



OPPORTUNITIES FOR THE IMPLEMENTATION OF RAPID SYPHILIS TESTS (RST) IN LATIN AMERICA FOR THE ELIMINATION OF CONGENITAL SYPHILIS

Report

November 18 -19th, 2010

Lima, Peru

TABLE OF CONTENTS

- i. Executive Summary**
- 1. Introduction**
- 2. Workshop Objectives**
- 3. Participants**
- 4. Program**
- 5. Lectures and Presentations**
 - 5.1 The Challenge for the Elimination of congenital syphilis in Latin America (LA)
 - 5.2 Rapid Syphilis Tests (RST)
 - 5.3 Rapid test experience in Peru
 - 5.4 Policies and actions to implement the RST as a strategy for the elimination of congenital syphilis and to improve prevention of HIV transmission in Peru
 - 5.5 Regulatory aspects of the RST. Results of the survey in LA countries
 - 5.6 Implementation of the RST in LA. Quick Poll Results
 - 5.7 Implementing RST in Rural areas: The Brazilian experience
 - 5.8 Presentation on experiences in other LA countries
 - 5.8.1 Honduras
 - 5.8.2 Bolivia
 - 5.8.3 Uruguay
 - 5.8.4 Paraguay
 - 5.9 Presentation and Group Discussions: Benefits, opportunities, challenges and alternatives for the introduction of RST in LA
 - 5.10 The RST Quality Control. Experiences and challenges
 - 5.11 Toolkit for the implementation of the RST in countries
- 6. Lessons learned**
- 7. Conclusions**
- 8. Appendices**

EXECUTIVE SUMMARY

Syphilis remains a major public health problem worldwide especially in developing countries and the countries in the region of Latin America (LA) and the Caribbean. Many of the countries of the region have committed to reduce cases of congenital syphilis to less than 0.5 cases per 1,000 live births, however many of them are very far from achieving the objectives prior to 2015.

The reduction or elimination of congenital syphilis can be performed with simple, cost-effective interventions. The use of rapid diagnostic tests could increase screening of pregnant women early in antenatal care and avoid lost opportunities for diagnosis of the disease. However, rapid tests for syphilis (RST) could also be used among many other populations.

In an effort to try to increase awareness about rapid testing in the region, the Universidad Cayetano Heredia (UPCH) with support from the World Health Organization (WHO) and the London School of Hygiene and Tropical Medicine (LSH&TM) organized a workshop called *Opportunities for implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis* held on November 18 -19th, 2010 in Lima, Peru. This workshop is the second regional meeting to address the problem of congenital syphilis after the one held in Brasilia. Peru welcomed representatives from the 17 countries of the region to participate in this regional workshop.

Prior to the workshop, a survey was completed by each of the participating countries. The survey included questions regarding information regarding regulations and regulatory issues for rapid testing in each country. During the workshop the group discussed the technical aspects, the role of quality control of rapid tests, and the cost-effectiveness of tests. Some countries shared their experiences with RST implementation. Brazil showed that RST can be implemented among different populations, such as indigenous groups. Peru had the opportunity to present the CISNE¹ project which showed two intervention models used in different Peruvian public health sector establishments. The workshop also enabled interaction between participants in work groups in order to identify opportunities, challenges and needs of countries related to RST. Finally, during the two day period, the participants noted the need to share experiences and to find ways to make use of the lessons learned as a region.

In conclusion, participants addressed the topics of advocacy and political commitment, awareness and training of health personnel, technical knowledge about the RST, communication, and dissemination of research findings. These are important steps towards the implementation of RST as a strategy for the elimination of congenital syphilis.

¹ The project “*Preventing congenital syphilis: Implementing rapid syphilis testing to improve access to screening for pregnant women in Peru*” or its acronym in Spanish CISNE [meaning *Cura Inmediata de la Sifilis Neonatal*] in English [*Immediate cure for congenital syphilis*] addresses two models for the implementation of rapid syphilis testing: the first model in a peri-urban health network and the second model in a tertiary hospital. Available at <http://proyectocisne.org/>

1. INTRODUCTION

The workshop "*Opportunities for the Implementation of RST in Latin America for the Elimination of Congenital Syphilis*" was held in Lima, Peru on November 18-19th, 2010. This event was organized by the World Health Organization (WHO), London School of Hygiene and Tropical Medicine (LSH&TM) and the Universidad Peruana Cayetano Heredia (UPCH). The workshop is the second annual regional meeting focused on the implementation and use of rapid tests for diagnosis of syphilis in Latin America and the Caribbean. Workshop participants included representatives from the Ministries of Health, Health Regions of the HIV/STD programs, programs for maternal and reproductive health, laboratories and institutes in Latin America, professionals working on STD and HIV, on sexual and reproductive health and on Maternal Health in Latin America, members of the Cooperation Agencies in Lima, Peru: PAHO, UNICEF, WHO and experts from LSH&TM. Also, the whole group of the Peruvian CISNE project participated. Eighty-three (83) people attended the workshop, representing seventeen (17) countries.

2. WORKSHOP OBJECTIVES

Participants will work towards the following objectives:

- a. Review technical aspects of Rapid Syphilis Tests (RST)
- b. Share experiences on the implementation of the RST in Latin America (LA) and the possible impact on the elimination of congenital syphilis.
- c. Discuss related issues of quality control in the use of rapid tests.
- d. Discuss regulatory issues related to rapid testing in LA.
- e. Discuss regulatory issues related to the introduction and purchase of rapid tests in countries.
- f. Discuss issues related to the cost-effectiveness of rapid tests.
- g. Discuss possibilities and requirements for implementation of the RST in LA

3. WORKSHOP PARTICIPANTS. See Appendix 1.

- a. Representatives of Ministries of Health, Health Regions, HIV/STD programs, programs for maternal and reproductive health, Laboratories and Institutes of Latin America.
- b. Professionals working on topics related to STDs/HIV, sexual and reproductive health and Maternal health in Latin America.
- c. Cooperation Agency Members in Lima from PAHO, UNICEF, WHO.
- d. Experts from London School of Hygiene and Tropical Medicine.

4. WORKSHOP PROGRAM

Thursday November 18th, 2010

1. Enrollment and Registration - Welcome and Opening of the Meeting
2. Meeting Objectives
3. The Challenge for the Elimination of congenital syphilis in Latin America
4. Rapid Syphilis Test (RST)
5. Rapid Test Experience in Peru:
 - Ventanilla – Callao health network: Experience integrating Syphilis and HIV tests in Maternal Health.
 - Rapid Testing Experience in a tertiary hospital: Instituto Nacional Materno Perinatal (INMP)
6. Questions and discussion
7. Policies and actions to implement the RST as a strategy for the elimination of congenital syphilis and to improve prevention of HIV transmission in Peru.
Roundtable
8. Questions and discussion
9. Regulatory Aspects of the RST. Results of the survey in Latin America countries.
10. Questions and discussion
11. Implementing Rapid Testing for Syphilis in Rural Areas: The Brazilian Experience
12. Implementation of the RST in AL. Quick Poll Results
13. Presentation on experiences in other LA countries
14. Group Discussion: Benefits, opportunities, challenges and alternatives for the introduction of RST in Latin America - WORKING GROUPS
15. Group conclusions

Friday November 19th, 2010

1. The RST Quality Control. Experiences and challenges
2. Questions and discussion
3. Toolkit for the Implementation of Rapid Syphilis Test in countries
4. Questions and discussion
5. Lessons Learned
6. Conclusions and Final Remarks

<p>The following are the most important agenda items presented during the workshop “Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis”, lessons learned and conclusions.</p>

5. LECTURES AND PRESENTATIONS

5.1 The Challenge for the Elimination of congenital syphilis in Latin America

Dr. Fernando Gonzales - PAHO representative

In 2007, 164,000 children were born with congenital syphilis and 6,400 children were infected with HIV in the Latin American and Caribbean region. Untreated syphilis infection during pregnancy can cause adverse outcomes including miscarriage, premature birth, and low birth weight. High rates of disease persist in the LAC region despite efforts to curb transmission. Poor knowledge of the severity of the problem among authorities and health program managers, barriers to accessing health services, and stigma and discrimination connected with STIs exacerbate the problem and serve as challenges for effective intervention.

Elimination of congenital syphilis is included implicitly in four of the Millennium Development Goals (Objectives 4, 5 and 6). Furthermore, prevention of mother-to-child transmission has proven to be a cost-effective intervention by avoiding later costs of treatment and care for congenital syphilis. In order to provide countries with a framework for achieving the Millennium Development Goals, the WHO laid out the Strategic Plan of Action for Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis². This plan calls for the reduction of transmission of HIV to 2% or less and reduction of cases of congenital syphilis to less than 0.5 per 1000 live births. The strategy includes important pillars such as expanding screening, increasing general access to health care, and establishing systems of surveillance, monitoring, and evaluation. At the regional level, PAHO is helping to adapt this strategy for countries in the region. PAHO's part in this regional initiative will include establishment of baseline information for countries and the region, advocacy, facilitation of inter-program coordination, and promotion of cross-country sharing of experiences. To this end, a monitoring system has been developed with specific indicators in order to track progress towards the 2015 goals.

Dr. Mario Tavera – UNICEF

PAHO and UNICEF are committed to collaborative action at the regional level towards the prevention of transmission of syphilis and HIV to children. The Regional Initiative^{3 4}, adopted in 2009, lays out a plan of action for elimination of these diseases in children. In order for the regional strategy to be successful, however, it needs to be explicitly placed as

² Strategy and Plan of Action for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis (DocumentCE146/15), based on the PAHO Strategic Plan 2008-2012.

³ 18th Meeting of the Caucus of CARICOM Ministers Responsible for Health, at the Headquarters of the Pan American Health Organization (PAHO) in Washington D.C. The "Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean" is supported by PAHO and UNICEF with inputs from all the major stakeholders including national governments, NGOs and other UN agencies.

