Policy and practice

Towards elimination of parent-to-child transmission of syphilis in India: a rapid situation review to inform national strategy

Vani Srinivas1,2, Prasad LN Turlapati2, Anil K Bholan, Anil K Singh2, Shobini Rajan2, Radha S Gupta3, Sunil D Khaparde3

ABSTRACT

In February 2015, India’s National AIDS Control Organisation, Ministry of Health and Family Welfare, launched a national strategy towards elimination of parent-to-child transmission (E-PTCT) of syphilis, with a goal to reduce the incidence of congenital syphilis to 0.3 cases per 1000 live births by 2017. As part of the development of the national strategy, a rapid situation analysis was undertaken to ascertain the current practices, challenges and barriers for E-PTCT of syphilis in India. The analysis was conducted during February and March 2014 in five states selected from five different regions of India. Key informant interviews were conducted with key stakeholders at facility, state and district level. Content analysis was used to identify the themes. Key barriers identified for E-PTCT of syphilis were: low priority for antenatal syphilis testing among providers, limited access to testing, untrained human resources, shortage of test kits and benzathine penicillin, nonadherence to the national protocol for syphilis testing, and poor recording and reporting of antenatal syphilis data. The analysis also identified opportunities for functional integration of E-PTCT within existing maternal and child health programmes. Health-care providers and programme managers expressed a need for training in the programme for E-PTCT of syphilis. The situation analysis identified that, for successful implementation of E-PTCT of syphilis, it is essential that state and district programme managers adopt this initiative; coordinate the programme; plan for an adequate budget in their programme implementation plan; ensure an uninterrupted supply of standardized diagnostics kits and drugs at all levels of health care; and adhere to E-PTCT guidelines when implementing the programme.

Key words: challenge, congenital syphilis, India, pregnant women, syphilis elimination

BACKGROUND

Globally, about 1.5 million pregnant women are infected with probable active syphilis each year, and approximately half of infected pregnant women who are untreated will experience a wide spectrum of adverse outcomes, such as early fetal loss and stillbirth, neonatal death, low-birth-weight infants, and infants with clinical evidence of infection (congenital syphilis).1 In the World Health Organization South-East Asia Region, nearly 600 000 pregnant women are estimated to be newly infected with syphilis each year;2 in 2012 there were 103 960 cases of maternal syphilis in India, with an estimated 16 324 cases of congenital syphilis.3 Congenital syphilis is a serious but preventable disease, which can be eliminated through effective screening of pregnant women for syphilis and treatment of those infected; thus, a global initiative to eliminate mother-to-child transmission of syphilis was launched in 2007.4 Subsequently a strategy was launched in 2009 for the elimination of congenital syphilis in the South-East Asia Region in 2011–2015.5,6 After wide discussions with the relevant stakeholders, and national and international experts, the National AIDS Control Organisation (NACO) in India also developed and launched a national strategy for elimination of parent-to-child transmission (E-PTCT) of syphilis in February 2015.7
The NACO E-PTCT of syphilis has the following targets: early screening of at least 95% of pregnant women for syphilis during their routine antenatal check-up, adequate treatment of at least 95% of seroreactive pregnant women, and treatment of 100% of neonates and partners exposed to syphilis. The goal of the initiative is to reduce the incidence of congenital syphilis in India from 0.6 per 1000 live births (current estimate) to 0.3 cases per 1000 live births by 2017.3

While developing the national strategy for E-PTCT of syphilis, it was clear that there was a scarcity of literature and studies in India on the contextual barriers and the factors that enable success in achieving such ambitious programme targets across diverse geographical locations. To inform the national strategy, a rapid situation review was undertaken to identify opportunities available and functional barriers to implementing E-PTCT of syphilis. The aim of this study was to highlight practices, challenges and opportunities around testing, treatment and reporting of syphilis-reactive pregnant woman, and their partners and exposed babies.

