



Congenital syphilis in Nigeria, Zambia, and India

Identifying policy pathways to eliminate mother-
to-child transmission of syphilis

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ACRONYMS

ANC	antenatal care
ANM	auxiliary nurse midwife
DHS	Demographic and Health Survey
DTECS	Dual Testing and Elimination of Congenital Syphilis
EMTCT	elimination of mother-to-child transmission
ENAP	Every Newborn Action Plan
EPTCT	elimination of parent-to-child transmission
HMIS	health management information system
LMICs	low- and middle-income countries
MoHFW	Ministry of Health and Family Welfare
MoH	ministry of health
MTCT	mother-to-child transmission
NACO	National AIDS Control Organization
NHM	National Health Mission
NHMIS	Nigeria Health Management Information System
PIP	Program Implementation Plan
PMTCT	prevention of mother-to-child transmission
POC	point-of-care
PTCT	parent-to-child transmission
RDT	rapid diagnostic test
RMNCAH	reproductive, maternal, newborn, child, and adolescent health
RMNCH+A	Reproductive, Maternal, Newborn, Child Health plus Adolescent
RPR	rapid plasma reagin
SIMS	Strategic Information Management System
STI	sexually transmitted infection
TWG	Technical Working Group
USAID	United States Agency for International Development
VDRL	Venereal Disease Research Laboratory
WHO	World Health Organization



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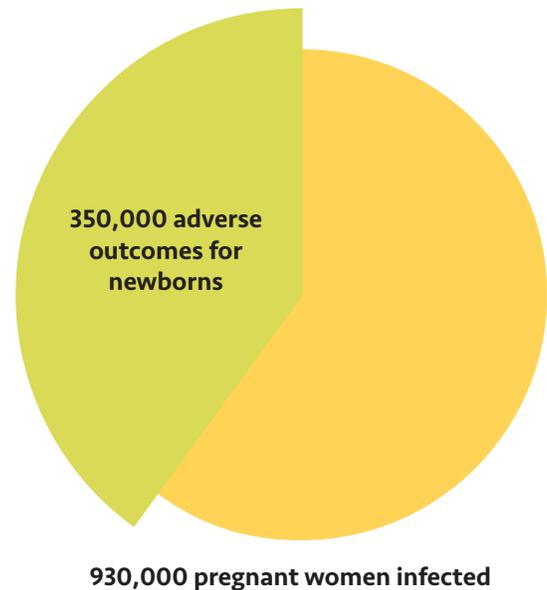
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INTRODUCTION

While maternal and newborn health is improving around the world, the well-being of every mother and newborn cannot be assured unless countries prioritize and address sexually transmitted infections (STIs), including syphilis. While not typically thought of as a maternal or newborn health issue, syphilis is one of several STIs that can be passed from a pregnant woman to her baby during pregnancy and childbirth, known as “mother-to-child transmission” (MTCT) or “parent-to-child transmission” (PTCT). In 2012, nearly 1 million pregnant women (930,000) were estimated to be infected with syphilis. These pregnancies resulted in 350,000 adverse outcomes, including early fetal loss, stillbirths, neonatal deaths, preterm or low-birth-weight babies, and babies born with syphilis (known as congenital syphilis).¹ Having syphilis can also increase a woman’s risk of acquiring HIV by two to five times, posing even greater risks to her and her baby, as HIV can also be transmitted from mother to child.²

The global burden of syphilis on pregnant women and newborns



Yet, no mother or baby needs to suffer from syphilis. Every effort should be made to prevent a woman from being infected with syphilis in the first place, including provider counseling on safer sex and provision of male and female condoms. Should a pregnant woman be infected, syphilis is relatively easy to detect and treat, and MTCT of syphilis is entirely preventable. A range of syphilis diagnostics are available, including rapid, point-of-care (POC) tests that can expand access and reach pregnant women in resource-constrained settings. Syphilis is also simple to cure with appropriate antibiotics. Syphilis diagnosis and treatment have been shown to be cost-effective and feasible in low-resource settings. The World Health Organization (WHO) includes routine syphilis screening of pregnant women—and treatment if positive—in its required package of basic antenatal care (ANC) services.

Over the past decade, several global policies have been issued that highlight the importance of syphilis screening and treatment in ANC. These include a range of guidelines and tools developed in support of WHO’s global initiative to eliminate congenital syphilis, as well as mention of congenital syphilis in United Nations strategies focused on reproductive, maternal, newborn, child, and adolescent health (RMNCAH), such as the [Every Newborn Action Plan \(ENAP\)](#) and the [Global Strategy for Women’s, Children’s, and Adolescents’ Health](#), among others (see Annex: Key global guidelines and strategies that address syphilis).

However, despite normative guidance and affordable, effective solutions, universal screening and treatment of syphilis in pregnancy does not occur in most low- and middle-income countries (LMICs). There are a number of factors that affect uptake and implementation of programs for elimination of mother-to-child transmission (EMTCT) of syphilis, including the fact that congenital syphilis is largely absent from high-level discussions on RMNCAH and is not a major focus of the newborn health agendas of most global health institutions or donors. This lack of global championship in turn diminishes impetus for countries to adopt the EMTCT of syphilis agenda.

Additionally, country-level policy-related barriers play a significant role in hindering progress. In Nigeria, Zambia, and India—three countries at different stages in their policy and programmatic response to EMTCT of syphilis—common challenges include low prioritization of congenital syphilis due to limited awareness and understanding of disease burden by key policymakers, limited funding for testing and treatment of syphilis in pregnancy, and inadequate implementation of existing policies. In order to ensure that all newborns have a healthy start to life—and that all mothers experience positive sexual and reproductive health—decision-makers must strengthen their commitment to EMTCT of syphilis and develop and implement policies that expand access to high-quality services at all levels of care.