⁴ <http://new.paho.org/hq/dmdocuments/2009/Caribbean%20press%20release%20about%20PMTCT%20and%20congenital%20syphilis.pdf>

⁴ Iniciativa regional para la eliminación de la transmisión materno infantil del VIH y de la sífilis congénita en América Latina y el Caribe [http://www.unicef.org/lac/Documento_Conceptual_Eliminacion_de_la_transmision_maternoinfantil_del_VIH_y_de_la_sifilis_congenita\(2\).pdf](http://www.unicef.org/lac/Documento_Conceptual_Eliminacion_de_la_transmision_maternoinfantil_del_VIH_y_de_la_sifilis_congenita(2).pdf)

a political priority: the success of the initiative depends largely on how it is introduced in each country.

The Rapid Syphilis Test (RST) offers the opportunity to expand screening for syphilis to difficult-to-reach populations, and therefore provides a strong opportunity for further implementation of the Regional Strategy: for example, screening coverage has improved in past years, and with the use of the rapid test can now be expanded to rural and indigenous populations. Peru has achieved high coverage of antenatal care, yet coverage of screening for STIs falls far short of antenatal care coverage when the two should be closely linked. This points to the need to integrate HIV/STI services into other essential health programs and create horizontal, all-encompassing programs for STI prevention and care, sexual and reproductive health, and maternal and infant health.

The implementation of rapid tests is a cost-effective intervention. These interventions, however, must be presented within a human rights framework and from a cultural and gender-appropriate perspective. Through technical assistance, UNICEF/PAHO can help guide the important process of revising national guidelines for screening to ensure that the appropriate policies are in place to guide implementation at the national level. Furthermore, implementation can be reinforced through successful use of advocacy and channels of communication.

5.2 Rapid Syphilis testing (RST)

Dr. Rossana Peeling – LSH&TM

Rapid tests are a powerful tool that can increase access to testing, increase effective treatment through the Same Day Testing and Treatment strategy (STAT), and decrease losses to follow-up of women screened. Currently, it is estimated that only 15 in 100 pregnant women with syphilis are adequately screened and treated for the disease. Rapid syphilis tests, with the ability to be used in mobile clinic settings, have the potential to vastly expand screening.

After observing the need for higher quality rapid tests, in 2001 the WHO approached companies and challenged them to create a test that satisfied the “ASSURED”⁵ criteria (affordable, sensitive, specific, user-friendly, rapid/robust, equipment free, and deliverable) (reference). A number of tests of varying quality are currently available on the Latin American market. This is partly because there is little regulatory oversight in the region for the quality of these tests. While some companies list sensitivity and specificity values on their product inserts, these are often based on small sample sizes and can be misleading.

In order to validate the quality of rapid syphilis tests, the WHO carried-out both laboratory and field-based evaluations on a number of test brands at varying sites worldwide. From this evaluation, seven tests were approved as being of significant quality⁶. These

⁵ R W Peeling, K K Holmes, D Mabey, A Ronald Rapid tests for sexually transmitted infections (STIs): the way forward *Sex Transm Infect* 2006;82(Suppl V):v1–v6. doi: 10.1136/sti.2006.024265

⁶ AJ Herring, RC Ballard, V Pope, RA Adegbola, J Chagalucha, DW Fitzgerald, EW Hook III, A Kubanova, S Mananwate, JW Pape, AW Sturm, B West, YP Yin, RW Peeling A multi-centre evaluation of nine rapid, point-of-care syphilis tests using archived sera. *Sex Transm Infect* 2006;82(Suppl V):v7–v12. doi: 10.1136/sti.2006.022707

companies were then included into the WHO bulk marketing scheme where countries were able to procure tests at between US\$0.19-1.00. Through mathematical modeling, the WHO found that tests must cost less than US\$0.63 to be as cost-effective an intervention as the RPR method of screening. 46% of the cost of screening programs can be attributed to the cost of the test itself, which underscores the importance of making tests available at prices that low and middle income countries can afford.

Even when countries are able to procure tests at reduced prices through the WHO bulk-marketing scheme, tests must be licensed in the country where they will be sold. Burdensome regulatory processes can serve as disincentives to companies wishing to register their products, especially in smaller markets. The WHO is encouraging countries to harmonize their regulatory processes in order to facilitate the process of product registration.

With the results from the test evaluation, RST was determined to be an effective child-health intervention (reference), and the WHO was able to approach the Gates Foundation to request funding for the study currently underway to increase access to syphilis screening in six countries around the globe with the use of RST. The study sites are also examining quality issues with rapid tests, including quality of tests procured, stability, and proficiency, and helping to define criteria for future procurement.

When planning to implement RST, screening sites should take into account that test results have been guaranteed up to 30°C. In a decentralized testing system where refrigeration is not available, some sites have found that storing tests in insulated boxes with water at the base keeps the tests cooler for a longer period of time. When stored at 4°C, tests should have a shelf-life of 1.5-2 years. The WHO uses the TPPA as a gold standard to assess test performance.

Evaluations are also currently underway on a number of variations on the rapid syphilis test. The CDC is assessing a rapid non treponemal test to detect current infection. Other tests in the pipeline include a combined HIV/Syphilis test and a quantitative treponemal test to assess whether treatment was effective. The WHO is interested in feedback from testing sites on how tests can be improved and what new wave tests they would like to see on the market.

5.3 Experience of Rapid Test in Peru:

In Peru, the coverage for syphilis screening is not ideal. A high percentage of screened women are not treated and there is lack of knowledge about their couples' treatment. The prevalence of syphilis in Peru is about 1 to 3 per 1,000 live births, Peru is far from the goal. In this context arises the project *Preventing congenital syphilis: Implementing rapid syphilis testing to improve access to screening for pregnant women in Peru* and its Spanish acronym CISNE [meaning *Immediate Cure for Neonatal syphilis*], which evaluates two models for implementing rapid tests: the first model in a peri-urban health network and the second model of a tertiary hospital.

For example, the experience showed that it was difficult to access the laboratories, because they are the ones who are responsible for carrying out various laboratory tests. However, the RST should be used outside the laboratories and performed at the bedside.

The project also enabled cost assessments and demonstrated that it is not enough just to know the cost of testing but should also include other costs such as: the cost of human resources, cost of electricity, the cost of the physical space, costs of equipment, gloves, etc.

We also determined the diagnostic accuracy of the test versus the Peruvian gold standard defined as RPR + TPPA or TPHA. Here we present the two models in the CISNE Peruvian project:

Ventanilla – Callao Health Network: Experience Integrating Syphilis and HIV Rapid tests in Maternal Health

Dr. Jorge Alcantara – Health Region at Callao

The CISNE project was founded in 2009 with the objective of assessing the feasibility, cost-effectiveness, and performance of rapid testing for syphilis in Peru. The project set out to demonstrate that RST was a viable alternative to the current national gold standard – RPR + TPPA – and that RST could be implemented in Peruvian health establishments with an effective quality control system.

In 2009, the CISNE (Cura Inmediata de la Sífilis Neonatal) project began working with 16 health establishments in Ventanilla-Callao, a resource-poor district to the north of Lima, to implement rapid testing for syphilis. The implementation process began with collection of baseline information, formation of alliances with local authorities, and training of health professionals.

Baseline data collection revealed inconsistencies in data reporting for antenatal screening and treatment for syphilis among different data sources. Researchers accompanied women through the syphilis screening process and found that it often took 27 days and 6 different contacts with health providers before a patient was screened, diagnosed, and treated for syphilis.

On Jan. 18th, 2010, Ventanilla-Callao health centers began implementing syphilis and HIV rapid tests side-by-side in for women receiving antenatal care and care for complications, miscarriage, and abortion. Over the course of the study, screening coverage and treatment rates also improved drastically. Screening coverage increased from 51% to 93% from 2009 to 2010. Whereas previously there was no system in place for registering partner treatment, study data reported that 53% of partners received treatment for syphilis during the study period. Key factors in the success of implementation were ongoing training, monitoring, and supervision of health providers who performed RST. The process of implementation in Ventanilla-Callao demonstrated that RST is an effective, acceptable, and cost-effective intervention. With rapid testing for both syphilis and HIV, the time lag between diagnosis and treatment of women and their partners was effectively reduced from 27 days to the first contact with the provider, showing that RST can serve as a powerful catalyst for improvements in quality of care.

Experience of Rapid test in a tertiary hospital: Instituto Nacional Materno Perinatal (INMP)

Dr. Carlos Velásquez - INMP

The INMP was chosen as the second site for RST implementation because of its importance as a national reference hospital specializing in maternal care, and active role in shaping national health guidelines. Similar to the Ventanilla-Callao health establishments, baseline research found that many days could pass before a woman received the results of her tests for syphilis and HIV. Little documentation was found for partner follow-up and treatment, and women who received care for abortion or miscarriage were not screened for syphilis or HIV. The institution also discovered that that screening was being performed excessively without any added patient benefit.

Through implementation of RST, the INMP achieved immediate diagnosis and treatment of women in antenatal, delivery, hospitalization, and emergency care. This was especially important in emergency care where testing was often neglected due to the short period of time and difficult conditions that often characterized emergency care. A concurrent assessment of the cost-effectiveness of RST compared to RPR also showed that RST represented a savings of US\$9,467 between February and September, 2010.

In addition, The INMP has spearheaded initiatives to promote the institutionalization of RST within their own hospital and around the country. Recognizing that awareness of syphilis was lacking among health providers, the institution created an online training tool for providers. The course introduces RST as a tool available to health professionals for prevention of congenital syphilis, and is currently being put into use all over the country. The INMP is also in the process of revising their institutional guidelines to include RST, and hopes that national-level policy change will follow.

5.4 Policies and actions to implement the RST as a strategy for the elimination of congenital syphilis and improved prevention of HIV transmission in Peru.

Dr. Lucy del Carpio – Estrategia Sanitaria Salud Sexual y Reproductiva

The National Sexual and Reproductive health Program has helped guide the process in Peru of developing and implementing national policies towards the achievement of Millennium Development Goals 4, 5, and 6; reduction of infant and maternal mortality, and control of HIV/AIDS. As part of the national strategy to achieve these goals, the country provides health insurance for the poorest sector of the population. All antenatal, delivery, and HIV/syphilis-related care are free-of-cost under this national program.

Through these initiatives, Peru has achieved impressive reductions in maternal and infant mortality and coverage of prenatal care between 2000 and 2009⁷. While screening coverage for HIV increased over this period, screening for syphilis declined slightly due to lack of resources and political will to expand coverage. The introduction of rapid syphilis tests presents a useful tool around which to create a platform for increased coverage of syphilis screening in Peru.