**APPROACH**

The rapid situation analysis was conducted by the sexually transmitted infections (STI) division of NACO during February and March 2014 in five states (Madhya Pradesh, Maharashtra, Sikkim, Tamil Nadu and Uttar Pradesh), which were purposively selected as representative of north, central, eastern, south and west zones of the country. The national health mission (NHM) categorized the states into four different regions based on health indicators and geographical area (see Table 1).7

One high-priority district (category A or B) for HIV intervention was purposively selected from each of Maharashtra, Tamil Nadu and Madhya Pradesh. In Uttar Pradesh, one category C, or lower-priority, district was selected, and in Sikkim two category C districts were selected for the study.8

In total, four medical colleges, five district hospitals, five community health centres, four primary health centres, three subcentres and two private health facilities were visited in the selected districts. All the facilities visited were delivery points for pregnant women. Delivery points are health facilities that have a high demand for services and performance above a certain benchmark, with the objective of providing comprehensive reproductive, maternal, newborn, child and adolescent health services (RMNCH+A).7

Ten key officials involved in planning and implementation of the STI programme at state and district level from the HIV and maternal health programmes were interviewed using a structured interview guide. Information was gathered on current practices and challenges in syphilis screening, and testing and treatment options for antenatal clients. The information enabled the identification of opportunities available and possible challenges to expanding syphilis screening and testing through functional integration of syphilis screening within existing programmes: RMNCH+A, the STI/RTI [reproductive tract infection] Control and Prevention Programme, and Prevention of Parent-to-Child Transmission (PPTCT) of HIV using Multi Drug Anti-retroviral Regimen in India.

At the facility level, information was gathered from 30 members (including doctors, nurses, designated STI/RTI clinic [DSRC] and PPTCT counsellors, and laboratory technicians) using a semi-structured interview guide. Interviews were led by an STI consultant and facilitated by programme officers and experts from the STI division of NACO. Information was gathered regarding routine services offered in antenatal care (ANC) and functional links with PPTCT centres and DSRCs, and challenges around diagnosis, treatment and reporting of maternal syphilis and congenital syphilis. Additional information on capacity-building, supervision, supply-chain management, and funding and resource allocation for ANC, PPTCT and DSRC/STI services was also collected.

For the analysis, the data from the semi-structured interviews and in-depth interviews with key stakeholder were categorized into two main themes, challenges and opportunities, using content analysis. All the responses were recategorized into domains such as accessibility to syphilis testing among pregnant women, recording and reporting practices, monitoring and evaluation systems, human resources available, training needs, supply of syphilis test kits and source of funding, point-of-care.

---

**Table 1: States and districts selected from five different geographical zones of India**

<table>
<thead>
<tr>
<th>State</th>
<th>Region of India</th>
<th>District selected (HIV district category)</th>
<th>National Health Mission: state categorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Madhya Pradesh</td>
<td>Central</td>
<td>Bhopal (B)</td>
<td>High-focus large state (weak public health indicators, high unmet needs for public health infrastructure and large population size)</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>West</td>
<td>Thane (A)</td>
<td>Non-high-focus large state (comparatively better public health indicators and large population size)</td>
</tr>
<tr>
<td>Tamil Nadu</td>
<td>South</td>
<td>Kancheepuram (B)</td>
<td>Non-high-focus large state</td>
</tr>
<tr>
<td>Sikkim</td>
<td>East</td>
<td>East and south districts (C)</td>
<td>High-focus small state (weak public health indicators, high unmet needs for public health infrastructure and small population size)</td>
</tr>
<tr>
<td>Uttar Pradesh</td>
<td>North</td>
<td>Sitapur (C)</td>
<td>High-focus large state</td>
</tr>
</tbody>
</table>
testing for syphilis, drugs for management of syphilis-reactive pregnant women and their partners and newborn infants, perspectives of programme managers, and perspectives of private practitioners.

**OBSERVATIONS**

**Key challenges to E-PTCT for syphilis**

The study revealed the key challenges to E-PTCT of syphilis, as summarized next.

