ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION

A WINNABLE BATTLE:

THE ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION-ZAMBIA'S 18-MONTH PROGRESS REPORT ON ACTIVITIES TOWARDS THE DUAL ELIMINATION OF HIV AND SYPHILIS

OCTOBER 2011 - MAY 2013

www.pedaids.org

TABLE OF CONTENTS

List of Acronyms

ANC	Antenatal care
CDC	U.S. Centers for Disease Control and Prevention
CIDRZ	Centre for Infectious Disease Research in Zambia
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
JSI	John Snow Inc.
MCDMCH	Ministry of Community Development, Maternal Child Health
MCH	Maternal and child health
MOH	Ministry of health
MSL	Medical Stores Limited
PMTCT	Prevention of mother-to-child HIV transmission
RPR	Rapid plasma reagin
RST	Rapid syphilis testing
SMAG	Safe motherhood action groups
SMGL	Saving Mothers Giving Life
STI	Sexually transmitted infection

1.0 BACKGROUND

Syphilis is a major cause of morbidity and mortality among women and children in developing countries.[1] Of the 12 million new syphilis cases that occur worldwide every year, the majority occur in developing countries. Pregnant women who are infected with syphilis can transmit the infection to their fetus causing congenital syphilis. An estimated two million pregnancies are affected, of which approximately 25% end in stillbirth or spontaneous abortion; 25% of newborns have low birth weight or serious infection, both of which greatly increase the risk of death. The prevalence of syphilis among pregnant women attending antenatal clinics in sub-Sahara Africa ranges from 2.5% to 17%; 500,000 fetal and neonatal deaths are attributed to syphilis. Congenital syphilis is a disease which could be eliminated through effective antenatal screening and effective treatment of infected pregnant women. The lack of diagnostic capabilities is a major impediment to syphilis prevention and control in most resource-constrained countries.

In Zambia, before 2011, the rapid plasma reagin (RPR) test was widely used to diagnose syphilis in pregnant women. RPR testing requires a laboratory with reliable electricity supply to keep the reagents at a temperature range of 2 to 8 degrees Celsius, and the procedure requires the use of a laboratory shaker. The RPR test can be difficult to interpret and therefore requires trained laboratory technicians. RPR tests are usually performed in batches, thus, the results may not be available at the same clinic visit; patients are asked to return at a later date for results and treatment and some do not return, and therefore remain untreated. RPR can only be found in health centers and hospitals, thus, many clients attending primary health care facilities have no access to screening.

Savings Mothers, Giving Life

- Global project aimed at reducing maternal and child mortality;
- Partnership between public, private, and non-government organization groups;
- In Zambia, four districts have been targeted: Mansa, Kalomo, Lundazi, Nyimba
- Interventions include:
  - Improve transportation to health facilities for emergencies
  - Train Safe Motherhood Action Groups (SMAG) to increase use of services
  - Implement the national electronic health record system to improve care and follow-up
  - Conduct maternal death audits
  - Ensure all mothers have access to HIV and syphilis testing and treatment during pregnancy

In view of these challenges posed by RPR, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), working in collaboration with Centre for Infectious Disease Research in Zambia (CIDRZ), conducted a study funded by Bill and Melinda Gates Foundation and the World Health Organization[2] to assess the feasibility, acceptability and cost-effectiveness of introducing rapid syphilis testing (RST), a one-step point-of-care test, within an integrated prevention of mother-to-child HIV transmission (PMTCT) package. The study demonstrated not only that RST was feasible in both busy urban (Lusaka) and rural (Mongu) sites where it was conducted but also that it was acceptable and cost-effective. The findings compelled the Ministry of Health (MOH) to adopt the use of RST in health service delivery.

