



The National Strategy & Operational Guidelines Towards Elimination of Congenital Syphilis

2015



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Operational Guidelines
Towards Elimination of
Congenital Syphilis**

2015

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भानु प्रताप शर्मा
सचिव
B.P. SHARMA
Secretary



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Foreword

Government of India is committed to the prevention and control of STI/RTI and HIV/AIDS. The estimated annual burden of syphilis among pregnant women in India is around 1.03 lakhs. Maternal syphilis leads to serious adverse outcomes of pregnancy in more than 50% of cases, such as spontaneous abortion, stillbirth, low-birth-weight babies and congenital syphilis babies with an increased risk of perinatal death.

National AIDS Control Organization had drafted the National Strategy towards Elimination of Parent-to-Child Transmission of Syphilis (E-PTCT). This document provides the background, rationale, guiding principles, key strategic directions and interventions to achieve the goal of eliminating parent to child transmission of syphilis; these in turn have been aligned to the guiding principles and monitoring framework of World Health Organization.

This document is aimed at policy-makers, programme managers of STI/RTI and maternal health programmes at national, state and district level, multilateral organizations, as well as other stakeholders, donors and foundations involved in implementing health programmes in India and working towards eliminating the risk of syphilis infection in new born. As the document also highlights the diagnosis and management of maternal and congenital syphilis, it will be useful for medical officers, especially pediatricians and obstetricians in providing antenatal care services in both the public and private sector.

"Elimination of Parent-to-Child Transmission of Syphilis" is a new national strategy launched by the STI/RTI Control and Prevention Programme under NACO in collaboration with Reproductive, Maternal, Newborn Child Health and Adolescent (RMNCH+A) programme under National Health Mission. The national strategy on E-PTCT of syphilis will contribute to achieve Millennium Development Goals 4 (reduce child mortality), 5 (improve maternal health) and 6 (combat HIV/AIDS, Malaria and other diseases).

All key stakeholders should take necessary action to strengthen the programme at the State, district and sub-district level so as to achieve the goal and set targets for elimination of parent-to-child transmission of syphilis, including congenital syphilis in India.

(B.P. Sharma)



सत्यमेव जयते

एन. एस. कंग, भा.प्र.से

अपर सचिव

NAVREET SINGH KANG, IAS

Additional Secretary



भारत सरकार

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

राष्ट्रीय एड्स नियंत्रण संगठन

Government of India

Ministry of Health & Family Welfare

National AIDS Control Organisation

Preface

Congenital syphilis is a serious but preventable disease, which can be eliminated proactively through effective screening of all pregnant women for syphilis; and treatment of those infected, including their partner and newborn. The syphilis sero-prevalence among the pregnant women in India was reported as 0.38%, the annual burden of syphilis among pregnant women is about 1,03,960 and estimated cases of congenital syphilis are 16,324. More newborn infants are affected by congenital syphilis than Human Immunodeficiency Virus (HIV) infection and tetanus.

The adverse pregnancy outcomes caused by untreated maternal syphilis are preventable and curable, and interventions to improve screening and treatment for syphilis in pregnancy can substantially reduce the current burden of preventable perinatal mortality and morbidity in India. Detection and treatment of syphilis has been identified as being one of the most efficient and cost effective interventions to eliminate congenital syphilis and improvement of child health.

"Towards Elimination of Parent-to-Child Transmission of Syphilis: National Strategy for India" is based on WHO's "Regional Strategy for Elimination of Congenital Syphilis in South East Asia Region 2011-15". Implementation of the said strategy will save many lives and will lead to not only elimination of congenital syphilis but also reduces reproductive wastage; which ultimately improves health of mother and new born.

The current national strategy will help the programme managers and field implementers in achieving the elimination goal and improving the quality of antenatal care so as to reduce maternal morbidity and perinatal and infant mortality.