METHODOLOGY

In 2016, PATH undertook an assessment to understand why congenital syphilis is not being prioritized, given the health burden and possibility of elimination, and to identify ways to strengthen prioritization, policy, and programming in three countries: Nigeria, Zambia, and India. The assessment built on the work of PATH's and WHO's Dual Testing and Elimination of Congenital Syphilis (DTECS) project, an investment case study funded by the Bill & Melinda Gates Foundation and carried out in the same three countries from 2012 to 2014.

PATH performed policy landscaping and conducted interviews with five to seven stakeholders in each country. Interviewees were selected based on their role and expertise regarding STI/HIV and RMNCAH policy and programming, as well as referral by in-country PATH staff and partner organizations. Interviewees in each country—including government officials, representatives of multilateral agencies, donors, medical associations, and nongovernmental organizations—generously contributed insights on their country's congenital syphilis efforts and recommendations for strengthening policies and programming. While the analysis in this paper examines gaps and opportunities specific to each setting, other countries may glean lessons that can be applied to their efforts to eliminate congenital syphilis.

About the Dual Testing to Eliminate Congenital Syphilis project (2012-2014)

The goal of DTECS, a joint project of PATH and WHO, was to work in three focus countries—India, Nigeria, and Zambia—to reduce adverse outcomes for pregnant women and newborns due to MTCT of syphilis by (1) strengthening the evidence base through synthesis of current knowledge and estimation of the burden of disease; (2) analyzing previous attempts to eliminate congenital syphilis and using the lessons learned to improve the enabling environment to support elimination of congenital syphilis; and (3) analyzing country-level readiness and developing scenarios, including costs associated with testing and treatment, for congenital syphilis. These countries were selected because they have diverse contexts and lessons learned for scale-up, including varied syphilis prevalence rates among pregnant women and differing levels of policy commitment to and program implementation of MTCT of syphilis.

Key project activities, especially those associated with the development of country investment cases for scale-up, produced notable results. For example, in Nigeria, the project helped increase prioritization of syphilis in pregnancy, as demonstrated by syphilis being added back into the ANC HIV sero-prevalence sentinel survey. In Zambia, activities rekindled national commitment to EMTCT of syphilis and forged agreement on key next steps. Activities in India were successful in supporting the country to launch a new national strategy and operational guidelines for EMTCT of syphilis, and policy changes were made to include syphilis testing and treatment as an essential component of the ANC package.

SCREENING AND TREATMENT OF SYPHILIS IN PREGNANT WOMEN: WHAT YOU NEED TO KNOW⁴⁻⁷

BEFORE REVIEWING THE POLICIES, GAPS, AND OPPORTUNITIES RELATED TO CONGENITAL SYPHILIS IN NIGERIA, ZAMBIA, AND INDIA, IT IS IMPORTANT TO UNDERSTAND THE LATEST SCREENING AND TREATMENT OPTIONS.

Safe, effective, low-cost tools exist for screening pregnant women for syphilis and treating them if needed. However, current approaches to syphilis testing and treatment have nuances that are important for policymakers and advocates to know. For example, different types of syphilis diagnostics are available, and each type has distinct advantages and disadvantages, especially regarding its use in low-resource settings. And while syphilis is simple to treat with appropriate antibiotics, supply and provision of the medicine (benzathine penicillin) remain a challenge for some countries. Ultimately, EMTCT of syphilis is possible, and country contexts and needs should drive how screening and treatment efforts are implemented.

How is syphilis diagnosed?

Most pregnant women with syphilis do not show any signs or symptoms and can only be identified through screening with blood tests. To diagnose active syphilis and facilitate appropriate treatment, the recommended practice is to administer two tests, one of each type: “nontreponemal” and “treponemal”:

- **Nontreponemal tests** detect antibodies in the blood due to injured cells, which could result from syphilis as well as other possible infectious or noninfectious causes. Nontreponemal tests are important because they identify whether an infection is active, which is valuable to know for administering appropriate treatment. Because a positive nontreponemal test

could indicate active syphilis or an active infection or medical condition that is not syphilis, confirmation with a treponemal test is recommended.

- **Treponemal tests** detect antibodies in the blood that are directly related to the bacteria that causes syphilis infection. Treponemal tests are important because they identify whether syphilis infection is present. A positive treponemal test, however, cannot distinguish between active syphilis infection and past-treated syphilis infection. Past-treated syphilis infection does not require antibiotic treatment, so treatment of a patient on the basis of a single positive treponemal test could result in potential overtreatment, particularly in settings where syphilis is endemic.

Syphilis screening algorithms

The traditional syphilis screening algorithm,* intended for settings with laboratory capacity, is to administer the nontreponemal test as the initial screening tool to identify active infection. If the nontreponemal test shows a positive result, then a treponemal test is administered to confirm syphilis infection.

In settings with limited laboratory capacity, either a single nontreponemal or treponemal test can be administered. A positive result on either test can be used

* In certain settings with low syphilis prevalence, the algorithm is flipped so that the treponemal (syphilis-specific) test is administered first, and if positive, the nontreponemal test is given to confirm active infection.

What kinds of syphilis diagnostics are available?

A variety of laboratory-based and rapid diagnostic tests (RDTs) are available for syphilis screening.

