recognized the need to implement quality assurance systems ensuring accuracy of syphilis testing at all levels. Ideally quality assurance would be under the leadership of the national reference laboratory. As possible, this effort could be linked with HIV testing quality assurance. **Recommendations**

1. PAHO jointly with CDC and the Ministry of Health of Brazil will establish a framework of activities for the strengthening of country capacities related to the prevention of congenital syphilis.
2. A regional expert working group will be established for the follow-up, implementation and evaluation of diagnosis tests and diagnosis syphilis algorithms that have bene approved in this meeting.
3. The countries should promote among its National Reference Laboratories, the up-date and / or implementation of quality control procedures and establish a program of evaluation of competencies to the centers that carry out syphilis diagnosis if not yet established.

ANNEX 1. AGENDA



Regional consultation on algorithms for the diagnosis of the syphilis in Latin America and the Caribbean

First day: 24 April 2014		
TIME	SUBJECT	Responsible
8:00–8:30	Registry	Gabriela of León (PAHO)
8:30–9:00	Safety instructions	Representative UN A
9:00–9:15	Opening	Dr. Guadalupe Verdejo (PAHO-Guatemala)
9:15–9:45	Introduction and presentation of the objectives of the meeting, the participants, and the logistics	Freddy Pérez (PAHO)
9:45–10:45	Presentation of the current situation as regards the diagnostic tests of the syphilis in the Region (survey): policies, practices, problems, and challenges. Round of questions discusses	David Ham (CDC)
10:45–11:00	Break coffee	
11:00–12:00	Recent progress in the approach of the tests detection of the syphilis (algorithms, inverse algorithm, rapid tests) Round of questions discusses	Mary Kamb (CDC)
12:00–13:00	Experiences of countries in the implementation of the tests for the testing/diagnosis of the syphilis: <u>Group A</u> - Guatemala (Leticia Castle) - El Salvador (Wendy Melara) - Jamaica (Tub Hylton-Kong)	Moderator: Hernando Gaitan (University National Colombia)
13:00–14:00	Luncheon	
14:00–14:45	Discussions of the presentations of the Group A	
14:45–17:00	<u>Group B</u> - Bolivia (Luisa Valentina Hurtado) - Peru (Ruben Vasquez) - St. Vincent & Gren. (Claudette Williams) - Guatemala (César Galindo)	Moderator: Maria Luiza Basso (Uni Fed Sta.Catarina)
17:00–17:45	Discussions of the presentations of the Group A Reaching a consensus with regard to recommendations with regard to the algorithms of detection//diagnostic of the syphilis in the Region of LAC: <i>Introduction</i>	Moderators: M Kamb (CDC)/F Pérez (PAHO)

Second 25 April, 2014		
8:30–9:15	Preliminary results of models of cost-effectiveness of algorithms of screening syphilis in Peru (video-conference)	FernTerris Prestholt (LSHTM)
9:15-10:15	<p>Diagnosis Syphilis and Quality Control - Iera Part</p> <p>Quality control laboratory and seguridad (<i>K. Karem</i>)</p> <ul style="list-style-type: none"> - Standards as CLIA (USA) - Principal Components–Functions Centralized versus Des-centralized <p>Diagnosis of Laboratory Syphilis (<i>M Kamb and K Karem</i>)</p> <ul style="list-style-type: none"> - Diagnosis Methods - Programa PT de CDC CDC PT <p>Round of questions discusses</p>	Responsible: Kevin Karem (CDC)
10:15-10:30	Break coffee	
10:30–11:30	<p>Diagnosis Syphilis and Quality Control - 2nd Part</p> <p>Development of an operational plan (<i>K Karem, J Matheu</i>)</p> <ul style="list-style-type: none"> - Working groups (affiliations, operations) - Exchange of operations of a laboratory/models (example. equivalent CLIA) - Checklists of the process <p>Supply quality tests for the Region (<i>JMatheu</i>)</p> <p>Round of questions discusses</p>	Responsible: Kevin Karem (CDC)
11:30–12:15	<p>Experience of Brazil in the use of rapid tests and external quality control</p> <p>Round of questions discusses</p>	Adele Schwartz Benzaken (MoH Brazil)
12:15–13:00	<p>Achieve a consensus on the recommendations for the algorithms of screening/diagnostic of the syphilis in specific environment of the Region</p> <ul style="list-style-type: none"> • What do countries need in order to accelerate the interventions? • What can be made immediately and in the mediated term 	<p>Moderators:</p> <p>F Perez, J Matheu (PAHO)</p> <p>Mariangela Freitas da Silveira (CLAPS)</p> <p>M Kamb (CDC)</p>
13:00–14.00	Lunch	
14:00–15:30	. Continuation: Achieve a consensus on the recommendations for the algorithms of screening/diagnostic of the syphilis in specific environment of the Region	
15:30–16:45	<p>Next steps:</p> <ul style="list-style-type: none"> • Creation of working groups (affiliation, operations) • Technical cooperation (of South to South, regional members..) • Health Policies 	Moderators: TB
16.45–17.15	Closure	

Annex 2. List of Participants

Regional Consultation on Algorithms for Syphilis Testing and Diagnosis in Latin America and the Caribbean

24-25th April, 2014 (Guatemala)

List of Participants

Expert	Institution	Country	E-mail
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