(N S Kang)

6th Floor, Chandralok Building, 36 Janpath, New Delhi - 110001, Telefax : 011-23325331

E-mail : nacoasdg@gmail.com

अपनी एचआईवी अवस्था जानें, निकटतम सरकारी अस्पताल में मुफ्त सलाह व जाँच पाएँ
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सत्यमेव जयते

K B Agarwal
IAS
Joint Secretary

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स्वास्थ्य एवं परिवार कल्याण मंत्रालय
राष्ट्रीय एड्स नियंत्रण संमन्त्रण
9वां तल, चन्द्रलोक बिल्डिंग, 36 जलपथ, नई दिल्ली -110001
Government of India
Ministry of Health & Family Welfare
National AIDS Control Organisation
9th Floor, Chandralok Building, 36 Janpath, New Delhi - 110 001

Message

National AIDS Control Organization (NACO) under Ministry of Health & Family Welfare and World Health Organization (WHO) has led an initiative of developing a National Strategy toward elimination of Parent to Child Transmission of Syphilis.

Congenital syphilis is a serious but preventable disease, which can be eliminated proactively through effective screening of all pregnant women for syphilis and prompt treatment of those infected, including their partner and newborn.

As per HIV Sentinel Surveillance 2011-12, syphilis sero-prevalence among pregnant women in India is 0.38%. With such low prevalence and by universal testing of syphilis in pregnancy and treatment of sero reactive pregnant women, her partner and her baby, it is possible to eliminate parent to child transmission and congenital syphilis in India. Treating maternal syphilis shall also improve pregnancy outcomes and will help us in achieving Millennium Development Goals 4,5 & 6 – reducing child mortality, improving maternal health and combating HIV/AIDS.

The universal coverage of screening pregnant women for syphilis has been a challenge, and testing for syphilis has been included in the essential antenatal service package so as to re-emphasize the importance of testing for syphilis among pregnant women. With advocacy aimed at all levels; high level commitment, coordination and cooperation by the key stakeholders (i.e STI/ RTI, PPTCT programme of HIV and RMNCH+A).

I am sure we can achieve universal coverage of syphilis screening among pregnant women.

(K B Agarwal)

9th Floor, Chandralok Building 36 Janpath, New Delhi -110001, Phones : 011-23325343, Fax : 011-23731748

E-mail : agarwkb@ias.nic.in

अपनी एचआईवी अवस्था जानें, निकटतम सरकारी अस्पताल में मुफ्त सलाह व जाँच पाएँ
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Message from WHO Representative to India

Syphilis has become a major public health problem globally, although it is relatively simple to prevent and treat. It is of particular concern in pregnancy because of the risk of transmitting the disease from the infected mother to her foetus. Mother-to-child transmission (MTCT) of the disease has caused a significant perinatal morbidity and mortality, globally. If left untreated, maternal syphilis can result in a significant reproductive health burden. It also contributes to syphilis-associated pregnancy, adverse outcomes including stillbirths and late foetal loss, neonatal deaths, premature and low-birth-weight infants, and congenital syphilis.

Globally, the latest WHO estimates suggest that in 2012, about a million pregnant women were infected with probably active syphilis, causing 371 000 serious adverse outcomes or congenital syphilis. In India, more recent estimates suggest that in 2012, 103 960 pregnant women were infected causing 53 187 adverse outcomes.

In 2007, the World Health Organization launched the global initiative to eliminate congenital syphilis and in 2011, an initiative for the dual elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. These initiatives are aimed at reducing childhood mortality, improving maternal health and combating HIV/AIDS and STIs.

Congenital syphilis and other adverse outcomes of maternal syphilis can easily be prevented by screening all pregnant women for syphilis and treating syphilis reactive women with injection benzathine penicillin.

Antenatal syphilis screening and treatment of infected pregnant women and their partners to prevent adverse health outcomes has demonstrated high cost-effectiveness even where syphilis prevalence in pregnant women is low.

To reach virtual elimination of congenital syphilis, programmes must expand coverage. In India, HIV and syphilis screening has been put in the essential Ante-Natal Care package in 2014, providing an opportunity to integrate this elimination programme into maternal, newborn, child health plus adolescent programme (RMNCH+A) services under the National Health Mission (NHM). This integration will allow universal coverage of all pregnant women to achieve elimination goals.

The National Strategy & Operational Guidelines for the Elimination of Congenital Syphilis brings together the essential interventions and an integrated platform between the Maternal & Child Health Programme and National AIDS Control Organization under the umbrella of the National Health Mission to target elimination of congenital syphilis. This initiative will provide the key guidance to NHM/MCH and HIV/STI programme managers to implement and monitor the progress towards the elimination congenital syphilis.