[1] TDR/World Health Organization (2007). The use of rapid syphilis tests. Geneva: WHO

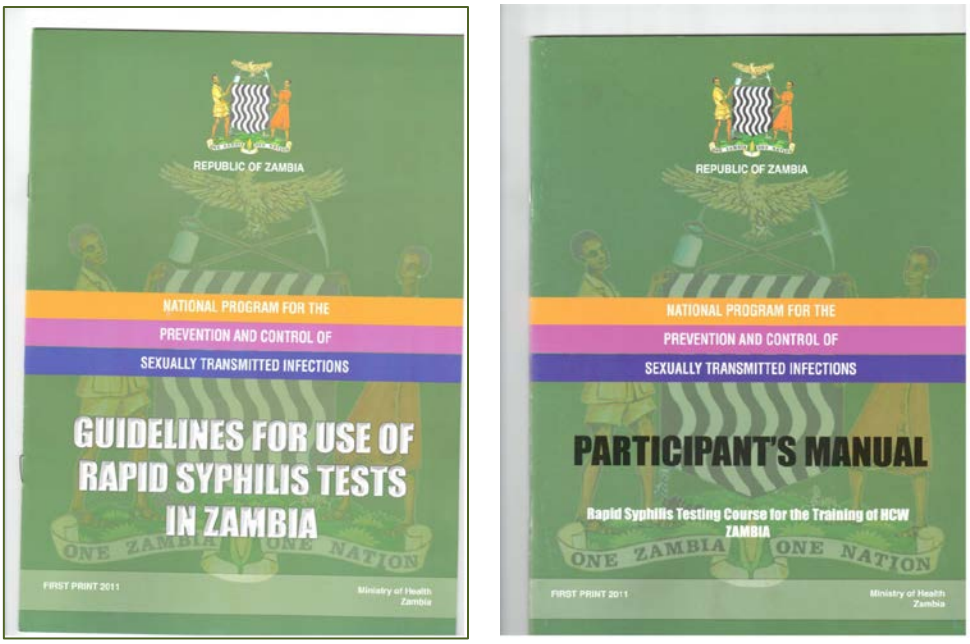
[2] Strasser S, Bitarakwate E, Gill M, Introduction of rapid syphilis testing within prevention of mother-to-child transmission of HIV programs in Uganda and Zambia: a field acceptability and feasibility study, J Acquir Immune Defic Syndr. 2012 Nov 1;61(3):e40-6

District nurses, EGPAF employees and London School of Hygiene and Tropical Medicine staff who took part in the original study.

2.0 EGPAF Rapid Syphilis Testing Program Overview

In 2011 under the CDC-funded Project HEART program, EGPAF held a number of meetings with key officials from MOH to disseminate study findings, with the view of influencing policy change toward the adoption of RST into the routine package of antenatal care. One crucial meeting was held in Lusaka with, among others, the Director for Public Health and the MOH spokesperson. The study findings were presented and discussed, and the MOH resolved to adopt RST as a point-of-care test for syphilis testing. This led to further planning meetings with the sexually transmitted infections (STI) technical working group aimed at mapping out a strategy for scaling up the use of RST.

Development of guidelines and training manuals followed. EGPAF took a leading role in the process, including the printing of a training manual and testing guidelines in 2011. Later, EGPAF along with the MOH successfully advocated for a phased introduction of RST beginning with the Saving Mothers Giving Life (SMGL) districts; namely Kalomo, Lundazi, Mansa and Nyimba.



Guidelines and training manuals developed to guide health care worker staff in administration of RST

2.1. Introduction of RST in the four SMGL districts

In the first quarter of 2012, EGPAF with support from U.S. Centers for Disease Control and Prevention (CDC) embarked on the roll out of RST, beginning with training health care workers from each of the health facilities in the SMGL districts. The course was made up of 11 modules covering the topics below.

1. Global overview of syphilis prevalence
2. Integration of RST into other PMTCT services
3. Syphilis testing technologies
4. Safety at RST testing site
5. Testing and treatment algorithms for Zambia
6. Preparation for RST
7. Quality control
8. Steps in performing RST
9. Supply and stock management
10. Documents and record management
11. Monitoring

RST trainings were conducted in collaboration with the MOH. Table 1 below shows number of HCWs trained in the four districts.

Table 1: RST Training Progress

District	Number of people trained	Number and percent of sites in district with trained personnel
Nyimba	26	17 (100%)
Mansa	33	33 (100%)
Kalomo	36	35 (97%)
Lundazi	48	48 (100%)
Total	**143**	**133 (99%)**

These trainings targeted key maternal and child health (MCH) staff from all the facilities in the districts and the district laboratory personnel responsible for quality assurance, kits storage and supply management of point-of-care diagnostics. From the district health offices, MCH coordinators and clinical staff attended the trainings. The MOH, in collaboration with EGPAF and along with the district health officers, was responsible for the identification of the health workers to be trained.