	Description	Type of test	Brands available
Laboratory-based syphilis tests	Tests that have been traditionally used to screen for syphilis. Tests require laboratory equipment, skilled technicians, refrigerators, and electricity to perform.	Can be either nontreponemal or treponemal	Nontreponemal tests: Rapid plasma reagin (RPR) and Venereal Disease Research Laboratory (VDRL) Treponemal tests: At least five different brands available
Syphilis RDTs	A POC test that can be used in all health settings to facilitate immediate treatment.	Treponemal	More than 20 brands are commercially available
Dual HIV/syphilis RDTs	A POC test that combines rapid tests for HIV and syphilis into one platform.	Syphilis component of dual test is treponemal	Five brands are commercially available, and one of these is prequalified by the WHO

as a basis to treat a pregnant woman—in spite of risks of overtreatment—in order to minimize risk to the fetus.

What are considerations for using the different kinds of syphilis diagnostics in low-resource settings?

Laboratory-based tests

Advantages: The main advantage of laboratory-based tests is that they are highly accurate. Nontreponemal tests like RPR and VRDL are inexpensive and have the ability to distinguish between active infection and past-treated infection, which aids in appropriate treatment.

Disadvantages: The main disadvantage is limited operability and availability in low-resource settings. The infrastructure required to administer the tests (e.g., laboratory equipment, skilled technicians, refrigerators, and electricity) is not always available at ANC and primary health care settings, which constrains availability of the tests. Furthermore, test results processed in laboratory facilities may not be available for days or even weeks. This can delay treatment of the pregnant woman and create loss to follow-up if she does not return to the facility for her results.

Syphilis RDTs

Advantages: The main advantages of syphilis RDTs are that they are easy to use in all health settings, are inexpensive, do not require special storage or transport conditions, and provide immediate results—generally within 5 to 30 minutes. Syphilis RDTs have comparable performance to laboratory-based tests.⁸ In settings lacking laboratory capacity, syphilis RDTs have been shown to be useful in detecting infection in pregnant women with no previous access to testing, those marginalized from ANC, and those unlikely to return for results.

Disadvantages: The main disadvantage is that all currently available syphilis RDTs are a treponemal test, meaning that they cannot distinguish between active infection and past-treated infection. If antibiotics are administered on the basis of a single positive syphilis RDT, overtreatment may occur. However, the benefits of immediate treatment have been shown to outweigh the risks of overtreatment, especially to prevent syphilis transmission from a pregnant woman to her fetus.⁹

Dual HIV/syphilis RDTs

Advantages: In addition to having the advantages of syphilis RDTs, HIV/syphilis tests allow for same-day testing and treatment of syphilis, as well as same-day referral for HIV confirmatory testing. This is important for increasing access to HIV and syphilis services for those who may be at risk for both STIs. Dual HIV/syphilis

tests have the potential for cost savings and may save time for health workers.

Disadvantages: Dual HIV/syphilis tests are not yet widely available in LMICs. Additional field testing and performance studies are needed in resource-constrained settings to strengthen the evidence base.

How is syphilis treated?

When a pregnant woman tests positive for syphilis, the infection can be treated effectively with antibiotics. A single dose of long-acting, intramuscular benzathine penicillin can cure maternal syphilis and prevent MTCT when administered early in pregnancy. Infants born to mothers with untreated or inadequately treated syphilis are at risk for congenital syphilis and should receive presumptive or preventative treatment with penicillin.

What are considerations for syphilis treatment with benzathine penicillin in low-resource settings?

Supply side: Benzathine penicillin is a generic injectable with few global manufacturers and is consequently susceptible to stockouts in health programs. In fact, in 2016, the 69th World Health Assembly recognized benzathine penicillin as an essential medicine that has been in short supply in recent years. Given the urgency of safeguarding the health of pregnant women and newborns, WHO and partners are conducting a market analysis to further refine estimates of benzathine penicillin demand, develop interventions to improve procurement and supply management, and increase access. In the near term, however, benzathine penicillin may not be consistently available to pregnant women or newborns who test positive for syphilis, which poses a serious threat to their health as well as EMTCT efforts.

Demand side: In some countries, health providers have heightened concerns about adverse reactions caused by benzathine penicillin, especially about life-threatening allergic reactions (known as anaphylaxis). Consequently, this may limit their use of the medicine. For example, recently in India, fear among providers reduced use of the medicine in ANC settings, which diminished demand and contributed to local manufacturing shortages. This occurred despite the fact that adverse reactions are extremely rare in clinical practice. A systematic review of the safety of benzathine penicillin for preventing congenital syphilis found that the risk of serious adverse effects in pregnant women was scarce and the incidence of severe adverse outcomes in the general population was very low.¹⁰ Provider attitudes in some countries may pose an additional barrier to testing and treating syphilis among pregnant women and should be taken into account in EMTCT program and advocacy efforts.

COUNTRY CASE STUDIES

Nigeria, India, and Zambia are each at a different stage in the journey from policy prioritization to implementation of EMTCT of syphilis:

- Nigeria has historically given low priority to elimination of congenital syphilis and continues to encounter barriers with elevating the issue in policy and program implementation, especially at the state level.
- Zambia has had national commitment and supportive guidelines in place for several years, though the country still faces challenges with resource mobilization for test kits and operationalization of testing guidelines.
- India has a strong policy and financing framework in place, but faces obstacles with policy rollout and implementation at the state level.

NIGERIA: THE POLICY PRIORITIZATION CHALLENGE

Although a number of strategies and guidelines in Nigeria include syphilis screening and treatment in pregnancy, EMTCT of syphilis has not been strongly championed at the national level or prioritized at the state level. As a result, even though some supportive policies at the national level exist, coverage for syphilis screening and treatment across the states is very low.