I congratulate the Ministry of Health & Family Welfare, National AIDS Control Organization and the Maternal & Child Health Division of the National Health Mission for collaboratively bringing out this important National Strategy and the Operational Guidelines for the Elimination of Congenital Syphilis.



Dr Nata Menabde
WHO Representative to India



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राष्ट्रीय एड्स नियंत्रण संगठन
9वां तल, चन्द्रलोक बिल्डिंग, 36 जनपथ, नई दिल्ली -110001

Government of India
Ministry of Health & Family Welfare
National AIDS Control Organisation

Dr. Sunil D. Khaparde

M.D. Ph.D
Deputy Director General
(NACO)

Tel : 91-11-23736851
Fax : 91-11-23731746
E-mail : sdkhaparde naco@gmail.com

9th Floor, Chandralok Building,
36 Janpath, New Delhi - 110 001

Acknowledgement

The Venereal Diseases Control Programme has been launched by the MoH & FW in 1946 which was further revitalised and is being currently implemented as National AIDS & STI Control Programme by the National AIDS Control Organization. We are happy to be on forefront of starting of this new national strategy "Towards Elimination of Parent-to-Child Transmission of Syphilis". Testing of pregnant women for syphilis has been the focus of the STI/RTI control and prevention programme through 1138 Designated RTI/ STI Clinics located mostly at the tertiary and secondary level health facilities. The National Strategy attempts to scale up this activity across all facilities in order to ensure universal screening and treatment of maternal syphilis and therefore elimination of congenital syphilis.

I would like to acknowledge the invaluable contributions made by technical staff from STI/RTI division of the National AIDS Control Organization especially Dr Shobini Rajan, Assistant Director General STI, Dr. T.L.N. Prasad, Technical Expert-National Technical Support Unit (NTSU), Dr. Aman Kumar Singh, Technical Expert-NTSU, Dr. Anil K. Bhola Programme Officer STI and Dr Raghuram Rao, NPO (ICTC), Basic Services Division, NACO for writing this document.

This strategy document has been developed and refined through qualitative inputs from Dr Himanshu Bhushan, Deputy Commissioner (Maternal & Child Health) MoHFW and Dr. Dinesh Baswal, Deputy Commissioner, (Maternal Health) MoH&FW, which guided the technical staff in improving the contents of the document. I highly appreciate the critical comments made by Dr. Ashok Kumar, Additional Director General BSD NACO

I would also thank Dr. Razia Narayan Pendse, Scientist HIV/AIDS, WHO SEARO, Dr. Nicole Seguy, Technical Officer HIV and Dr. Naina Rani, PPTCT Consultant, WHO Country Office; who were part of various round of meetings held at the NACO for providing regional perspective and practical inputs to refine the document.

A special expression of appreciation is for Dr. Lori Newman, Medical Officer - RHR, WHO Headquarters, Dr. Xiang-Sheng Chen, Director, National STI Programme China and Dr. Laxmikant Chavan, Strategic Information Consultant, WHO Country Office for providing technical support in developing estimates for maternal and congenital syphilis. Dr. Vani Srinivas- WHO Consultant -has supported the data collection, analysis, documentation of expert group meetings and preparation of the draft strategy.

I am thankful to all the experts who attended the various rounds of national expert consultations for E-PTCT held in New Delhi.


Dr. Sunil D Khaparde

Executive summary

Mother-to-child transmission of syphilis is an important preventable cause of maternal morbidity and newborn morbidity and mortality. Untreated maternal syphilis results in adverse outcomes of pregnancy in 50% of cases. It can lead to spontaneous abortions, stillbirths, premature and low-birth-weight babies, neonatal deaths and congenital syphilis. Interventions to improve the coverage and effect of antenatal screening for both syphilis and HIV contribute to achieving three important Millennium Development Goals - reducing child mortality, improving maternal health and combating HIV/AIDS.

As per the 2009 UNICEF Coverage Evaluation Survey, 89.6% of pregnant women in India access antenatal services at least once. The programme data on coverage for syphilis screening of pregnant women accessing antenatal care (ANC) services is incomplete and ranges from 12% as per Health Management Information System (HMIS) to 65% as per Computerized Management Information System (CMIS) in 2012-13. Of the identified infected pregnant women, only 35.8% were treated for syphilis based on the annual STI/RTI report from NACO.