⁷ Encuesta Demografica y de Salud Familiar 2009 (ENDES). <http://desa.inei.gob.pe/endes/documentos.asp>

Based on the demonstrated success of RST through the CISNE project, 300,000 rapid tests have been purchased for distribution in 2011 as part of the national strategy for prevention of syphilis. In order to ensure future funding, rapid tests for HIV and syphilis have been added to the guidelines and costing structure for maternal and neonatal care programs at all levels of care.

Looking ahead, with the new inclusion of RST in the national Strategy for Sexual and Reproductive Health, increases in screening coverage and reduction of disease will continue to be achieved. The Strategy hopes to continue to expand screening to rural areas, increase the number of women who receive prenatal care during their first trimester, guarantee opportune screening and treatment for HIV and syphilis, increase quality of care, and guarantee that stock-out of screening and treatment supplies will not occur.

Dr. José Calderón - Programa Nacional de ITS / VIH, MINSA-Perú

The National Program for STIs/VIH, in collaboration with many key actors, is developing tools that will contribute to the elimination of HIV and syphilis in Peru. Specifically, the Program is working to revise the National Guideline for Prevention of Mother-to-Child Transmission of HIV and Syphilis to include the rapid syphilis test. This will include a special focus on the treatment of syphilis prior to 24 weeks of gestation, and therefore emphasize the importance of early prenatal care and screening in all health establishments. The new guidelines will also outline processes for quality control of testing and supplies. The Strategy also hopes to adjust patient clinical histories in order to easily glean information from these records that can be used for research and programs.

The National Program also seeks to establish and strengthen monitoring and evaluation for STI-related initiatives. In order to track the progress of these initiatives, WHO indicators were used to create the Project's monitoring and evaluation plan. Through inclusion in the National Strategic Program Budget, which is a framework for the financing of priorities in health based on demonstrated program results, this initiative will be guaranteed financial sustainability that will allow for progress over the course of several years.

The issue of partner treatment continues to present a challenge for prevention of HIV and syphilis. The revised version of the National Guideline will outline preventative actions that should be taken so the patient may protect herself from re-infection of syphilis, such as condom distribution.

5.5 Regulatory Aspects of Syphilis Rapid Test. Results of the survey of countries in Latin America.

Stephanie Garth - LSHTM

LSHTM conducted a survey examining diagnostic regulations in Latin America. The survey, sent to clinical trial coordinators and Ministry of Health (MOH) participants, asked questions related to in-country regulatory requirements, organizations, guidance, enforcement, product approval, and financing. Respondents from 17 countries participated, including three initial sites (Brazil, Peru, Haiti). In contrast to a 2001 WHO study, which found that 50% of 18 Latin American participant countries regulated medical devices and in vitro diagnostics, 88% of respondents reported that their countries now regulate both categories of devices. Only Haiti and Paraguay still have no regulation system. Positive responses are summarized in the table

Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis – REPORT

below. Other topics discussed were external influences upon regulatory affairs (US FDA, EU CE Marketing, WHO bulk procurement, US CDC), timeframes of diagnostic approval, and funding sources. Although approximately 50% of respondents said that statutory approval time was less than 6 months, actual timelines of approval are much longer (typically 6-12 months).

%	Regulatory affairs indicator	%	Regulatory affairs indicator
88	Regulatory organization role is both administrative and technical	60	Minimum quality system standards ^a for foreign manufacturers
88	Government purchases HIV infectious disease diagnostic tests	57	Rapid POC tests utilized for syphilis
83	IVD specific guides and documents available online or by request	53	Product stability and shipping data available (temperature extremes)
82	Government purchases syphilis infectious disease diagnostic tests	53	Manufacturers required to have an in-country distributor
82	Rapid POC tests utilized for HIV	47	Product comparison testing to a local gold standard
76	Technical review of product performance data	40	Factory inspection program for manufacturers
71	Importation fees for diagnostics	0	Minimum requirements for sensitivity and specificity ^b

^aSuch as ISO13485 or ISO9001

^b76% had ideal sensitivity and specificity for diagnostic tests.

5.6 Implementation of RST in LA: Results of Rapid Regulatory Survey

Dr. Patricia Garcia - UPCH

A survey was conducted through an email questionnaire sent to all workshop participants. The purpose of this questionnaire was to understand the regulations that each country has governing rapid tests. A total of 17 countries were sent the survey, and a total of 22 surveys were returned (there were more than one response for some countries). The baseline information obtained showed that even in countries where regulations are present, the technical and/or administrative evaluations are not effective and do not ensure that tests in use are of high quality. The regulations should consider two important aspects: a) allowing entry of a sufficient quantity of appropriate products and b) high quality of those products. Maintaining a balance between these two aspects is difficult.

Some problems that have been identified include the cost, timing and transparency of systems and the presence of intermediaries that add to the overall purchase cost of tests (this information was given by the distribution companies). One example of the result of this has been seen with HIV rapid

testing in Peru. The market is saturated with almost 70 brands, and 25% of them are inaccurate or of poor quality.

Baseline collected information:

Rapid tests are in use in 13 of the 17 countries that responded to the survey; the remaining four did not have rapid tests available on the market. The fact that rapid tests are not available on the market is a barrier to their implementation, and presents the impression that there is not interest in introducing them.

There are several brands of tests available on the market in countries that use them. Many of tests, when compared with those tested by WHO, would not have passed the evaluation. This needs to be taken into account when tests are purchased at low cost as is usually done in countries in the region. We should compare the WHO's list with the list of tests that are available in each country.

Availability in the public sector: Seven countries have the tests available in the public sector: Brazil, Chile, Guatemala, Honduras, Uruguay, Panama and Paraguay. Of the countries that are not using RST in the public sector, six countries plan to use tests in the public sector and four do not. It is interesting to note prior to each implementation pilot projects were undertaken. Why are pilot projects important to the success of future implementation?

Bolivia is an example of where implementation occurred long after the pilot project, which possibly was due to funding availability.

Some countries plan to implement RST in 2011. It is important that technical assistance is given by countries that have experience implementing, as many of the difficulties these countries are likely to encounter are the same or similar. A community of knowledge exchange can be created among those that have already implemented RST and those that will continue to implement it.

Populations: It is important to recognize that the introduction of the RST could achieve greater screening coverage and that this increase is already being observed. Many countries have already implemented RST in antenatal care, delivery and abortion services, and among sex workers.

Among some populations, the prevalence of syphilis is higher, which could present a problem as the number of women with a history of syphilis will be higher. Nevertheless, it is important to detect and treat the disease regardless of whether it is past or current infection. Paraguay and Guatemala are both using RST among groups of men who have sex with men (MSM) or in vulnerable populations who need a rapid diagnosis. In Argentina, rapid tests are used for specific projects, whereas Colombia uses them in remote areas. In Chile, donors give routinely for rapid testing, quality control systems are in place, and rapid tests are used as a confirmatory test in place of the TTPA or TPHA. There was no information provided in the survey responses on treatment of sexual partners.

There are different ways that the rapid test can be performed, for instance with intravenous blood or blood drawn from a fingerstick.

Many of the rapid tests are completed using intravenous (blue) blood in countries that work with test packages for pregnant women (different blood tests) done during antenatal visits. In this case, the blood that is drawn is used for rapid testing.

Experience with venous blood: Using Vacuteiner ® (a suction device) takes time, requires a trained person to take one drop from the tube, and the needle does not permit the isolation of just one drop. It is also a bio-safety hazard.

Who performs RST? In Uruguay, midwives and physicians perform the test. In Guatemala, Panama and Chile, the test is performed by laboratory personnel and the results are not necessarily immediate. In Chile, as mentioned previously, it is used as a confirmatory test.

When both HIV and syphilis testing were done together, health care workers fear they will have to return a positive test result for HIV. However, it is possible to perform the tests concurrently yet confirm HIV test results at a later time. Six countries do not perform both tests together. A group of countries are working with both tests together in the public sector.

The support of the Global Fund has had an interesting effect on the introduction of rapid tests. PAHO, UNFPA and WHO have also contributed funding.

The introduction of rapid tests also has to do with the maturity of countries' policies governing syphilis diagnosis and treatment and the amount of government in order to ensure sustainability. Only three countries plan to introduce rapid testing because they already have a funding source secured, which is worrisome.

The use of guidelines or national standards, training materials and methods of dissemination for RST

Some countries that have already implemented the rapid tests have all these tools in place. There is a large group of countries that do not have national guidelines that include the test, which threatens the sustainability of RST implementation. Training materials could be shared by countries such as Peru and Brazil and stored online.

Materials for patients must be adapted to each country's specific context. For example, in some countries women are afraid of a fingerstick, and educational materials could address this fear. Brazil and Peru have worked to implement quality control systems at the same time as RST is implemented.

5.7 Implementing RST rural areas: The Brazilian experience

Dr. Adele Benzaken - Alfredo de Matta Foundation, Manaus, Amazonas, Brazil

In 2002, the Brazilian experience with the RST began with pilot projects among specific populations, and eventually reached about 800 people. The tests were validated among pregnant women, transvestites and other vulnerable groups through STI clinics in the remote border region of Manaus.

It was decided to introduce RST through the organization FUNASA⁸, working within the Ministry of Health. FUNASA is an independent agency in charge of indigenous health in the state of Amazonas. The state of Amazonas was chosen because it is the largest state in Brazil and most Brazilian districts border this region.

In Brazil there are more than 195 indigenous ethnic groups living in the Amazon and representing more than 50% (90,000 people) of the Brazilian indigenous population. Most of the indigenous communities are difficult to reach and have no laboratory infrastructure for testing, although they do have antenatal care programs which use rapid tests for syphilis and HIV.

In the state of Amazonas, there are 62 municipalities; in 32 of these syphilis testing is performed. It was a great challenge working with FUNASA to implement this new tool/technology because the all sexually active people were included in the target population (access to communities was difficult, and therefore it was important to take advantage of RST in order to spread coverage to the entire population, not just pregnant women).