The EMTCT environment in Nigeria

Nigeria is ranked as one of the leading countries in the WHO Africa region for maternal syphilis disease burden, and disparities in syphilis prevalence across states are staggering. A WHO informal analysis from 2008 suggested that approximately 62,000 pregnant women had probable active syphilis.¹¹ In 2012, modeling under the DTECS project estimated that 75,000 pregnant women in Nigeria had probable active syphilis, with nearly 80% of these cases occurring in the southern region.¹²

Despite the health burden, antenatal syphilis screening was not prioritized in Nigeria, especially prior to the DTECS project. This was likely caused in part by controversies between experts about whether syphilis among pregnant women is really a problem in the country and whether routine screening in this population with low prevalence is still cost-effective.^{13,14} Nigeria even stopped collecting data on syphilis in pregnancy; in 2005, syphilis screening was removed from the ANC HIV sentinel survey.

Against this backdrop, there is no single overarching strategy or guideline that addresses syphilis screening and treatment in pregnancy. Several national

RMNCAH strategies and guidelines, however, do incorporate the intervention, though all are silent on use of RDTs. Syphilis screening and treatment are included in national ANC guidelines. Nigeria's *Integrated Maternal, Newborn and Child Health Strategy (2007)* lists detection and management of syphilis in pregnancy as a key preventive health intervention. *New National Guidelines for Maternal and Perinatal Deaths and Surveillance and Response in Nigeria (2015)* capture information on syphilis screening and confirmation.

Syphilis is also beginning to be integrated into many of Nigeria's guidelines on HIV, prevention of mother-to-child transmission (PMTCT) of HIV, and STIs. Nigeria's *Integrated National Guidelines for HIV Prevention and Care 2014* and *National Guidelines for PMTCT of HIV 2010* each recommend syphilis screening for HIV-positive mothers using laboratory-based tests. The country's National Operational Plan for the EMTCT of HIV 2015-2016 provides costing estimates for syphilis screening of pregnant women and treatment for infants. Further, national STI guidelines and syndromic management training documents include recommendations to test and treat maternal syphilis and HIV.

After deprioritizing data collection on syphilis, the federal government is working to strengthen data collection. In 2012, a National General Antenatal Register was put in place to routinely collect information on syphilis screening, prevalence, and treatment. In 2014, with support from the DTECS project, syphilis screening was included once again in the ANC HIV sero-prevalence sentinel survey. Syphilis indicators are included in the Nigeria Health and Information Management System (NHMIS).

The emergence of dual HIV/syphilis RDTs has reinvigorated efforts to scale up testing and treatment for pregnant women and newborns in Nigeria, especially those at lower levels of care. Laboratory studies have been conducted on dual tests in the country, and they have been made available in a small number of clinics in Abuja, though a pilot introduction study still needs to be implemented.

Challenges on the road to EMTCT

Nigeria does not currently have a strategy or plan for EMTCT of syphilis, even though the country has a plan for EMTCT of HIV. This is one factor in the lack of ownership, funding, and champions for the issue in the country. In addition, policy fragmentation is an issue. Syphilis screening and treatment in pregnancy are mentioned in quite a few policies, but are missing from key strategy documents. For example, neither the national HIV strategy nor the national PMTCT of HIV strategy—important strategy documents guiding the country's HIV/AIDS response—addresses syphilis.



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Existing guidelines, moreover, reference RPR and VDRL laboratory-based tests as the only screening option. These tests are only available at secondary and tertiary facilities—where laboratory networks exist—and many women in remote settings have difficulty accessing these facilities. For this reason, most women who access care at the lowest levels are not being tested for syphilis. And even if women are screened with laboratory-based tests, results are not available immediately, requiring a return visit that a woman may not be able to make.

A lack of policy implementation and budget prioritization at the state level is another main driver of low coverage of maternal syphilis testing and treatment. Syphilis screening and treatment with laboratory-based tests is included in national ANC guidelines, yet this component of the guidelines has yet to be domesticated at the state level. Screening efforts across states are uneven and severely lagging in places. A DTECS field assessment in three states found that primary, secondary, and tertiary facilities rarely conduct syphilis testing.¹⁵ And because

syphilis testing is not being conducted, benzathine penicillin often is not in stock. Finally, state decision-makers often deprioritize syphilis interventions within their ANC budgets and redirect the budget elsewhere, especially if they perceive syphilis prevalence to be low.

Lack of robust data on the burden of disease is another major factor holding back political will to pursue a comprehensive screening and treatment effort. Data collection systems are weak, and facilities do not always report data into the NHMIS. A self-reinforcing cycle exists, where poor data feeds into perceptions that syphilis prevalence is low or nonexistent, which dampens prominence of syphilis as a priority and further diminishes data collection.

Recommendations

1. **Develop a national EMTCT of syphilis strategic plan that sets targets and is fully aligned with HIV/STI and MNCH policies and initiatives.** The federal ministry of health (MOH) should develop a

strategic plan for ETMCT of syphilis and ensure its full integration with the EMTCT of HIV plan. Focus states should be identified for EMTCT of syphilis efforts, especially those in the South East, South South, and South West zones where the burden of disease is among the highest in Nigeria, to target efficient use of resources. As the implementation of the national strategy for elimination of congenital syphilis progresses, a committee should be set up to look at national data and develop a roadmap for convening a national validation process for EMTCT.