In Kalomo, one facility was not represented in the training but was later, during supervisory visits, provided with an on-site orientation during the first round of support supervision visits. After the trainings, the districts were supplied with RST kits for distribution to facilities.

2.2 National-level Technical Assistance and Support

At the national level, EGPAF continued to advocate for the inclusion of RST kits into the national procurement and supply chain and a wider roll-out of the tests to additional districts. Meetings were held with MOH/Ministry of Community Development, Maternal and Child Health (MCDMCH) and other key partners like John Snow Inc's (JSI) supply chain management program, leading to inclusion of RST kits into the national supply chain. For the first time, in 2012, a bulk of RST kits were procured and distributed initially to 13 additional districts that are receiving training from the trainers. These district trainers were trained by EGPAF staff in collaboration with the national STI trainers from MCDMCH. The distribution of the test kits is being done through the national supply chain, managed by Medical Stores Limited (MSL) and procured with support from JSI.

2.3 Supply Chain Management Support and Procurement

Generally, all medical supplies for the health facilities are managed by MSL. This company is responsible for storage and distribution of national supplies. In the case of RST kits for SMGL districts, EGPAF was procuring and managing the distribution of the stock in 2011-2012. This is because RST was initially implemented in the four SMGL districts and there were fears that, if channeled through MSL, there may be challenges ensuring that supplies are only distributed to the intended districts. The number of test kits supplied to the districts was determined using estimates of the expected number of pregnancies per month per district.

The districts have been ordering test kits on a quarterly basis. Delivery of supplies usually coincides with support supervision visits by EGPAF and MOH staff. Table 2 shows the number of test kits that were procured and distributed between February and August 2012.

Table 2: RST kit distribution by district in a six-month period

District	Number of test kits supplied	Total tests
Nyimba	390	11,700
Lundazi	270	8,100
Mansa	372	11,160
Kalomo	381	11,430
Total	1,413	42,390

2.4 Supportive Supervision and Mentorship

The importance of support supervision and mentorship in RST, as is the case with other rapid diagnostic tests, cannot be over-emphasized. The purpose of these visits is to reinforce quality assurance measures at the facilities by ensuring that the trained health personnel and those oriented by their colleagues maintain quality standards when performing the tests. This includes accuracy of test results by staff, especially weakly positive results and testing new supplies of RST against known positive and negative samples.

At least once every six months, EGPAF alongside MOH central and district health officers, provided supervision and mentorship support to the facilities in the SMGL districts. The visits helped to ensure smooth implementation of RST in the districts, build capacity of district health officers, so they can provide similar support independently, and promote local ownership of the program.

At the district-level, the laboratory personnel responsible for supply management and quality assurance, as well as the district health information officers, joined EGPAF and MOH teams at site visits. A support supervision tool modeled from the checklist used in the RST study was used to ensure a thorough assessment of RST provision was done during the visits. The tool covers all aspects of RST provision from pre-test counselling, preparation of testing cassettes, performing actual testing through to recording of the test results. It also assesses stock management and quality control. During the visits, registers were also reviewed to ensure that records were up-to-date. Each of the four supported districts received two eight-day support, supervision and mentorship visits in the period under review. In the first round, the target was to cover as many health facilities as possible. Sites prioritized were the hard-to-reach rural health centres.

Training of health care workers on RST

In the second round, the facilities targeted were those with previously assessed challenges, those that were not visited in the first round, and the newly opened health posts or centres. At the end of this round, all the facilities in the SMGL districts had received at least one supervisory support and mentorship visit.

3.0 ACHIEVEMENTS

EGPAF working in collaboration with MOH and district staff managed to introduce RST within all the facilities in the targeted SMGL districts.