**Accessibility to syphilis testing among pregnant women**

Participants reported different practices among states and among the levels at which antenatal care was provided. In medical colleges and district hospitals, screening for syphilis (either rapid plasma reagin [RPR] or venereal disease research laboratory [VDRL] test) was offered to all ANC clients in all the five states except in the district hospital in Sitapur in Uttar Pradesh, where the rapid syphilis test (treponemal-based) was used. The rapid syphilis test was also used at primary health centres and community health centres in Maharashtra, Tamil Nadu and Uttar Pradesh. In Madhya Pradesh, the syphilis test was not offered to ANC clients attending facilities below district level. In Madhya Pradesh, gynaecologists prescribed the syphilis test to selected ANC clients, based on certain eligibility criteria, such as history of a previous caesarean section or blood transfusion, or a complex obstetric history.

Participants reported that sera found to be reactive qualitatively or by the rapid point-of-care treponemal test were not subjected to a quantitative test (titres). The reasons given by participants were: overburdened laboratory technicians, lack of laboratory staff (unfilled approved positions), shortage of test kits, and lack of clear allocation of responsibilities.

Participants reported that the observed syphilis reactivity among pregnant women was very low and this was reported in official data at the district level. However, there were no systems of quality assurance and quality control for syphilis testing at any level of health-care facility. Further, it was also observed that there was a wide variation in the type of test kits used for syphilis screening, (ranging from RPR to modified VDRL, to point-of-care immunochromatographic tests).

**Recording and reporting practices**

Record keeping and reporting of syphilis data were found to be poor. Participants reported inconsistent practices in recording syphilis screening and test results on ANC cards and in reproductive and child health registers. Information on the number of ANC clients screened and found to be reactive for syphilis was routinely reported by all DSRCs supported by NACO through its Strategic Information Management System, but this was carried out in only a limited number of facilities. However, the health facilities under the NHM-reported syphilis screening data in the Health Management Information System (HMIS) and the Mother and Child Health Tracking System (MCTS). There was no reporting of congenital syphilis cases in any of the facilities.

**Monitoring and evaluation systems**

According to the participants, ANC syphilis testing and treatment was poorly monitored by state AIDS prevention and control societies, and NHM. This was because of the low priority of the STI programme in the NHM programme, and lack of national guidelines on E-PTCT. The district hospital and medical college facilities were monitored by an STI focal person in state AIDS prevention and control societies. The subdistrict-level facilities were monitored by NHM functionaries. The state programme officers felt that E-PTCT of syphilis might be functionally integrated into NHM across all states and union territories, to enable it to reach a large number of ANC facilities for syphilis screening.

**Human resources**

Participants reported a significant number of vacancies for approved laboratory-technician posts in the subdistrict-level health facilities across the states. As a consequence, there was poor adherence to standard operating procedures. Doctors working at primary health centres and community health centres reported that they do not routinely manage cases of syphilis-reactive mothers and babies at their facilities. Most of them stated that they preferred to refer the syphilis-reactive cases to medical college hospitals for further management.

**Training needs**

Health-care providers from all levels of facilities (that is, from medical colleges to subcentres) expressed the need for training in the interventions recommended in the programme for managing maternal and congenital syphilis. Staff generally lacked a clear understanding of national guidelines. The state programme officers suggested that there might be an opportunity to train and use community health workers, such as accredited social health activists. In Uttar Pradesh, the programme managers also expressed a need to train doctors practising other forms of medicine, such as homeopathy, unani or ayurveda, who were providing services to ANC facilities.

**Supply of syphilis test kits and source of funding**

There had been a shortage in supply of RPR kits at all DSRCs for the past year. The medical college hospitals procured syphilis test kits from hospital funds. In Maharashtra, Uttar Pradesh and Tamil Nadu, state governments procured rapid-test kits from Janani Shishu Suraksha Karyarama (JSSK) funds, Rogi Kalyan Samiti funds of NHM/State Health Mission, or the state health budget. It was also observed that test kits were stored inadequately, and that the first-expired, first-out
principle was not being followed for kit use. Participants also noted poor adherence to protocols for disposal of biological waste in most of the subdistrict-level facilities.