- 2. Generate data to inform updates to national strategies and guidelines on introduction and use of RDTs, including dual HIV/syphilis RDTs, as appropriate.** Field assessments of the dual HIV/syphilis RDTs should be funded and implemented, and if the data is favorable, an integrated testing algorithm that incorporates HIV and syphilis should be completed and included in national policy. Existing RMNCAH and HIV/AIDS guidelines should also be updated to allow for use of RDTs at the primary health care level as a strategy to increase access to testing and treatment and decrease loss to follow-up.
- 3. Adopt and implement national and state guidelines and include funding to scale up screening and treatment for pregnant women in budgets and health plans.** States must adopt, align, and implement national ANC, RMNCAH, and STI/HIV guidelines on syphilis testing and treatment in pregnancy. RMNCAH and HIV programs should prioritize maternal syphilis screening and treatment in national and state budgeting for ANC. Nigeria should also consider donor opportunities that fund integrated PMTCT of HIV and syphilis efforts, such as the Global Fund.
- 4. Strengthen data collection and surveillance to increase knowledge about the burden of disease and inform decision-making.** While some data collection systems are in place for syphilis, monitoring and reporting should be enhanced. This is especially true of the NHMIS, where data collected at the facility level is not always entered into the system. Results from the ANC HIV sero-prevalence sentinel survey, as well as data generated by the Maternal and Perinatal Death Surveillance and Response initiative, should be leveraged to increase awareness about the burden of syphilis on pregnant women and newborns and advocate for increased policy and funding prioritization. Efforts to sustain syphilis prevalence estimates in subsequent ANC sero-prevalence sentinel surveys should be strengthened.

ZAMBIA: THE POLICY FINANCING CHALLENGE

The government of Zambia has shown commitment to EMTCT of syphilis. Zambia has prioritized maternal syphilis screening and treatment in a number of its strategies and guidelines, including the use of syphilis RDTs, though some policies need further alignment. Funding and operationalization of the EMTCT effort remain the major challenges in Zambia. Although 96% of pregnant women attend ANC at least once, fewer than half are tested for syphilis, due in part to stockouts of test kits and limited operationalization of testing procedures.¹⁶

The EMTCT environment in Zambia

Over the past two decades, syphilis prevalence among pregnant women has steadily declined in Zambia, though thousands of women and newborns continued to be affected. Informal WHO estimates from 2008 suggested that 19,000 pregnant women were infected with syphilis.¹¹ In 2012, modeling under the DTECS project estimated that more than 9,000 pregnant women in Zambia had probable active syphilis, resulting in nearly 3,000 adverse outcomes for their newborns.¹⁷

In response, the government of Zambia made scale-up of maternal screening and treatment of syphilis a health policy priority. In 2006, the MOH recommended routine syphilis screening in ANC. The following year, the government developed Guidelines for Use of Rapid Tests in Zambia (2007), released by the MOH's National Program for the Prevention and Control of Sexually Transmitted Infections. This guidance included RDTs in the standard package of services provided during ANC. RDTs were designated as the initial screening tool, with the RPR test used as confirmation in places with laboratory capacity. In 2011, RDTs were introduced in facilities where there was no laboratory capacity and could be performed by nonlaboratory staff.

In addition to the syphilis RDT guidance, many HIV/STI and MNCH policies and guidelines recognize syphilis screening and treatment as an important issue. *The National HIV/STI/TB Policy (2005)* acknowledges the importance of screening and treatment for STIs, including syphilis, and the challenges posed by limited access to test kits. The country's *2010 Protocol Guidelines for Integrated PMTCT of HIV* also recognizes screening for maternal syphilis as an important part of a maternal health package. Zambia's safe motherhood guidelines, which inform maternal health service delivery, are currently being updated to incorporate syphilis screening and treatment of pregnant women with RDTs.

Historically, data collection on syphilis in pregnant women has been fairly robust. The Zambia ANC HIV



sentinel survey collected data on syphilis in pregnancy from the 1990s to 2008. The Zambia Demographic and Health Survey included syphilis data collection in 2001–2002 and 2007. At the facility level, a newly updated ANC register contains a place to record both syphilis testing and treatment, and this information is aggregated into the Zambia HMIS.¹⁶

During the last two years, Zambia further reinvigorated efforts toward elimination, conducting field tests on dual HIV/syphilis RDTs and reactivating the government’s STI Technical Working Group (TWG), within which PATH helped establish a subgroup to focus specifically on the elimination of congenital syphilis. The STI TWG brings together key STI stakeholders in Zambia, including representatives from the MOH, ministry of defense, researchers, implementing partners, and advocacy groups.

Challenges on the road to EMTCT

While Zambia has incorporated syphilis screening and treatment—including RDTs—into specific guidelines, it

does not have a strategy or targets for EMTCT of syphilis. Zambia participated in a WHO consultative process on EMTCT in 2010, though no concrete plan emerged. The absence of a clear strategy may be one factor contributing to limited funding and coverage of syphilis efforts.