⁸ Foundation for health (FUNASA) <http://www.funasa.gov.br/internet/index.asp>

**Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis
– REPORT**

Organization of districts: The districts are divided into centers, and each center has to have a team of health care workers. Sometimes there is a primary care unit, but most often teams travel in boats up the river providing care to communities along the way.

Implementation sought to integrate the two tests: the RST and the rapid HIV test, which is already used widely in Brazil. Both tests were done in one fingerstick. The rapid HIV test is produced in Brazil and distributed for free throughout the country's health system. This is the first experience in the country with integrating both tests in a large area.

During implementation, a system of quality control was implemented in nine districts. A cost-analysis of syphilis testing introduction was also performed.

Of the 9 districts, the implementation work included 83 health district centers. At the beginning, during coordination meetings health professionals from FUNASA wanted to expand the coverage to other district centers. Finally a total 162 district centers were included. Thus, the number of health professionals who were employees of FUNASA also increased.

The introduction of RST included training of health professionals in rapid testing and training in counseling, syphilis, treatment and revision of the national guidelines for syphilis and HIV.

The materials produced were laminated for protection because the work was done in rural conditions and not in health establishments. Included in the materials was a guide on the testing procedure.

The data on testing was collected by mail, and more than 30,000 people have been screened with an HIV test. This was the first time that indigenous people in the Amazonas region were tested for HIV. Previously this population was tested for malaria, but HIV testing uses a different methodology. Eventually, screening was achieved in more of 32% of the indigenous population.

Syphilis prevalence was 1.3% in the district of Manaus excluding the pregnant population. The highest prevalence was found in the tri-border region of Peru, Brazil and Colombia.

During 2010, RST was also applied in other contexts, such as the state's prison system. Over 2,000 were screened from January to November 2010. The prevalence of syphilis among this population was 6.6% and 2% for HIV. A higher prevalence was found in the women's prison, which is considered a good starting point for intervention.

A one minute video was aired on local television and presented at a congress in Brazil. This was a method of disseminating the work that has been achieved.

A main activity of the project is quality control; in Brazil the HIV test is available through different programs including some anonymous screening centers. The HIV test does not have quality control using DTS, which can be transported and does not need refrigeration. The level of health professional conducting the tests was evaluated. With this we were able to discover when professionals should be trained, retrained, or should leave the program according to their performance in testing evaluations. If performance was <70%, the professional was immediately suspended. It is important to mention that the quality control evaluation also includes other aspects. For example, during the program we found that the capillaries were breaking when exposed to pressure, and that some brands were superior to others. Special care was taken to adhere to the stipulated time for reading results, which is 15 minutes. If this time is exceeded there is a risk that negatives will turn to positives.

Quality control also included assessment of RST during transport. The use of DTS is recommended to compare results is recommended for every site at which RST is used (to be performed on departure or arrival).

In Brazil, there are very few studies of the costs associated with RST. The tri-border area of Chimoio was chosen to participate in a study of costs because of the diversity of communities present: communities near the city, fairly remote communities, and very remote communities where the prevalence of syphilis is high.

One of the problems identified in the logistics of the program was transportation because it increased the cost of testing. For example, tickets for transportation from Manaus to Tabatinhas are equivalent to travel to Rio de Janeiro. Another problem identified in the cost study was that some providers buy RST through the federal government and purchase the tests at different prices. A special box was created to carry the tests in order to prevent overheating.

The project was implemented according to Ministry of Health standards. In Brazil, the MOH already bought RST for all pregnant women in Brazil to implement in antenatal care settings, including among indigenous populations. Adult populations also have tests available for the diagnosis of syphilis.

Upcoming meetings between Brazil and Colombia will discuss the possibility of implementation of the same program on both sides of the border. The dissemination of research will be done through a National event in Brazil in March 2011 when the project ends. People from FUNASA, the MOH and country's state coordinators will be invited to attend.

A socio-anthropologic documentary was made on syphilis in Brazil. The story begins in Brazil by highlighting the area with the highest number of flora and fauna species in the world, the longest river in the world, and the diversity of people living there. The documentary focuses on stories of community impact, health professionals working on the project, and the sexuality of the indigenous population.

The idea of harmonization of regulations in the region

Victor Dongo-DIGEMID

Victor Dongo is Director of the Peruvian General Department of Medicine, Supplies and Drugs. He is now responsible for the drug committee of the Andean Community, participates in the Union of South American Nations (UNASUR), and is part from the PAR network policy.

Background

In Peru, 45% of the drug supply comes from national or regional companies. The remainder is imported from outside of the region. For reagents, the situation is worse, with importation of 90% of products. It is worthwhile to mention that regulations for both products are different and that each country has different regulations.

The Andean Community has been in existence for over 30 years and from the beginning the agenda of the ministers of health (REMSA) has included harmonizing the health registries of the Andean Community. Since then, however, few changes have been made, for example changes to the registry of cosmetics: it is now sufficient to register cosmetics in Colombia for use in Peru. For the most part, however, this harmonization has not occurred for many important products.

The diversity of countries leads to differences in regulations, which thereby determines progress towards product introduction in each country. It is difficult to harmonize the health registries for

drugs because the requirements of each country are quite different. In the 90's there was an attempt to regulate health registries. Almost all countries were affected; some reacted quickly, while others resisted or delayed change, as was the case in Peru. New requirements were for product registration went into effect in Peru in November, 2009. Prior to this registration could be obtained in only 7 days.

We are now beginning a new era. In 2010, UNASUR and the Andean Community made major political decisions, and ministers agreed that topics such as health regulations on products must be addressed as a region. UNASUR has created a committee to address these issues. Now the impetus exists to achieve harmonization in all aspects related to the manufacturing of goods. However, if for example a manufacturer in Peru would like to sell their products in Venezuela, the Argentinean regulatory agency has to certify the Peruvian manufacturing practices. This can create a level of distrust. This is considered a barrier for a comprehensive harmonization of product regulation.

Harmonizing regulatory frameworks would take time. In February 2011, Peru will be host a meeting that will address opportunities for harmonization. UNASUR has begun to work to standardize regulations in the region.

Rapid tests in Peru

The government of Peru has agreed to purchase 100% of needed RST at the national level. Thus, centralized purchasing in volume requires that quality control to be monitored through international health agencies; manufacture evaluations are no longer the only option for guaranteeing quality control.

One way to achieve the introduction of rapid tests in the region could be through the revolving fund or strategic fund (used in vaccines for example) of PAHO. The diversity of regulatory frameworks among countries in the region, however, could create a bottleneck.

At the regional level, UNASUR could move forward with the harmonization of labeling. Labeling has nothing to do with quality, is immediate, and would facilitate the entry of products through PAHO. An additional identified problem is the responsibility for the goods entering the country. The intermediary and PAHO are facilitators of the processes but are not responsible for products once they enter the country.

The existing rules in the region do not require that an official body be responsible for the products entering countries or for damaged products.

It is difficult to define the needed requirements to ensure that a product is of high quality when it hits the market, and these requirements vary by country. In Europe, for example, a company may determine who ensures the quality of products, and there is no longer another authority which re-certifies quality.

There are different levels of risk depending on the product. Demands for ensuring quality must be based on these levels of risk. For low risk products, the demand for quality must remain simple. For example, it is faster to authorize product registration for reagents than for pain medication, where the opposite should be true.

In Peru, there are new regulations and laws for reactants, pharmaceuticals, and related devices (find them on web page of the MOH). According to a process of transparency, The Andean Community can make observations for a period of three months. Peru is leading this process

**Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis
– REPORT**

independently through meetings of DIGEMID which include participants from universities, medical schools, laboratories, and the MOH.

5.8 Presentation of experiences in other countries of LA

5.8.1 Honduras

Marco Antonio Urquía Bautista – Chief of the National Program of Sexually Transmitted Diseases, Secretaría de Salud

In Honduras, maternal syphilis prevalence is 1.2%. This prevalence remains high despite the fact that antenatal care coverage is above 84%. However, only 42% of pregnant women are screened for syphilis, leading to high rates of congenital syphilis. More than 14,000 births occur in hospitals each year; of newborns, 1.4% are born with congenital syphilis (not counting women seeking care for post-abortion complications and stillbirths who are not screened for syphilis). In Honduras, there are 20 health districts that serve 97% of the population. In order for rapid tests to be introduced, they have to be certified first.

In 2008, a small project was begun with funding from the UNFPA to implement rapid testing for women in antenatal care services. The test was evaluated, and 100,000 women were screened each year. The type of test used was the Abbott Determine ®.

Those conducting the tests are trained microbiologists. At first they were opposed to RST implementation because they believed that it was not effective and led to false positives. Over time, however, they came to support the use of RST, and are involved in constant training and quality control.

Since 2008, Honduras has celebrated the "International Day for the Elimination of congenital syphilis" on October 20th. This is a national event which involved the 20 health regions, health authorities, and other health programs (maternal-child and adolescent health programs). The event was also supported by UNICEF, USAID, UNFPA and others. There were presentations, forums, and interviews about maternal and congenital syphilis prevention.

Barriers encountered: the inputs are purchased with external funds or grants with no equity of distribution of funding. Each region is beginning to have to purchase rapid tests with use of their own funds.

When tests are inconclusive, samples are sent to a central laboratory for quality control assessments. After a positive RST, an RPR is performed to determine active infection.

Materials produced included leaflets, promotional shirts, and posters on the importance of antenatal care and controlling maternal and congenital syphilis.

Acceptability: The health districts and their leaders have witnessed the need for testing in pregnant women. Where there are no laboratories, the use of RST has proved most important. 10/20 regions have implemented RST. As a result, coverage of syphilis screening in pregnant women has increased from 31% in 2006 to 42% in 2010

Sustainability is not a problem due to the commitment of the health department leaders and sufficient human resources. Currently, 50% of health districts are trained to use RST.

Lessons learned: Creation of the International Day for Congenital Syphilis Prevention was important to raising awareness among health professionals. The institutionalization of RST in 20 regions of the country was very important to its success. Among pregnant women, HIV and syphilis rapid tests are performed concurrently with one drop of blood, but are prepared separately. The constant

support of the CDC and financial support of the UNFPA were essential to successful implementation. An increase of 10% coverage in syphilis screening has occurred, allowing for increased detection and early treatment of women and sexual partners. Treatment of sexual partners has proved difficult, and the country is working on strategies to improve it.