Table 3: Syphilis testing before and during RST implementation

District	Kalomo	Lundazi	Mansa	Nyimba
Implementation Period	Feb 2012-Mar 2013*	Feb 2012-Mar 2013*	Feb 2012-Mar 2013*	Feb 2012-Mar 2013*
Total Number of Health Facilities (HF)	36	48	33	18
Number of HFs Implementing RST (Percentage Facility Coverage)	36 (100%)	48 (100%)	33 (100%)	18 (100%)
Total First ANC Visits	13,606	18,176	14,117	5,800
Total Tested with RST	8,976 (44%)	11,146 (61%)	10,612 (75%)	4,825 (83%)
Total Tested Positive (Percentage tested HIV positive)	417	128	415	147
Syphilis Prevalence	5%	1%	4%	3%
Baseline Period	Jan 11-Jan 13	Jan 11-Feb 12	Jan 11-Jan 12	Jan – Dec 11
Total First ANC Visits	12,661	18,240	7,989	4,589
Total Tested for Syphilis (%)	2,749 (22%)	4,788 (26%)	2,457 (31%)	2,574 (56%)
Total Tested Positive	156	47	248	162
Syphilis Prevalence	6%	1%	10%	6%

**Time periods may differ depending upon when districts started implementing RST.*

As can be seen in Table 3, syphilis testing for pregnant women on their first visit significantly increased in the four districts when comparing the baseline period (2011) against the implementation period (between February 2012 and March 2013). Testing in the four districts increased from 22%-56% at baseline to 61%-83% during intervention. See Table 4 for comparison of percentages tested for syphilis before and after RST implementation.

Table 4: Change in percentage tested for syphilis before and after RST implementation.

District	Before	After
Kalomo	22%	66%
Lundazi	26%	61%
Mansa	31%	75%
Nyimba	56%	83%

During most of the period under review, stocks of RST were stable, with minimal stock outs recorded. Infrequent artificial stock outs occurred when test kits were available within the district, such as at the district head office, but did not reach the final destination of the clinic because of miscommunication between the facilities at district office. Ensuring the adequate and consistent supply of a new commodity requires constant vigilance and oversight.

High coverage for training and peer orientation was noteworthy. Only one facility from Kalomo did not have representation in the initial training among all the facilities in the SMGL districts. The newly trained HCWs went back and oriented their colleagues at their facilities in the use of the new test kit. The successful cascade of training may be attributed to the desire for diagnostics and the perceived (and real) benefits of having this test available for use. Further, during the technical support visits, newly opened health facilities received onsite training as needed. EGPAF also built the capacity of district laboratory staff to provide continued technical support to the facilities. Good records management was reinforced and good record keeping practices were noted in most facilities. A separate register for RST was made and updated. There are a few facilities, especially in Lundazi, where records were lacking and such were some of the important targets for mentorship support.

4.0 Challenges

Although the four SMGL districts have implemented RST testing as hoped, there have been a few challenges that were faced, some of which are ongoing but are being addressed. These challenges included failure by district laboratories to support ongoing quality control systems. The labs have not been providing quality control samples for the facilities to use to check that new supplies of test kits are in good condition. The district has been engaged to ensure this important component of rapid diagnostic test quality assurance is routinely supported.

Other challenges at a few facilities were with the actual test procedure. Some HCWs recorded false results due to prolonged waiting time (more than the number of minutes required for a lateral flow assay) to read results. The technical support team reinforced the steps in performing the test and the need to read the job aids whenever the staff performing test were not sure. A very practical component of supportive supervision was ensuring the job aids were always available and prominently displayed in testing area.

There also have been challenges in a few facilities on same-day testing and treatment due to myths surrounding administering the drug treatment - benzathine penicillin. Some people believe one cannot receive an injection on an empty stomach and must eat before getting an injection. Yet, it is known that some people who leave for food never return for treatment and that the injection can be given regardless. Some HCWs ask their patients to have something to eat before they can be given the drug. This may result in a missed treatment opportunity in instances where a pregnant woman has nothing to eat in the near vicinity and goes home and does not return.

5.0 Recommendations

There is need for a solid district-driven quality assurance system that will help ensure that the standard operating procedures are adhered to and the diagnostic tests are routinely subjected to quality control to avoid compromising the quality of the tests. The district laboratories should consistently provide the facilities with quality control samples and regular onsite technical support and mentorship. There is also need to continue reinforcing good supply chain management practices to avert artificial stock outs. EGPAF will continue to advocate for the inclusion of RST supplies in the national procurement and supply chain.