Policy work also remains to be done in Zambia on fully integrating screening and treatment protocols into related policies—especially those focused on increasing access to RDTs—and ensuring providers implement testing procedures according to the RDT guideline. The RDT guideline states that “the national goal is to increase access to syphilis testing and integrate it into Reproductive Health, STI, Tuberculosis and HIV services,” yet RDTs have not been included in some important PMTCT, RMNCAH, and STI policies. Furthermore, providers often lack awareness of the RDT guideline or clarity on testing protocols. A DTECS site visit to three facilities in a district where RDTs had been introduced revealed uneven use of the 2007 RDT guideline and confusion on when to use RDTs and RPRs.¹⁸

Lack of funding for test kits remains perhaps Zambia's primary challenge to scaling up screening and treatment, and widespread test kit stockouts continue to plague health centers. To date, syphilis test kits have been purchased using United States Agency for International Development (USAID) donor funds—according to the USAID | DELIVER PROJECT (written communication, August 2016), a total of 13,500 kits (30 tests in each kit) were procured in 2013 for distribution through Medical Stores Limited. The national government has been unable to dedicate its own resources for procurement and distribution, and USAID funding has been piecemeal, resulting in a chronic lack of availability of tests in facilities. On the other hand, supply of benzathine penicillin is not reported to be a problem.

Data collection and procurement systems further complicate efforts to illustrate disease burden and to ensure an adequate supply of test kits. The latest version of the Zambia Demographic Health Survey (DHS) (2013–2014) did not include syphilis screening data. Syphilis data captured in the Zambia Health and Information Management System (HMIS) does not distinguish between RPR and RDT use, which complicates forecasting and procurement because planners do not know which tests have been used. Until recently, one of the largest barriers to procurement and distribution was that RDTs had not been incorporated into any supply chain and logistics systems, so ordering and stocking was performed ad-hoc by facilities; RDTs are currently in the process of being added to Zambia's laboratory products list.

New diagnostics, particularly the new dual HIV/syphilis RDT, hold promise for Zambia's screening program, creating the potential to streamline ANC testing processes and leverage HIV and PMTCT funding. At the same time, the emergence of this technology has created some uncertainty about the appropriate diagnostics mix for the country. Performance studies on dual tests have been conducted, but data has not yet been fully evaluated. This is a critical step that must be completed before the country determines how or whether to incorporate this new technology into its national policies and program.

Recommendations

1. **Develop a national strategy for EMTCT of syphilis that sets targets and is fully aligned with HIV/STI and RMNCAH policies.** Zambia could leverage momentum by developing a national strategy for EMTCT of syphilis, and the STI TWG is in an ideal position to initiate this process. EMTCT of syphilis efforts should be integrated with elimination of PMTCT of HIV where possible.

2. **Fully integrate national policies on syphilis screening and treatment in pregnancy, and in particular use of RDTs, into RMNCAH and HIV/AIDS strategies and guidelines.** With the review of the country's National AIDS Strategic Framework and STI guidelines currently underway, now is an ideal time to further prioritize the issue of congenital syphilis, and particularly the use of RDTs. Specifically, The National AIDS Strategic Framework (2011–2015) should be updated to reference EMTCT of syphilis alongside HIV. The National STI Syndromic Case Management Guidelines (2006) should be updated to include references and algorithms for RDTs in addition to RPR. The National PMTCT Protocol Guidelines (2010) should also be updated to underscore that HIV and syphilis have common risk factors and that syphilis infection can make one more susceptible to HIV acquisition, as well as to incorporate guidance on RDTs. The STI and PMTCT guidelines should be harmonized when it comes to treatment, clarifying existing discrepancies in dosage recommendations. And finally, the MOH should ensure the RDT guideline is disseminated to all public health facilities and that health workers are trained on its use.
3. **Increase budget allocation for syphilis screening and treatment in pregnancy to facilitate availability at health facilities.** Procurement and distribution of syphilis test kits, including RDTs, should be incorporated into government health plans and RMNCH budgets. To bridge domestic budget shortfalls, Zambia should examine opportunities to include syphilis testing and treatment in current or future donor funding, such as the Global Fund or the US President's Emergency Plan for AIDS Relief. The MOH should ensure health providers are trained on and have access to guidelines on use of RDTs, as well as benzathine penicillin.
4. **Strengthen surveillance systems and reporting on syphilis in pregnancy.** Syphilis data collection should be added back into future editions of the Zambia DHS. Data on RPRs and RDTs should be included in ANC registers, as this information feeds into the Zambia HMIS and is used as a critical tool for supply planning.
5. **Use data to inform updates to national strategies and guidelines on introduction and use of dual HIV/syphilis RDTs.** The STI TWG should closely examine research and results of dual HIV/syphilis RDTs in the country and make a recommendation on how and whether to incorporate the dual tests into national policy. A first step would be revising the RDT policy to include dual testing protocols and algorithms, with clear instruction on operational procedures for testing and treatment during ANC.

INDIA: THE POLICY IMPLEMENTATION CHALLENGE

India is making significant progress toward elimination of parent-to-child transmission (EPTCT) of syphilis—the term commonly used in the Asia Pacific region—though policy rollout and implementation across the states continue to be a challenge.

The EMTCT environment in India

Elimination is viewed as feasible given India's low maternal syphilis prevalence, which was estimated recently at 0.38% among ANC attendees.¹⁷ This prevalence was used to determine that 103,960 pregnant women nationwide were affected by syphilis in 2012, leading to 53,187 adverse events for newborns. The national prevalence estimates, however, obscure disparities among states. The state of Arunachal Pradesh (2.86%) has the highest prevalence, followed by West Bengal (1.91%) and Rajasthan (1.17%). In addition to these disparities, there is a gap between rates of ANC attendance and rates of coverage for syphilis testing. While 90% of pregnant women in India attend at least one ANC visit, syphilis screening during ANC is reported to range from 12% to 65%.¹⁸

During the last several years, the Indian government has redoubled its commitment to eliminating congenital syphilis. Syphilis testing is now a requirement, rather than a recommendation, during ANC. In 2014, syphilis screening was included in the essential ANC package (alongside HIV testing), integrating elimination efforts into the existing Reproductive, Maternal, Newborn, Child Health plus Adolescent (RMNCH+A) program and fostering improved coordination among government departments of the Ministry of Health and Family Welfare (MoHFW), including the National AIDS Control Organization (NACO) and the National Health Mission (NHM).