**Point-of-care test for syphilis**

States were willing to roll out syphilis screening using the point-of-care test, provided that the test kit could use finger-prick whole blood as the sample. The auxiliary nurse midwives in Maharashtra, Tamil Nadu and Madhya Pradesh were willing to use the point-of-care test for syphilis at the subcentre level, provided they were trained on how to do the test. The programme managers were of the opinion that the point-of-care test would not only ensure rapid scale-up of screening for syphilis among pregnant women, but also enable screening of pregnant women who arrive in the labour rooms without previous test reports for syphilis. The providers and managers expressed the concerns that large numbers of false-positive cases could be reported by use of the point-of-care test, and that storage of the point-of-care test kits may be a challenge in the summer season.

**Drugs used in the management of syphilis-reactive pregnant women, and their partners and neonates**

Benzathine penicillin is the drug of choice for managing maternal syphilis. Because of infrequent syphilis screening in the lower-level facilities and very low prevalence of maternal syphilis, injection of benzathine penicillin was not available in facilities below district level in Madhya Pradesh, Tamil Nadu and Uttar Pradesh. However, in Maharashtra, the drug was available in all levels of facilities. Azithromycin and erythromycin were available at all levels of facilities in the five states included in the study; these antibiotics are indicated only when the mother has a history of anaphylactic reaction to penicillin, and their use must be followed by adequate treatment of the neonate. Below district level, health-care providers were not very confident with using injections of benzathine penicillin because of fear of anaphylaxis. Overall awareness and alertness for early detection and management of maternal and congenital syphilis was observed to be low in all states in the study.

**Perspectives of programme managers**

Programme managers demonstrated a lack of awareness regarding the burden of maternal syphilis and the cost-effectiveness of intervention. They reported that syphilis is given a low priority throughout the ANC setting and they highlighted the absence of any policy documentation to guide them. Irrespective of the health-care setting, logistic planning for syphilis in pregnancy was lacking in all facilities. It was clear that planning was hindered by complexities such as dual funding from NACO and NHM for syphilis testing in different levels of facilities, and lack of coordination between state AIDS prevention and control societies and NHM. As a consequence, programmes were poorly monitored, and reported data were not utilized to improve services.

**Perspectives ofprivate practitioners**

Private practitioners reported that they were not regularly screening pregnant women for syphilis, as this was not seen as an essential test in ANC. Most were of the opinion that syphilis is no longer an important disease to be included in ANC screening programmes. They were not seeing many cases of syphilis either clinically or serologically. Private practitioners were not using injection of benzathine penicillin to treat any of the illnesses and had expressed fear of managing anaphylactic reactions.

**Key opportunities for E-PTCT of syphilis**

The key opportunities identified are summarized in Table 2.

<table>
<thead>
<tr>
<th>LESSONS LEARNT AND THEIR APPLICATION TO NATIONAL STRATEGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>The rapid situation analysis identified many missed opportunities and functional barriers to implementing E-PTCT of syphilis. The key barriers identified prior to the launch of the national strategy for E-PTCT for syphilis were: inadequate testing kits and drugs at all levels of health care, significant numbers of vacancies for laboratory-technician posts, lack of trained laboratory technicians, inconsistency in the testing protocol, lack of awareness among providers, use of nonstandardized test kits, fear of using benzathine penicillin among providers, gaps in recording and reporting of syphilis testing and results, and not including syphilis testing as an essential test in ANC.</td>
</tr>
<tr>
<td>The main opportunity to implement E-PTCT of syphilis is to provide services through an existing functional maternal health programme, such as JSSK, and also the recent inclusion of syphilis in the essential ANC package of services. Functional cooperation between HIV/STI and RMNCH+A programmes, along with provision of point-of-care testing at the subcentre level and task shifting, will enable universal syphilis screening in India, including an estimated 29 million pregnant women. The importance of implementing a combined E-PTCT programme as an integrated initiative to eliminate both HIV and syphilis, as highlighted by The Asia-Pacific Prevention of Parent-to-Child Transmission Task Force for HIV and syphilis, in a regional strategy released in 2011, will enable the programme to achieve the dual elimination goal.</td>
</tr>
</tbody>
</table>