As per HIV Sentinel Surveillance 2010-11, seroprevalence of syphilis using the rapid plasma reagin (RPR) test among pregnant women was 0.38%. Of the estimated 29 681 000 pregnancies in India during 2010-11 using HIV sentinel surveillance (HSS) 2010-11 seroprevalence, the estimated burden of syphilis among pregnant women in India was 103 960 in 2012 (range from 99 761 to 108 159). With the assumption that 52% of pregnant women infected with syphilis would experience some adverse events (including birth of newborns with congenital syphilis), the estimated number of adverse outcomes due to syphilis in pregnancy in India for 2012 was 53 187. As per the available data, the estimated incidence of congenital syphilis is 0.6 cases per 1000 live births.

The goal of the National Health Mission is to have universal pregnancy registration and ANC coverage, promote institutional deliveries for all and provide community-based support to women throughout pregnancy, childbirth, postnatal period and follow up of their infants. The low prevalence of syphilis and improved coverage of services for pregnant women provide the foundation for elimination of parent-to-child transmission of syphilis (E-PTCT).

The goal of the E-PTCT strategy is to reduce the incidence of congenital syphilis to less than 0.3 cases per 1000 live births by 2017.

The programmatic targets to achieve the goal are:

- ANC coverage (pregnant women having at least one ANC visit) of $\geq 95\%$
- coverage of syphilis testing of ANC attendees of $\geq 95\%$
- treatment of ANC attendees seroreactive to syphilis of $\geq 95\%$.

The initiative has four strategic directions:

1. Ensuring sustained high-level commitment and advocacy through partnerships at the national and international level; raising awareness of syphilis in pregnancy and its adverse outcomes; clear messaging on the benefits of early antenatal care; and close collaboration with the RMNCH+A programme.

2. Increasing access to, and improving the quality of RMNCH+A and other relevant services. Ensuring that all pregnant women are screened and adequately treated; sexual partners of the infected pregnant women are treated; engagement with communities and families for improved access to healthcare services; maximising opportunities for syphilis testing through decentralised service delivery; capacity building of staff for improving quality of care; establishing/strengthening functional linkages between RMNCH+A and STI programmes.

3. Screening pregnant women and treating syphilis-positive women, their partners and newborn infants. Treating all pregnant women who test positive with (at least) one dose of inj. benzathine penicillin - 2.4 million IU, given intramuscularly; follow-up of women where feasible for confirmation of syphilis and appropriate treatment; follow-up and management of the treatment of exposed infants and partners.

4. Establishing/strengthening surveillance, monitoring and evaluation systems; linkages with RMNCH+A programme recording and reporting systems; routine monitoring and reporting on key programmatic indicators through HMIS; investigation of all infants born to syphilis-reactive mothers; and reporting of congenital syphilis cases.

PART A:
NATIONAL STRATEGY FOR INDIA

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Abbreviations (part A)

AIDS	acquired immunodeficiency syndrome
ANC	antenatal care
ANM	auxillary nurse midwife
ASHA	accredited social health activist
BOH	bad obstetric history
CBO	community-based organization
CHC	community health centre
CMIS	Computerized Management Information System
DAPCU	district AIDS prevention and control unit
DSRC	designated STI/RTI clinic
E-PTCT	elimination of parent-to-child transmission
ECS	elimination of congenital syphilis
EQAS	external quality assurance scheme
F-ICTC	facility integrated counselling and testing centre
FOGSI	Federation of Obstetric and Gynaecological Societies of India
FRU	first referral unit
Gol	Government of India
HIV	human immunodeficiency virus
HMIS	Health Management Information System
HRG	high-risk group
HSS	HIV Sentinel Surveillance
IADVL	Indian Association of Dermatologists, Venereologists and Leprologists
IAP	Indian Academy of Paediatrics
IAPSM	Indian Association of Preventive and Social Medicine
ICTC	integrated counselling and testing centre

IEC	information, education and communication
IMA	Indian Medical Association
IPHA	Indian Public Health Association
JSSK	Janani Shishu Suraksha Karyakram
LHV	lady health visitor
M&E	monitoring and evaluation
MDG	Millennium Development Goal
MMU	mobile medical unit
MoHFW	Ministry of Health and Family Welfare
NACO	National AIDS Control Organization
NGO	non-governmental organization
NHM	National Health Mission
PHC	primary health centre
POC	point-of-care
PIP	project implementation plan
PPTCT	prevention of parent-to-child transmission
RCH	reproductive and child health
RMNCH + A	reproductive, maternal, newborn, child and adolescent health
RPR	rapid plasma reagin
RTI	reproductive tract infection
SACS	State AIDS control society
SC	sub-centre
SPMU	state programme management unit
STI	sexually transmitted infection
VDRL	venereal disease research laboratory
VHND	village health and nutrition day
WHO	World Health Organization