In 2014, NACO released its *National Guidelines on Prevention, Management and Control of RTIs/STIs*, which included a chapter on elimination of congenital syphilis, containing screening and treatment protocols. That same year, with support from the DTECS project, the Maternal Health Division of the MoHFW updated its *Screening of Syphilis in Pregnancy Technical and Operational Guidelines*, which acknowledged a national goal of elimination of congenital syphilis alongside an operational framework for screening and treating pregnant women. New guidance emphasized use of syphilis POCs tests (RDTs) by auxiliary nurse midwives (ANMs) down to the primary care subcenter level, early screening of all pregnant women, and standardized treatment regimens for pregnant women and exposed infants.

In February 2015, the MoHFW and NACO, in collaboration with WHO, released the *National Strategy and Operational Guidelines for the Elimination of Congenital Syphilis* that brought together the essential interventions in an integrated platform under the umbrella of the NHM to target EPTCT. In line with the WHO's EMTCT initiative, the strategy aims to eliminate PTCT of syphilis by 2017.* Indicators include increasing coverage to ≥95% of ANC attendance, syphilis testing of ANC attendees, and treatment of syphilis-reactive ANC attendees.

The NHM and NACO both collect data on syphilis through their respective RMNCH+A and HIV/AIDS programs. NHM data feeds into the India HMIS, while NACO data feeds into the Strategic Information Management System (SIMS). Syphilis indicators were added to the Reproductive and Child Health register used at the subcenter level, which will aid in systematic data collection. Moreover, a variety of stakeholders have been actively involved in strengthening data collection and monitoring on syphilis, including national and state officials working on RMNCH+A and HIV, professional societies, pediatricians, and data specialists. Recently, these stakeholders have worked to harmonize data on ANC coverage, screening for both HIV and syphilis, and mother-baby-child tracking and reporting mechanisms through 18 and 24 months, respectively.

Looking ahead, meeting India's EPTCT of syphilis goal will require introduction and scale-up of RDTs. Toward this end, in March 2016 the NHM and NACO, under the auspices of the MoHFW, launched an *Action Plan for Universal Screening for HIV and Syphilis in Pregnant Women*. The action plan confirms the government of India's policy decision for universal screening of pregnant women for HIV and syphilis as part of the essential ANC package and includes plans to procure and distribute 15 million syphilis POC tests (RDTs), as well as 25 million HIV POC tests funded jointly by NHM and NACO. In July 2016, according to WHO India officials (written communication, July 2016), the NHM released a budget of 30 crores (300 million rupees, approximately US\$4.5 million) to purchase the HIV and syphilis POC tests, with the aim of having the test kits in place at the state level by November 2016.

Challenges on the road to EMTCT

Despite an enabling policy environment, challenges remain, particularly in rolling out new screening guidelines to the primary care level. Operational guidelines were launched without a follow-up plan for capacity-building of health providers to effectively

* The strategy's goal is to reduce incidence of congenital syphilis to <0.3 cases per 1,000 live births.



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implement them. Consequently, prioritization and ownership of EPTCT efforts among health program managers at the state level have been weak, and frontline workers such as ANMs have received little training on guidelines in the areas of testing, referral for treatment, and reporting.

Due in part to low prioritization, some states are failing to take advantage of available funding. The national government has adequate domestic resources for each state to purchase and distribute syphilis test kits and treatment and has prioritized availability of funds for this purpose. States are required to develop a budget for syphilis testing and treatment and submit it to the national government as part of the annual Program Implementation Plan (PIP) process. However, some states have either failed to include syphilis test kits and treatment in their budgets or have failed to spend their budgets on this intervention among other ANC priorities.

Even with a comprehensive national policy framework in place and domestic funding available, some states and districts still struggle with stockouts of syphilis test kits and benzathine penicillin. Again, this traces to

poor policy uptake at the state and district level, limited awareness and demand among providers, and poor data collection to inform budgeting and procurement. Syphilis POC tests (RDTs) have not yet been systematically introduced, and dual HIV/syphilis RDTs are not approved for use in India. Some providers in India fear using benzathine penicillin due to the small possibility of severe allergic reaction. This dampened demand for—and consequently local manufacture of—the medicine. However, with the national government's EPTCT push, domestic supply of benzathine penicillin is ramping up again and is no longer reported to be a critical issue.

Lastly, surveillance and data gaps hinder progress toward India's elimination agenda. Out of approximately 28 million pregnant women in India, the national government has screening data for about half of these women. Data flow from state to national levels remains a challenge. The HMIS and SIMS are currently on different platforms, and currently there is no mechanism for bringing them together into one easy-to-understand dashboard/interface at the national level. This is critical for monitoring progress toward EPTCT and for facilitating a robust inventory management system.