5.8.2 Bolivia

Rita Revollo – Coordinator for HIV/AIDS. Socios para el Desarrollo

The introduction of rapid testing was started with support from the Population Council. We sought to determine the feasibility and acceptability of RST in pregnant women using the Determine® whole blood test in four urban maternity hospitals and 47 first level rural health facilities. 11,618 pregnant women were screened with RST during the study period. The tests were performed by nursing aides, who are the principal attending medical personnel in first level primary care settings, whereas in maternity hospitals the tests were performed by laboratory personnel.

The implementation process was conducted with the coordination and management of the government authorities in the four political regions, with training on theory and practice related to test performance in each setting. Quality control of tests was carried out at the National Laboratory INLASA.

The informational materials used during the implementation process included posters, banners, radio spots, and cards, which were eventually used by the Bolivian Ministry of Health.

The prevalence of maternal syphilis was determined to be 5.5% in antenatal care, while in post-partum care, 12 of every 1,000 women who gave birth were diagnosed with syphilis, both very high figures. It was determined that the acceptability and feasibility of the RST was high in rural areas of Bolivia. The sustainability of RST in Bolivia is guaranteed through its coverage by the current state-provided maternal and infant health insurance plan. This insurance program will expand to provide universal coverage in the future. A pertinent resolution (0521) was also passed in May of 2010. We are in the process of implementing RST within the national health insurance program. Implementation of RST ensures that syphilis screening will be performed during antenatal care, as with mandatory HIV antenatal care testing. Thanks to the international collaboration in support of testing, the political will now exists within the ministry of health to ensure that RST implementation will continue to be supported.

Furthermore, Determine® syphilis tests are now being offered by companies at a cost of \$1.30, rendering it accessible for purchase by the public sector. Second and third level health establishments are now purchasing RST.

Lessons learned

RST is feasible for use with pregnant women. Nursing assistants in first level health establishments are able to successfully perform RST in comparison with medical doctors. This includes performing the test and adherence to bio-safety guidelines. Women with positive test results were treated immediately. Partner notification was often performed subsequently for partners who attended antenatal care visits with pregnant women.

5.8.3 República Oriental del Uruguay

Libia M. Cuevas

The use of RST in Uruguay was approved by the Uruguayan Ministry of Health in 2003. After nearly four years, in 2007 a pilot study was started in first level public sector health establishments. In these health centers, the rapid test for HIV had already been performed since 1997 for women who came to give birth without having been seen previously for antenatal care. In 2000, it was approved that all women who had not received antenatal care would be tested with the HIV rapid tests in all maternity wards.

Similarly, RST is also performed in first level public sector health centers with whole blood alongside the rapid test for HIV. The personnel that perform the test are nurse interns, midwives, or family doctors in polyclinics (which are satellites of a first level care centers) that are in charge of a specific population.

The regulation of syphilis tests dates back to 1993, a period during which syphilis was mandatorily reported by law to the national council.

In 1967 it was documented that a syphilis test should be performed in the first and third quarter with umbilical cord blood.

In 2005 the AIDS program began to report what was happening with syphilis, which led to a increase in political awareness and an epidemiological commission, child health commission, HIV program, and program for women, all of which were responsible for regulating the syphilis rapid test and deciding to offer it to all pregnant women at all levels of care. Later, it was also instituted for use in maternity units for women who had not received antenatal care.

The Legal Code governing recording of syphilis cases first specified that all cases of congenital syphilis should be documented, but was then expanded to include the general population (syphilis in men, women, newborns, and stillborns) in order to assess the country's situation.

Uruguay adopted the Latin American and Caribbean Day for Congenital Syphilis Prevention; 2010 was the third year that this day was celebrated. It has provided an opportunity for dissemination of information and outreach to the general population with the use of advertising and popular media. The introduction of rapid tests to communities was conducted through the public sector integrated health system. It is currently being determined what problems and difficulties exist with implementation.

The introduction of RST was challenging. On the same day that RST is performed, intravenous blood samples are also collected for the RPR and VDRL tests in order to assess the situation and be able to ask the Ministry of Health for a greater quantity of tests based on existing evidence.

The quality control system began to be implemented by the Ministry of Public Health in 2004, and still exists to date.

As part of implementation, flowcharts were completed to assess how diagnosis and treatment is carried out, in addition to documentation of results and notification of patients.

Informational materials including brochures, publications, and posters are in use today.

524 RST were performed, with an observed incidence of 8.4 cases. 504 HIV rapid tests were performed. The difference is due to the fact that in some cases the fingerstick did not produce enough blood to complete both tests, and the patients did not want to be stuck again, which

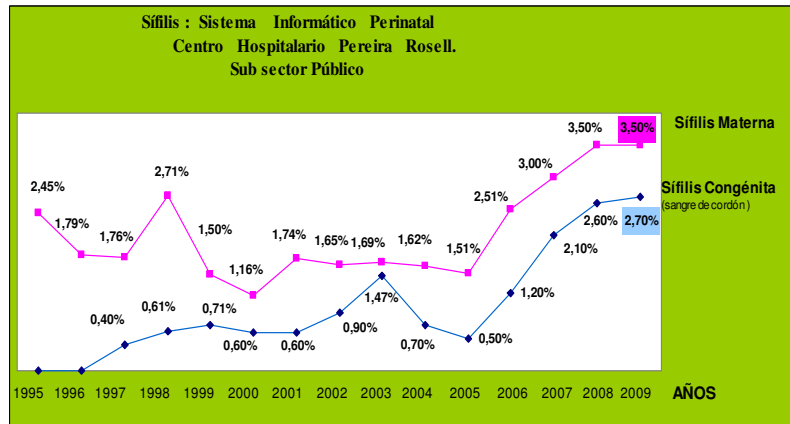
Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis – REPORT

constitutes a barrier for testing. With the VDRL, the incidence was observed to be 7.4. Treating partners proved difficult, with a partner treatment rate of only 50%.

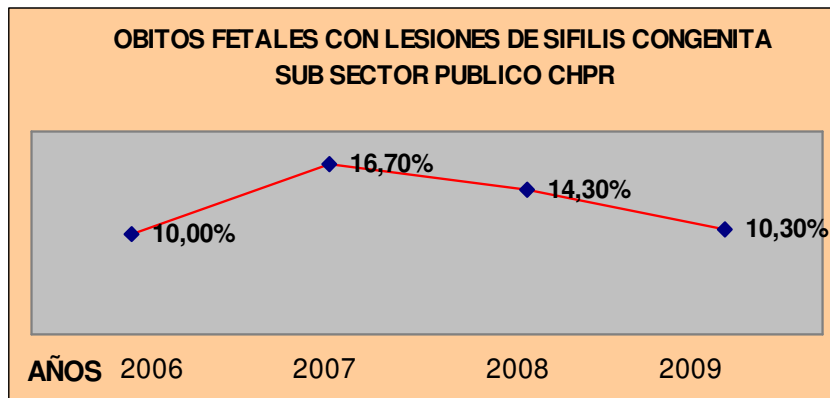
Currently, testing is performed in first level polyclinics, as well as in clinics with practicing family physicians.

During the pilot, pre and post test counseling was performed by nurses. In addition, home visits were performed in order to treat partners, but this strategy has presented many challenges.

Maternal and Congenital Syphilis Trends.



Studying the pathology of stillborn deaths in hospitals was a way to show the success of RST introduction: in 2008, 14.3% of deaths could be attributed to congenital syphilis, whereas in 2009 this rate decreased to 10.3%.



Barriers encountered included:

Problems with equipment, acceptance among health personnel, and discrepancy of results with concurrent RPR tests.

5.8.4 Paraguay

Gloria Celeste Aguilar Barreto – Department of Strategic Information and Neonatal Surveillance of HIV and STIs. National Program for Control of HIV/AIDS and STIs.

Every year, 130,000 women receive antenatal care in Paraguay, with a prevalence of 3.89% for syphilis in pregnant women, and incidence of congenital syphilis of 8.3 of every 1000 live births. The treatment rate for maternal syphilis is around 50%. In 2008, implementation of RST began. This process was accelerated due to financing provided by UNICEF, which initially funded the prevention of mother-to-child transmission of HIV, and subsequently expanded funding to include RST. This included funding for the purchase of tests, personnel training, and monitoring of pregnant women. Currently, the Paraguayan Ministry of Health - Public Health Department is responsible for the purchase of tests.

Rapid tests are also offered in a community testing center run by an NGO that serves the MSM population.

Prior to RST implementation, it was observed that syphilis testing took place in laboratories with limited hours for test taking and processing of results. Furthermore, it was mandated that all tests be free-of-cost, which resulted in an administrative bureaucracy in order to grant access to tests in laboratories (without rapid care) with limited hours in the afternoon and on weekends.

Implementation began in Central Asunción, the capital, in health centers with and without laboratories of first, second, and third levels of care. It changed the process for care of pregnant women receiving antenatal care. Whereas normally the woman would have her blood pressure and temperature taken and receive counseling she would now receive the results of her syphilis test at the same time. With this change more women were able to access both the syphilis and HIV rapid tests at the same time.

Barriers

The program is still a vertical program, and therefore depends on a limited number of staff available. There is a centralized procurement system, which sometimes results in a lack of supplies. There are structural weaknesses inherent to the health systems that inhibit the expansion of diagnosis of syphilis in pregnant women. It was decided that RST would be performed in the first trimester of pregnancy. Nevertheless, 15% of tests are still performed in the laboratory.

5.9 Presentations and Group Discussions: Benefits, opportunities, challenges and options for RST introduction in Latin America

Group 1: Honduras, El Salvador, Nicaragua, Bolivia, Panamá, Perú, Guatemala, República Dominicana.

Opportunities

Each country has the political will necessary to implement RST which needs to be used. After this workshop, the process should begin to negotiate prices at a regional level within a criteria of a harmonized regulatory framework.

The group talked about the possibility of horizontal technical assistance within the region, with the countries with the most experience with implementing rapid tests aiding those that are beginning the process of implementation.

Funding should be sought through the Global Fund and other funding agencies. Funding could be more successfully procured if the rapid test for syphilis is combined with the HIV rapid test, as HIV testing benefits from ample funding resources.