This study highlighted that it is essential to empower health-care providers in diagnosis of maternal and congenital syphilis and use of benzathine penicillin for treatment. Adequate budgetary provision in state programme implementation plans will ensure adequate allocation of resources for procuring test kits and drugs such as injectable benzathine penicillin, azithromycin and erythromycin, to treat syphilis in all levels of facilities. No proven alternative to penicillin exists for the treatment of syphilis during pregnancy. Use of azithromycin and erythromycin should be restricted to pregnant women who have a history of severe penicillin allergy (for example,
All infants of pregnant women treated with a non-penicillin regimen should be treated at birth as if the mother was inadequately treated.3

However, in the light of very low prevalence of maternal syphilis, the district health authorities or the head of the facility should be granted permission to procure the drugs, if required, on a case-by-case basis, to facilitate the timely availability of drugs to treat the disease. Uninterrupted supply and maintenance systems for diagnostic kits and drugs for syphilis treatment are key elements for smooth implementation of an E-PTCT programme. These will facilitate universal syphilis screening in ANC and enable prompt treatment of women testing positive; these are the basic interventions that have been proven to be cost-effective, even in settings where there is a low prevalence of syphilis.14 Women found to be syphilis reactive in subcentre facilities should be referred to the nearest primary health centre/community health centre/district health centre for treatment on the same day, and other facilities should also treat syphilis-reactive pregnant women on the same day as diagnosis.3

There should be training and capacity-building for those staff involved in providing ANC and those who are responsible for reporting cases. National-level orientation is required for state-level key stakeholders, to ensure that there is standardized management of cases of maternal and newborn syphilis, and regular reporting. The training should be integrated into maternal and child health training programmes. A special recruitment drive to fill job vacancies for all levels of staff will give a strong impetus to effective implementation of the programme for E-PTCT of syphilis.

According to the programme data available from NACO and HMIS, around 5 million pregnant women were screened for syphilis in 2012–2013.3 Of the pregnant women found

<table>
<thead>
<tr>
<th>Domain</th>
<th>Opportunities for improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC syphilis testing</td>
<td>• Consider syphilis testing as part of the essential ANC package at all levels</td>
</tr>
<tr>
<td></td>
<td>• Link syphilis testing with client’s first ANC visit</td>
</tr>
<tr>
<td></td>
<td>• Link syphilis programme with PPTCT programme</td>
</tr>
<tr>
<td>Recording and reporting</td>
<td>• Record syphilis test results and treatment in ANC cards</td>
</tr>
<tr>
<td></td>
<td>• Include E-PTCT of syphilis core indicators in HMIS and MCTS</td>
</tr>
<tr>
<td></td>
<td>• Train staff in recording and correct reporting of E-PTCT indicators by health facilities at all levels</td>
</tr>
<tr>
<td>Human resources</td>
<td>• Recruit laboratory technicians to fill vacant approved positions</td>
</tr>
<tr>
<td></td>
<td>• Involve existing paramedical staff in syphilis testing by introducing POC testing</td>
</tr>
<tr>
<td></td>
<td>• Adhere to existing standard operational procedures for testing and disposal of biological waste</td>
</tr>
<tr>
<td>Training and capacity-building</td>
<td>• Train all groups of maternal and child health staff on E-PTCT for syphilis</td>
</tr>
<tr>
<td></td>
<td>• Train laboratory technicians on standard operating procedures</td>
</tr>
<tr>
<td></td>
<td>• Train paramedical staff on use and storage of POC test kits</td>
</tr>
<tr>
<td></td>
<td>• Train staff on external quality-assurance services at all levels</td>
</tr>
<tr>
<td>Diagnostic and drug logistics</td>
<td>• Procure drugs and diagnostics through Janani Shishu Suraksha Karyakram funds</td>
</tr>
<tr>
<td></td>
<td>• Implement external quality-assurance services at all levels</td>
</tr>
<tr>
<td></td>
<td>• Display standard operational procedures for quality testing at all facilities</td>
</tr>
<tr>
<td></td>
<td>• Develop cooperation between NACO and NHM for procuring diagnostic kits and generic medicines</td>
</tr>
<tr>
<td>Programme managers</td>
<td>• Develop a policy document to enable programme managers to understand their roles and responsibilities</td>
</tr>
<tr>
<td></td>
<td>• Develop dashboard indicators that state and district programme managers can use for monitoring</td>
</tr>
<tr>
<td></td>
<td>• Facilitate joint planning by state AIDS prevention and control societies and NHM to enable adequate procurement and supply of test kits and drugs</td>
</tr>
<tr>
<td></td>
<td>• Enable monthly review and monitoring of commodities at state and district levels</td>
</tr>
</tbody>
</table>