Recommendations

- 1. Scale up guideline dissemination and training for state program managers and health care workers at lower levels of care to improve screening and treatment in ANC.** HIV/AIDS and RMNCH+A officers at state and district levels should be sensitized to existing policies—including the elimination strategy, operational guidelines, and the Action Plan for Universal Screening. Training and capacity-building should be implemented for all medical officers and frontline workers, including ANMs, many of whom are not aware of the new recommendations on POC (RDT) tests. All ANMs attend a monthly meeting at the PHC level, and NACO in particular can capitalize on these meetings to provide training on syphilis testing and treatment at little additional cost.
- 2. Ensure that state-level decision-makers utilize designated funding for syphilis screening and treatment efforts in ANC, and implement the action plan for universal screening.** The NHM should clearly communicate national elimination policy targets and state-specific disease burden as available to encourage state decision-makers to include funding for screening and treatment of syphilis in pregnancy in their PIPs. In accordance with the action plan, state program managers should develop comprehensive activity plans and budgets for universal screening, including scale-up of POC tests (RDTs). To aid in this, effective inventory management systems should be created for facilitating forecasting and procurement of test kits and treatment in an uninterrupted manner.
- 3. Generate evidence on the use and effectiveness of dual HIV/syphilis RDTs to inform introduction in India.** To support national EPTCT of HIV and syphilis goals, the MoHFW should consider supporting in-country testing of dual HIV/syphilis RDTs. Data should also be collected on the cost-effectiveness of the dual HIV/syphilis RDT and how it could help overcome logistic and human resource constraints. Such evidence could then be leveraged to add dual tests to the national essential laboratory list and to update the relevant guidelines.
- 4. Create a syphilis monitoring “dashboard” at the national level that rolls up data from multiple systems across all states to increase understanding of progress toward targets and screening and treatment coverage.** Currently, there is no easy way to track aggregated state data for a given time period, such as the number of syphilis tests administered to pregnant women, the number of pregnant women who test positive for syphilis, and the number of syphilis-positive women who receive treatment. The MoHFW should create a syphilis dashboard/interface specifically to roll up state data into one location and send a monthly monitoring letter to states to spotlight and track the issue. Such data will be critical for monitoring trends across the states and also for informing procurement of POC (RDT) tests, which will be centrally procured by NACO and distributed to the states under the new action plan for universal screening.

CONCLUSION

Elimination of congenital syphilis will be a critical component of the Sustainable Development Goals’ target of ending preventable newborn deaths by 2030. It is an inspiring and feasible goal, even for LMICs that face challenges with health financing and infrastructure. Relatively low prevalence rates combined with new technologies, awareness, and commitments mean that elimination is within sight. However, reaching the global goals of EMTCT of syphilis will require concerted action, support, and prioritization at all levels. To ensure progress, governments and global stakeholders—including donors, multilaterals, and civil society—must develop strong policies and strategies aligned with existing programs, advocate for political prioritization that includes clear national targets, finance diagnostics and treatment, and consistently implement policies throughout the health care system.

ANNEX: KEY GLOBAL GUIDELINES AND STRATEGIES THAT ADDRESS SYPHILIS

WHO: The Use of Rapid Syphilis Tests (2006)	Provides comprehensive guidance on syphilis RDTs, including use, effectiveness, and considerations for introduction.
WHO: Global Elimination of Congenital Syphilis: Strategy and Rationale for Action (2007)	Outlines a strategy for elimination of congenital syphilis based on four “pillars”: 1) sustained political commitment and advocacy; 2) increasing access to and quality of maternal and newborn health services; 3) comprehensive screening and treatment for all pregnant women and their partners; and 4) establishing surveillance, monitoring, and evaluation systems.
WHO: Global Guidance for Criteria and Processes for Validation: Elimination of Mother-to-Child Transmission of HIV and Syphilis (2011)	Offers standardized processes and criteria for validation of EMCT of HIV and syphilis in a country; provides a description of global EMCT validation targets and indicators; explains operation of validation committees and secretariats; and reviews the validation procedure itself.
WHO: Methods for Surveillance and Monitoring of Congenital Syphilis Elimination within Existing Systems (2011)	Provides guidance on harmonized, core indicators for elimination of congenital syphilis that can be integrated into existing data collection efforts at the regional or country level.
WHO: Investment Case for Eliminating Mother-to-Child Transmission of Syphilis (2012)	Promotes EMCT of syphilis as a public health problem that is feasible, achievable, and affordable to address and makes evidence-based health and financial arguments for scaling up EMCT efforts.
United Nations Every Woman, Every Child: Every Newborn Action Plan (2014)	Advances a global initiative to save nearly 3 million newborn lives by achieving high-quality and equitable coverage of care for all women and newborns. Encourages ANC as a platform for integrated service delivery, including detection and treatment of syphilis in pregnancy.
WHO: Pregnancy, Childbirth, Postpartum and Newborn Care A Guide for Essential Practice (3rd edition) (2015)	Includes guidelines for routine syphilis screening—with RPR tests—and treatment for pregnant women during ANC.
United Nations Every Woman, Every Child: Global Strategy for Women's Children's, and Adolescents Health (2016-2020)	Supporting the Every Woman, Every Child movement and building on the 2010 Global Strategy, the updated Global Strategy gives implementation guidance on how to accelerate health and well-being for women, children, and adolescents. Recognizes syphilis prevention, detection, and treatment as an evidence-based health intervention.
WHO: Global Health Sector Strategy on STIs (2016-2020)	Recently adopted at the 2016 World Health Assembly, the strategy sets out goals, targets, guiding principles, and priority actions for ending the STI epidemic. It focuses on three STIs that require immediate attention, including syphilis, and sets an ambitious global target on congenital syphilis.
UNAIDS: UNAIDS 2016-2021 Strategy: On the Fast Track to End AIDS	Lays out global goals and targets for 2020 that will aid in the ultimate ambition of ending the AIDS epidemic by 2030. Recognizes that integrating HIV and syphilis testing and treatment services for pregnant women is a cost-effective way to reduce neonatal deaths, stillbirths, and congenital syphilis.

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