Challenges

It is a challenge to heed the recommendations put forth by the WHO for which tests should be eligible for registration within countries: many times it is known which are the better quality tests, yet because of cost constrictions and administrative processes the tests that are bought are not of the highest quality, but instead are those that cost less. For this reason it would be beneficial if the list included products that were accepted for purchase for each individual country.

Improve coverage of HIV and syphilis screening in pregnant women given that different difficulties exist in each country: in Honduras, for example, coverage is 50%, similar to Guatemala, Bolivia and El Salvador.

Increase the notification and immediate treatment of partners.

We must give women of childbearing age access to syphilis screening before they become pregnant, although this is considered a very ambitious goal.

Needs

Funding for the purchase of tests and sustainability of testing in the mid-term. The government needs to establish testing as a right of all women. Example: In Bolivia the state guarantees RST for all pregnant women, yet in rural areas many women do not have access because there are no mechanisms in place for management of testing.

Review existing standards and protocols: it is essential to revise and update standards to incorporate RST.

Incorporate quality control with the help and expertise of countries that have already implemented RST.

Finally, ensure the quality of tests by evaluating the performance of reagents in each batch.

Group 2: Colombia, Chile y Ecuador

Opportunities

Improve access to RST, especially in populations without access to other testing methods, as well as for confirmatory testing in populations that already have access to syphilis screening but do not have access to immediate results. The problem in our countries is the time between taking tests and when the woman receives her test results. In other words, the problem is often not a question of access to these tests.

Enlist the help of countries that have succeeded in buying RST with help of the UNFPA and other agencies that facilitate the purchasing process.

Implementation of RST for use among vulnerable populations (imprisoned or displaced populations such as in Colombia), STI clinics, or among transgender populations.

Implement the RST in the case of women with miscarriages and complications from abortions, especially since monitoring is not adequate in these areas and cases are underreported.

Challenges

Coordination between laboratories and primary care clinics to coordinate procedures for carrying out RST.

Develop standards for diagnostic and treatment algorithms, as well as educational materials.

**Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis
– REPORT**

Design compatible information systems in order to make cross-country and cross-regional comparisons.

Standardization of indicators.

Needs

In Colombia there is interest in assessment of medical technology and economic evaluation.

Group 4: Peru-Callao, Mexico, London

Opportunities

There are legal and normative frameworks that are well-established by the HIV/STI program. There is a laboratory administrator that can coordinate the formation of a network of laboratories that carry out the quality control of tests.

There is extensive antenatal care coverage, and integrated programs for maternal and neonatal health, as well as the prevention of HIV/AIDS.

Educational materials have been developed with an inter-cultural focus, which should be reviewed by communities.

There is the opportunity to purchase tests at the regional level through the WHO and UNICEF.

Challenges

The use of RST at the national level, and joint HIV/syphilis testing.

The sustainability of the program for the implementation of rapid tests

Political decisions need to be coordinated between countries

Funding needs to be secured and interdisciplinary teams should be established

Spread awareness of the importance of testing, including of men

Needs

Establish a political platform

Train all levels of health professionals

Establish internationally recognized standards of quality control

Secure funding for the implementation of RST and immediate treatment of positive cases (the two go hand-in-hand)

Indispensable conditions for achieving these goals:

Training of interdisciplinary teams.

Mass media campaigns

Male involvement and strengthening of counseling.

Group 5: Argentina and Uruguay

The epidemiological map of both countries is quite similar, while their policies with regards to rapid testing are very different.

Uruguay has experience with rapid testing and implementation of RST has focused in two areas of the country, while in Argentina there is a varied health system. Both countries have high institutional delivery rates, which leads them to establish common strategies for RST.

Opportunities

Uruguay has already had experience in the implementation of the RST, and will share this with Argentina. Both countries have RST trade exchanges, of which there are several in Uruguay and at least one in Argentina.

Challenges

Raise international support in order to garner stronger commitment from in-country authorities.

PAHO is supporting Uruguay and Argentina in the establishment of a baseline of zero prevalence. It

was difficult for these countries to qualify as eligible for assistance from UNICEF for purchase of RST. They are waiting for an answer from UNICEF.

Maintain a trained workforce - the constant rotation of personnel leads to a decrease of awareness about syphilis testing.

Establish and define quality control systems for the use of rapid tests.

Argentina faces the challenge of including other tests in addition to spreading awareness among authorities so that rapid tests can be quickly approved.

Uruguay would have to legislate for use of RST, while in Argentina the use of RST would have to be standardized because the federal government suggests recommendations and rural provinces decide whether to accept these recommendations or not.

Needs

A plan for sustainability. Argentina has received support from agencies in the past, but in order to win the support of the government they must show that after initial assistance, a plan is in place for continuation of testing.

Establishment of a plan for monitoring and evaluation: previously, a plan has been implemented and was rapidly abandoned.

In Argentina it is better to include state policies and not just projects.

Conduct a baseline survey at the national level. It is not well known in any country in the region what is the baseline for syphilis. For MERCOSUR, this was a common objective from the time of its formation. For this reason, Argentina and Uruguay are working to establish a baseline for syphilis and HIV in pregnant women.

Approve and market more rapid test brands.

Reduce costs - in Argentina there is only one approved rapid test, which is marketed by Abbott and costs US \$5. This does not allow for sustainable purchasing.

Grupo 6: Paraguay

Through this meeting, recommendations can be made that will add to the sustainability of this initiative.

The resources need to be procured and an agenda should be prepared for a regional meeting in 2011 which allows for sharing of experiences and mutual technical support.

Ensure that in the next meeting a report will be provided that will include information on the rapid test including costing information.

Recommend that countries engage in cost-effectiveness vs. cost of non-intervention assessments.

5.10 The Quality Control of Syphilis Rapid Tests. Experiences and challenges

Katherine Soto - UPCH

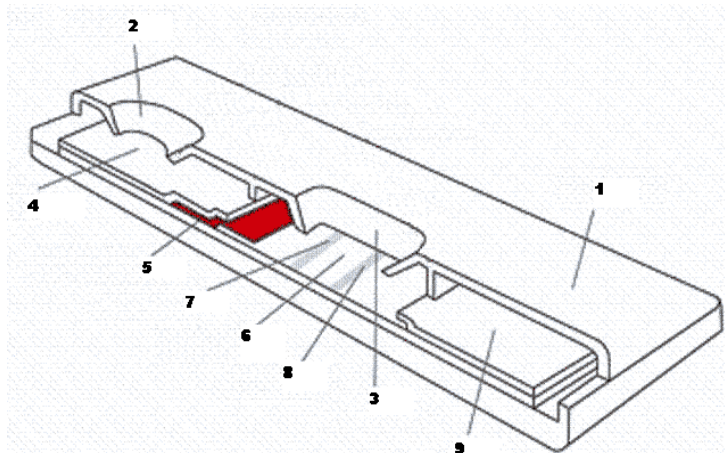
The process of using RST includes three steps: a) conditions prior to testing, including storage conditions, location, control of temperature, humidity and inventory control (very important), evaluation of batches of RST, and information for the patient on RST which allows for a clear understanding of what RST entails; b) performing the test, which includes monitoring, safety precautions, bio-safety, ensuring that the lines of the strips work well, obtaining an adequate quantity of blood, and the procedure for the evaluation of RST and interpretation of results; and c) after the test, which includes documentation of RST (register), reporting of results to patients and patient follow-up, and disposal of hazardous material.

The **quality assurance** of these steps needs to be guaranteed at all times. For this reason, a set of planned activities ensures that quality requirements are met. **Quality control** includes the operational techniques that are performed to find and correct problems that may occur, and include the monitoring, assessment, prevention and detection of problems. This process can help to reduce costs, avoid setbacks, and reduce the occurrence of errors during the testing process.

The RST

In Peru, we worked with the SD Bioline ®. The parts of the test are:

1. Plastic frame: 2) the sample well (S) (where you put the sample and diluents) 3) the output window 4) pad that absorbs the sample and diluents 5) the pad that comes with the absorbed conjugate (conjugate of recombinant antigens of *Treponema pallidum* - colloidal gold) 6) nitrocellulose membrane that will allow for sample to run, conjugate and diluent which also contains the test line and control line 7) test line (T), which will be visible if the sample is positive for syphilis and contains recombinant antigens of *Treponema pallidum* 8) the line of control (C), which records whether or not the fluid has moved 9) absorbent pad shows that sample has reached the end of the case.



The T-test line is what matters for quality control. To do this, a Dried Tube Specimen (DTS) is used. This is a serum sample previously analyzed, colored to make it visible, and dried at room temperature. There are 5 steps for developing a DTS system:

Steps for Producing DTS (Dried Tube Specimen)	
1.	Procurement of samples (from health establishments)
2.	Evaluation of samples (RPR)
3.	Formation of “pools” for evaluation (RPR y TPPA)
4.	Preparation and evaluation of DTS
5.	Preparation of panels

The basic procedure for preparing the DTS is to place 20 µl of blood serum in a tube, allow it to dry, and store it at four degrees centigrade. DTS are produced and evaluated prior to being sent to the field. Once in the field, the DTS are reconstituted to a liquid state and allowed to incubate overnight. The results are then evaluated with RPR and TPPA to ensure that the test results are as desired prior to being used for quality control of RST.

Benefits of DTS

Panels can be used at room temperature; a cold chain is not necessary.

DTS are cheap to prepare and maintain in comparison to liquid samples which would normally be used.

Disadvantages of DTS

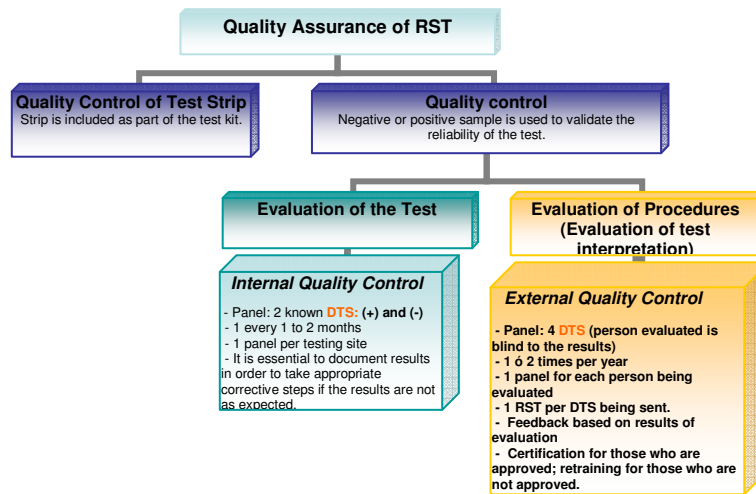
In order to use the serum as if it were a normal sample, the “reconstitution” process is necessary. For this, serum with high titles are needed in order to perform RPR.