to be infected, only 35.8% were treated for syphilis.\textsuperscript{15} The low levels of screening for syphilis in ANC could be due to lack of a policy for syphilis testing, and the fact that syphilis testing is not essential in ANC services.\textsuperscript{16} The new policy that includes syphilis testing as part of the essential ANC package is an opportunity for ANC to significantly increase testing for syphilis.

In this study, it was found that there was no standard format for recording of service-delivery data. There is a need to set up a surveillance system for maternal and congenital syphilis. Once a robust surveillance system is established, as specified in the implementation guidelines, the monitoring of core indicators will play a crucial role in the steps taken towards validation of E-PTCT of syphilis.\textsuperscript{17}

\section*{Study limitations}

The study findings cannot be generalized to the entire country. Although an attempt was made to represent five different regions, each state/union territory has a unique context in India. Therefore, it is possible that there are more state-specific challenges and opportunities that were not identified in this study because of the limited number of facilities visited. The findings of the study were helpful in refining the national strategy for E-PTCT of syphilis that was launched in February 2015.

\section*{CONCLUSION}

This study facilitated the opportunity for the RMNCH+A programme to revise the ANC services and to include syphilis and HIV screening in the essential package of services for ANCs. The successful implementation of E-PTCT for syphilis requires state and district programme managers from AIDS control societies and health missions to coordinate and plan a definitive road map for adequate resource allocation for procurement of sufficient quantities of test kits (including point-of-care tests) and benzathine penicillin for screening and treating syphilis in all ANC facilities. HMIS should include core indicators to monitor E-PTCT of syphilis. There should be ongoing mentoring and supportive supervision of staff, and monitoring of programme implementation. The private providers are also encouraged to screen, treat and report maternal syphilis.

\section*{ACKNOWLEDGEMENTS}

The authors would like to acknowledge key national and state officials, including participants of this study from the states, for permitting and facilitating visits, and giving input to help in the understanding of the challenges and opportunities. Special thanks go to Dr Nicole Seguy, HIV Officer, WHO India Country Office, for reviewing and providing invaluable input. At the time this work was done, Dr Vani Srinivas was a consultant at the National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India, New Delhi, India.

\section*{REFERENCES}


How to cite this article: Srinivas V, Prasad TLN, Bhola AK, Singh AK, Rajan S, Gupta RS, Khaparde SD. Towards elimination of parent-to-child transmission of syphilis in India: a rapid situation review to inform national strategy. WHO South-East Asia J Public Health 2015; 4(2): 197–203.

Source of Support: Nil. Conflict of Interest: None declared.

Contributorship: VS was involved in study design, selecting states, developing data collection tools, data collection and conception of the paper. AKB, TLNP and AKS facilitated data collection in the field. VS and AKB did a literature review and prepared the first draft. VS, TLNP and AKB reviewed the analysed content. VS, TLNP and AB contributed to revising the manuscript critically for substantial intellectual content. All authors read and approved the final manuscript.