Introduction

Syphilis is a systemic, sexually transmitted infection caused by the bacterial spirochaete, *Treponema pallidum*. If it is not treated adequately in the primary, acute stage, it leads to chronicity and many adverse systemic outcomes.¹

In more than 50% of cases, untreated syphilis in pregnant women can result in numerous adverse outcomes of pregnancy including stillbirths, premature or low birth weight infants, neonatal deaths or birth of a congenital syphilitic baby.² Congenital syphilis is an easily preventable and curable disease, which can be eliminated through effective screening of pregnant women for syphilis and adequate treatment of those infected.

The global strategy to eliminate congenital syphilis was launched by World Health Organization (WHO) in 2007, and the “Regional Strategy for the Elimination of Congenital Syphilis in South East Asia Region 2011–15” was launched in 2012. The importance of implementing this as an integrated initiative was highlighted by the Asia–Pacific Task Force for Elimination of Parent-to-Child Transmission of HIV and Syphilis in its conceptual framework for elimination of parent-to-child transmission of HIV and syphilis in the Asia–Pacific Region.³ Both global and regional strategies focus on four key pillars:

- providing access to the essential ANC package to all pregnant women, preferably in the first trimester
- early screening of all pregnant women for syphilis
- treating all syphilis-reactive pregnant women and their partners
- treating all newborn infants of syphilis-reactive pregnant women.

This document uses the term elimination of parent-to-child transmission (E-PTCT) of syphilis instead of elimination of congenital syphilis (ECS), as it better reflects the management of the complete range of adverse outcomes including management of partner/s and newborns.²

1.1 Epidemiology

The draft global estimates of adverse outcomes of syphilis in pregnancy for 2012 is about 371 000. Early foetal deaths/stillbirths are 151 000; neonatal deaths 65 000; preterm/low birth weight 46 000 and congenital diseases are 107 000.³ Worldwide, an estimated 96% of maternal syphilis infections and 98% of adverse outcomes occurred in low- and middle-income countries. From 2008 to 2012, maternal syphilis infections and adverse pregnancy outcomes declined by 35.3%.⁴

Indian scenario: syphilis in pregnancy and incidence of congenital syphilis

There are limited data on screening of pregnant women for syphilis and adverse outcomes due to untreated maternal syphilis in India, as these data are not routinely reported through the Health Management Information System (HMIS). Similarly, data on the incidence of congenital syphilis among live-born infants is also limited due to difficulties in diagnosis, asymptomatic infections and absence of surveillance or reporting systems.

Around 89.6% of pregnant women in India access antenatal services at least once. The National AIDS Control Programme (NACP) III Report on Mid-Term Review of Sexually Transmitted Infection Services (December 2009) highlighted that there were several missed opportunities for syphilis screening. The data on screening coverage of pregnant women at antenatal care (ANC) services is incomplete; 12% screening coverage was reported from HMIS and 65% from Computerized Management Information System (CMIS) of National AIDS Control Organization (NACO) in 2012–13. According to the programme data available from NACO and HMIS, around 5 million pregnant women were screened for syphilis in 2012–13. Of the identified infected pregnant women, only 35.8% were treated for syphilis as per the annual sexually transmitted infection/reproductive tract infection (STI/RTI) report from NACO.

The programme data from NACO shows a declining trend of seropositivity of syphilis (defined as being rapid plasma reagin [RPR]/venereal disease research laboratory [VDRL] positive) among ANC attendees at designated STI/RTI clinics (DSRCs), from 1.7% in 2005–06 to 0.8% since 2010–11.