Lessons learned from the use of DTS

DTS are stable up to 37°C, both dry and reconstituted (if using RPR serum above a title of 1:2).

DTS are versatile, and can be used for RTS, RPR and TPPA.

Quality assurance of rapid tests is a set of processes and includes the a) quality control of the control strip that comes with the case b) quality control of procedures for testing and evaluation. See figure 1.



In order to evaluate the test, internal quality control is performed. For this, one panel of two DTS is used that is labeled with known results. We use a panel for each storage location. It is essential to record results in order to later evaluate whether RST are working correctly.

Evaluation of procedures is the evaluation of test performance and interpretation, also known as external quality control. This evaluation uses a panel of 4 DTS, for which the subjects performing the test do not know the results. This quality control is performed 1 or 2 times a year, and requires one panel for each person tested. The end goal is to obtain feedback for personnel who are performing the test.

Quality Control and experience of the Maternity Hospital of Lima, Peru (INMP) and the Ventanilla-Callao Health Network:

One important aspect is the training of health personnel in quality control procedures, which was carried out by study coordinators in Lima. At the time that evaluations were performed, coordinators communicated to front-line health providers (midwives, nurses, and other professionals) about the importance of quality control, and whether or not the tests were working properly.

In order to perform internal quality control, a user-friendly approach to working with DTS was created. Providers were shown positive and negative re-constituted DTS, and then conducted the evaluation.

For external quality control, four reconstituted DTS were read by the person being evaluated, and feedback was given accordingly.

The form for reporting occurrences: this document allows for documentation of each step in the quality control system. This includes recording of dates on which evaluations are performed and recording of corrective actions taken in order to determine whether problems were resolved.

For the Callao internal quality control, there were two rounds of evaluation. In the first round two negative DTS were used and correlation of results was 100% in the 19 evaluation sites. In the second round 20 sites were assessed, all of which achieved 100% correlation. These evaluations also proved important in order to allow people who had never seen a positive test result to understand how one looks.

In the Maternity Hospital three rounds of evaluations were performed. During the first round, four sites were evaluated, all of which achieved 100% correlation. In the second and third rounds three sites were evaluated, all of which also achieved 100% correlation of test results. The ongoing assessment of panels is highly important, even when health professionals do not necessarily recognize the importance of re-evaluation. For this reason monitoring and appropriate training are essential.

In Callao, the external quality control is performed with a panel of four DTS, and is performed in 57 health establishments.

We worked with midwives, nurses and lab technicians, and the correlation of test results was found to be 98%. The way in which the evaluation was performed had to be adapted over time due to the fact that in many cases the people who reconstituted the DTS were not the same ones that worked the next day with the panels. Of all the evaluations performed, four health personnel expressed doubts while reading results, which was because they had been instructed to interpret any intensity of colored line as a positive result. This led to the development of the scale of intensity for use when teaching health professionals to interpret tests.

Lessons learned during the first round

Managing the constant rotation of health personnel is important. A color intensity scale should be used to avoid confusion when reading results. Health care workers learned that even in the case of a very weak line, they should consider the test to be a positive result. The process also allowed for the identification of vision problems among health professionals, for which corrective actions were taken.

The **quality control system** included a) the pre-implementation process: preparation of DTS, development of an SOP, and piloting of the assessment; b) the actual implementation: first round, feedback given to staff in both the field and laboratory, quality control of RPR was performed with use of DTS and field staff were retrained in proper performance of RPR; and c) transfer of quality control system to public sector health establishments.

Perspectives of health personnel

Challenges encountered: The reconstitution time needed for the DTS, documenting the results, the difficulty of reading weak results, use of the capillary, the volume of reconstituted DTS needed, and environmental conditions needed to prepare DTS.

Acceptability was high. Health personnel felt empowered to communicate results to patients knowing that the results were reliable.

5.11 Toolkit for the Implementation of Rapid Syphilis Test in countries

Helen Kelly – LSH&TM

Between 2009 and 2010, as part of a project funded by the Gates Foundation for Access to Quality Assured Diagnostics for sexually transmitted diseases, RST was implemented in seven low-income countries. The objectives were to assess the feasibility and cost-effectiveness of the test.

Past experience revealed that introduction of the rapid test kit did not guarantee successful implementation.

The Toolkit is a series of working papers to guide countries through the process of RST implementation. It is being developed based on the experiences of the seven countries in collaboration with the WHO and LSHTM. The purpose of the Toolkit is to provide political decision makers, program managers, and health care providers with the tools necessary to introduce RST.

This package allows users to identify problems and challenges with introduction of RST, and develop a strategy to address these challenges through the use of these tools and information. Every country is contributing its individual experiences towards the development of these documents. The Toolkit will also include case studies that can be used as a model for other programs.

Documents that form part of the Toolkit include:

1. Policy and program guidelines for countries, including costing guidelines for syphilis screening strategies, a technical guide for the development of algorithms used for the delivery of testing and treatment, and a model for the Integration of STI services into pre-existing maternal and perinatal primary care programs.
2. A guide for program administrators who are responsible for the introduction of RST. This includes operating manuals based on laboratory assessments of RST, regulatory guidelines for test selection, guidelines for managing the quality control process, tools for follow-up and evaluation, and a package of communication tools.

6. LESSONS LEARNED

The following is a list of lessons learned compiled during the workshop:

- We can learn from successful experiences with RST implementation in a variety of countries.
- Materials for test introduction and implementation should be shared among countries.
- A technical platform should be created in order to support implementation and monitoring of tests.
- Harmonization of test purchasing and regulatory frameworks can be achieved in Latin America.
- Political will and commitment are important.
- Training of all medical staff is essential for successful implementation of RST
- Quality control of the RST is a fundamental part of the implementation and can be led by laboratories.
- RST can lead to improvements in health systems and services both in first and higher levels of care.
- We have identified opportunities for implementation of the RST among interesting populations and points of care, for example: antenatal care, post-abortion care, indigenous populations, and incarcerated individuals.
- We should seek to integrate both HIV and syphilis testing in order to achieve horizontal programs.
- Strategies should be developed to reach partners, including services for males and extended hours.
- The cost of implementation of RST includes several aspects, including labor, logistics, and infrastructure, not just the purchase of kits.

- Prices for RST are acceptable, and can be purchased for US\$ 0.60. Countries need to look for opportunities for centralized purchasing among countries. It is important to know at what price RST is currently being purchased.
- We must take advantage of the opportunity to reach patients at the time they receive antenatal care, and avoid lost opportunities.
- In many cases the laws, standards, or guidelines established for diagnosis and treatment of syphilis are not well known or applied by health care providers.
- Systems of documentation are often poor.
- It is important to have key allies inside the institutions in which RST is being implemented in order to facilitate the process.

7. CONCLUSIONS

The workshop in Lima allowed for representatives of national programs and other institutions to interact with experts from LSHTM in order to discuss key aspects of RST implementation. RST is considered a cost-effective tool for the elimination of congenital syphilis in the Latin American and Caribbean region. The lessons learned from the experiences of Brazil, Uruguay, Honduras, Paraguay, Bolivia and Peru in the introduction and implementation of RST will allow other countries in the region to learn from these experiences as they begin to use this new technology. During the two days of the workshop, opportunities, challenges, and needs of each country were identified for the successful implementation and sustainability of RST.

To create a good framework for the introduction of this new test, political commitment must complement national policies and technical knowledge of RST. These are the basic inputs needed for successful implementation of rapid testing. Monitoring and evaluation of testing should be continuous during the early stages of implementation. Tools are available to facilitate implementation. It would be very interesting to conduct a training of trainers for test performance, quality control, and monitoring and evaluation. Working groups could be established for each aspect of implementation, for example a group for quality control, a group for advocacy, etc.

Finally, we suggest compiling a report of the workshop and creating a space for the sharing of materials and documents useful for the implementation of RST. Some of these materials and the presentations from this workshop can already be downloaded from the CISNE project website at: <http://proyectocisne.org>.

8. Appendices

Appendix 1. Workshop Attendees

Workshop “OPPORTUNITIES FOR THE IMPLEMENTATION OF RAPID SYPHILIS TESTS (RST) IN LATIN AMERICA FOR THE ELIMINATION OF CONGENITAL SYPHILIS ” 18 Y 19 DE NOVIEMBRE 2010 LIMA – PERU

Nº	País	Name	Cargo
1	Argentina	Alicia Esther Farinati	Universidad del Salvador - Argentina
2		Carlos Alejandro Falistocco	Coordinador Asistencial de la Dirección de Sida e ITS. Ministerio de salud de la Nación Argentina
3		Miguel Tilli	Hospital Interzonal de Agudos Eva Perón BA.
4		Patricia Graciela Galarza	Jefa del Servicio de Infecciones de Transmisión. Instituto Nacional de Enfermedades Infecciosas. ANLIS
5	Bolivia	Rita Revollo	Coordinadora de ITS VIH.Socios para el Desarrollo
6		María Lourdes Zegarra	Responsable de Diagnóstico de VIH, Sífilis y Herpes. Instituto nacionalde Laboratorios de Salud (INLASA) de Bolivia
7	Brasil	Adele Schwartz Benzaken	Directora Presidente. Fundación Alfredo de Matta, Manaus, Amazonas, Brasil
8	Chile	Anibal Ignacio Hurtado Pinochet	Docente Departamento de Dermatología. Hospital del Salvador facultad de Medicina Universidad de Chile
9		Carolina Peredo Couratier	ENCARGADA AREA ITS. Ministerio de Salud de Chile
10		Miriam Del Tránsito Gonzales Opazo	Ministerio de Salud de Chile
11	Colombia	Liliana Isabel Gallego Vélez	Miembro del Comité de Sífilis Congénita. Centro NACER Universidad de Antioquía
12		Julio Cesar Vergel Garnica	Ministerio de la protección Social de Colombia
13	Ecuador	Maria Belen Nieto Castro	Líder Salud de la Mujer. Ministerio de Salud Pública de Ecuador
14		Susana Guadalupe Tamayo Tello	Responsable de Prevención y Promoción VIH/Sida - ITS y Grupos Prioritarios.Ministerio de Salud pública de Ecuador
15	El Salvador	Guillermo Ortiz	Técnico Médico en Infecciones de Transmisión Sexual. Programa Nacional de ITS/VIH/sida Ministerio de salud de El Salvador
16		Wendy Patricia Melara Vaquero	Técnica Medica Encargada del Programa de la Prevencion de la Transmisión Vertical de VIH y Sífilis. Ministerio de Salud Pública y Asistencia Social de El Salvador en el Programa Nacional de ITS/VIH/Sida

Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis – REPORT

17	Guatemala	Estuardo Diaz	Programa Nacional de Prevención y Control de ITS,VIH y sida.
18	Honduras	Marco Antonio Urquía Bautista	Jefe del Programa Nacional de ITS. Secretaría de Salud Honduras
19		Freddy Abraham Tinajeros Guzmán	Consultor, Epidemiólogo Senior, Líder de País en VIH/SIDA Honduras.TEPHINET - CDC/GAP
20		Javier Rodolfo Pastor Vasquez	Viceministro de Riesgos Poblacionales. Secretaría de Salud Honduras
21	México	Lucila Villegas Icazbalceta	Sub directora de Coordinación Estatal. Centro Nacional para la Prevención y el Control del VIH/SIDA
22	Nicaragua	Luis Adolfo Carballo Palma Carballo	Asesor para ITS VIH. Nicaragua
23	Panamá	Aurelio Eliecer Nuñez Maitin	Programa Nacional de ITS, VIH y sida. Ministerio de salud de Panamá.
24		Alcibiades Elias Villarreal Dominguez	Ministerio de salud de Panamá
25	Paraguay	Graciela Russomando	Profesor y Jefe, Dpto de Biología Molecular y Genética. Instituto de Investigaciones en Ciencias de la Salud - Universidad
26		Gloria Celeste Aguilar Barreto	Jefe del Departamento de información estratégica y Vigilantenatal careia de VIH sida ITS. Programa nacional de control de VIH SIDA ITS
27	República Dominicana	Osvaldo Antonio Lorenzo Jimenez	Encargado del programa de reducción de la transmisión materno infantil del VIH. Dirección General de Control de las ITS/VIH/SIDA
28	Uruguay	Libia Mabel Cuevas Messano	
29		María Luz Osimari	Programa ITS/Sida. Ministerio de Salud Pública de Uruguay
30		John Aldao Gonzalez	Referente del área Niñez y Adolescencia. Administración de Servicios de Salud del Estado (ASSE) República Oriental del Uruguay
31	Londres	Rossana Pelling	LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE. PROFESSOR AND CHAIR OF DIAGNOSTICS RESEARCH
32	Londres	David Mabey	LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE. PROFESSOR AND CHAIR OF DIAGNOSTICS RESEARCH
33	Londres	Hellen Kelley	LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE. OVERSEAS PROJECTS SCIENTIFIC COORDINATOR
34	Londres	Andrea Hartley	LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE
35	Londres	Stephanie Garth	LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE
36	Perú	Jose Del Carmen Sara	GERENTE REGIONAL DE SALUD REGION CALLAO
37	Perú	Ricardo Lama	DIRECTORDIRESA CALLAO

Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis – REPORT

38	Perú	Pedro Guerrero	ASESOR DE LA DIRECCION GENERAL DIRESA CALLAO
39	Perú	Jorge Alcantara	JEFE DE LA ESTRATEGIA SANITARIA DE CONTROL DE ITS VIH Y SIDA. DIRESA CALLAO
40	Perú	Walter Martin Loayza Lupaca	DIRECTOR DE LABORATORIO DIRESA CALLAO
41	Perú	Magda Hinojosa Campos	DIRECTORA DAIS
42	Perú	Ruth Escalante	COORDINADORA DE OBSTETRICES
43	Perú	Alvaro Santibanez	COORDINADOR DE LA ESTRATEGIA DE SALUD SEXUAL Y REPRODUCTIVA
44	Perú	Marisela Mallqui Osorio	DIRECTORA DESP
45	Perú	Paula Del Rosario Candela Caderon	COORDINADOR DE LA ESTRATEGIA SANITARIA DE SALUD SEXUAL Y REPRODUCTIVA C.S. MI PERU -VENTANILLA CALLAO
46	Perú	Maria Larriega Valentin	OBSTETRIZ C. S. CIUDAD PACHACUTEC - VENTANILLA CALLAO
47	Perú	Pilar Del Carmen Ortiz Julca	RESPONSABLE DE SALUD REPRODUCTIVA. C.S: ANGAMOS - VENTANILLA CALLAO
48	Perú	Edith Castillo Acevedo	Asistente de la Gestión de la Dirección de Laboratorio. Responsable de MODS. DIRESA CALLAO
49	Perú	Victor Dongo	DIRECTOR GENERAL DIRECCION GENERAL DE INSUMOS MEDICAMENTOS Y DROGAS (DIGEMID) DEL PERU
50	Perú	Pedro Garcia Aparcana	DIRECTOR DE EPIDEMIOLOGIA. INSTITUTO NACIONAL MATERNO PERINATAL (INMP)
51	Perú	Carlos Velasquez Vasquez	RESPONSABLE DE LA ESN PC ITS VIH/SIDA – INSTITUTO NACIONAL MATERNO PERINATAL (INMP)
52	Perú	Ricardo Alvarez Carrasco	JEFE DE LABORATORIO DE INMUNOLOGIA INSTITUTO MATERNO PERINATAL (INMP)
53	Perú	David Calle Zurita	DIRECTOR EJECUTIVO DE APOYO DE ESPECIALIDADES MEDICAS Y SERVICIOS COMPLEMENTARIOS
54	Perú	Marilu Huaman Brizuela	LICENCIADA EN ENFERMERIA INSTITUTO MATERNO PERINATAL
55	Perú	Marlene Toribio Paconpea	LICENCIADA EN OBSTETRICIA INSTITUTO MATERNO PERINATAL
56	Perú	Soloedad Rodriguez Castillo	LICENCIADA EN OBSTETRICIA INSTITUTO MATERNO PERINATAL
57	Perú	Nantenatal carey Costa Conchucos	LICENCIADA EN ENFERMERIA INSTITUTO MATERNO PERINATAL
58	Perú	Jose Luis Portilla Carbajal	COORDINADOR LAB. BTS-CNSP.INSTITUTO NACIONAL DE SALUD DEL PERU
59	Perú	Marita De Los Rios Guevara	EQUIPO TECNICO DE LA ESTRATEGIA SANITARIA DE SALUD SEXUAL Y REPRODUCTIVA. MINISTERIO DE SALUD - PERU.

Opportunities for Implementation of Rapid Syphilis Tests (RST) in Latin America for the Elimination of Congenital Syphilis – REPORT

60	Perú	Lucy Del Carpio Antenatal careaya	COORDINADORA NACIONAL DE LA ESTRATEGIA SANITARIA DE SALUD SEXUAL Y REPRODUCTIVA. MINISTERIO DE SALUD - PERU.
61	Perú	Mery Fernandez	EQUIPO TECNICO DE LA ESTRATEGIA SANITARIA DE SALUD SEXUAL Y REPRODUCTIVA. MINISTERIO DE SALUD - PERU.
62	Perú	Jose Luis Sebastian Mesones	COORDINADOR NACIONAL DE LA ESTRATEGIA SANITARIA DE CONTROL DE ITS VIH Y SIDA. MINISTERIO DE SALUD - PERU
63	Perú	Jose Calderon Yberico	RESPONSABLE DE TRANSMISION VERTICAL DE LA ESTRATEGIA SANITARIA DE CONTROL DE ITS VIH Y SIDA. MINISTERIO DE SALUD - PERU.
64	Perú	Mario Tavera	ESPECIALISTA EN SALUD UNICEF - PERU
65	Perú	Fernando Gonzales	REPRESENTANTE DE LA OMS PERU
66	Perú	Patricia Garcia Funegra	UNIVERSIDAD PERUANA CAYETANO HEREDIA
67	Perú	Cesar Carcamo	UNIVERSIDAD PERUANA CAYETANO HEREDIA
68	Perú	Marina Chiappe	UNIVERSIDAD PERUANA CAYETANO HEREDIA
69	Perú	Sayda La Rosa	UNIVERSIDAD PERUANA CAYETANO HEREDIA
70	Perú	Marcela Lazo	UNIVERSIDAD PERUANA CAYETANO HEREDIA
71	Perú	Patricia Mallma	UNIVERSIDAD PERUANA CAYETANO HEREDIA
72	Perú	Claudia Morales	UNIVERSIDAD PERUANA CAYETANO HEREDIA
73	Perú	Beth Williams	UNIVERSIDAD PERUANA CAYETANO HEREDIA
74	Perú	Katherine Soto	UNIVERSIDAD PERUANA CAYETANO HEREDIA
75	Perú	Lorena Lopez-Torres	UNIVERSIDAD PERUANA CAYETANO HEREDIA
76	Perú	Magaly Blas	UNIVERSIDAD PERUANA CAYETANO HEREDIA
77	Perú	Yliana Solis	UNIVERSIDAD PERUANA CAYETANO HEREDIA
78	Perú	Gabriela Ildefonso	UNIVERSIDAD PERUANA CAYETANO HEREDIA
79	Perú	Lourdes Pilar Palomino Salazar	DIRESA CALLLAO
80	Perú	María Del Carmen Calle Davila	DIRESA CALLLAO
81	Perú	Marina Soto Calderon	ICW -PERU
82	Perú	Munoz Zambrano Maria E.	INSTITUTO NACIONAL DE SALUD
83	Perú	Walter Curioso	UNIVERSIDAD PERUANA CAYETANO HEREDIA