2.1 Level of syphilis sero-prevalence (RPR/VDRL test reactive) among ANC attendees⁵

As per HIV sentinel surveillance site data of 696 selected ANCs, the average seroprevalence of syphilis (qualitative test result) among ANCs during the 2010–11 round of HIV sentinel surveillance was 0.38%. Arunachal Pradesh (2.86%) had the highest prevalence of syphilis among ANCs, followed by West Bengal (1.91%), Rajasthan (1.17%), Punjab (0.95%), Meghalaya (0.90%), Madhya Pradesh (0.66%), Andaman & Nicobar Islands, Uttar Pradesh and Tripura (0.63% each) and Orissa (0.62%). The rest of the states had syphilis prevalence among ANC attendees of less than 0.6%.

2.2 Incidence of congenital syphilis in India

The exact incidence of congenital syphilis in India is not known due to the absence of active surveillance or any specific programme focused on investigating infants born to syphilis-reactive mothers. Literature reviews show that though there are a few hospital-based case series reported, they cannot be generalized to the whole country.

Due to limited data on congenital syphilis, the tool developed by WHO for estimation of maternal syphilis and its adverse outcomes has been used to calculate the incidence of congenital syphilis by using the seropositivity status of ANC attendees, the proportion of pregnant women accessing ANC services and the proportion of women tested and treated for syphilis in pregnancy. The tool is available at http://www.who.int/reproductivehealth/topics/rtis/syphilis/measurement_tool/en/.

Estimates for India (Table 2.1) were based upon sero-reactivity of syphilis as per HIV Sentinel Surveillance (HSS) 2010–11 for ANC attendees and the proportion of pregnant women accessing ANC services as per HMIS 2010–11⁷ out of the estimated 29 681 000 pregnancies.

Table 2.1. Estimated number of adverse outcomes from syphilis-reactive pregnant women in India for the year 2012 (based on WHO tool for estimation)

Outcome	Estimated number of adverse outcomes in India for the year 2012
Early foetal loss/stillbirths	21 488
Neonatal deaths	9213
Prematurity or low birth weight babies	6161
Clinical evidence of syphilis in newborns	16 324
Any adverse outcomes	53 187

Opportunities and challenges for E-PTCT of syphilis in India

3.1 Opportunities

Screening for syphilis is an important intervention that is being included in the essential antenatal package of services in the National Health Mission.

The biggest opportunity for the elimination of parent-to-child transmission (E-PTCT) of syphilis initiative is to create synergy with other programmes through coordinated activity of the human immunodeficiency virus (HIV)/STI and Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCH+A) Programmes. Functional convergence of HIV, STI and RMNCH+A Programmes under a comprehensive national prevention of parent-to-child transmission (PPTCT) of HIV and E-PTCT of syphilis response will help to achieve the broader goals of improving maternal and child health survival in the context of HIV/acquired immunodeficiency syndrome (AIDS).

Functional convergence of E-PTCT of syphilis initiative with the existing Janani Shishu Suraksha Karyakram (JSSK) of the National Health Mission will ensure the following:

- access to the essential ANC package for all pregnant women
- early screening of all pregnant women for syphilis, preferably in the first trimester
- ensuring institutional delivery of all syphilis-reactive pregnant women
- treating all syphilis-reactive women and their partners
- treating all newborn infants of syphilis-reactive women
- ensuring follow-up of syphilis reactive mothers and their babies.

Inexpensive and simple laboratory tests are available for the diagnosis of syphilis. Syphilis can be treated with penicillin, which is highly effective in treatment as well as prevention of congenital syphilis.⁸ Penicillin is an off-patent, cheap drug and is included in the National List of Essential Medicines in India.⁹

There is no known resistance to penicillin by *Treponema pallidum*. Screening and treatment of syphilis-reactive women in pregnancy is widely recognized as a cost-effective intervention even in low-prevalence settings like India.²

International and national focus on achieving the Millennium Development Goals, due in 2015, provides an impetus for expanding and scaling-up efforts at addressing E-PTCT of syphilis.

3.1.1 Potential contribution to Millennium Development Goals (MDGs)

The potential contributions of E-PTCT of syphilis to the health-related MDGs 4, 5 and 6 are:

MDG 4 – reduce child mortality

Addressing maternal syphilis contributes to reduced incidence of low birth weight babies, perinatal deaths and congenital syphilis.

MDG 5 – improve maternal health

Fewer stillbirths and spontaneous abortions will help improve pregnancy outcomes and reduce maternal morbidity.

MDG 6 – combat HIV/AIDS, malaria and other diseases

Treatment of syphilis and other STIs in women will help reduce risk of HIV transmission.

Using the ANC platform for screening all pregnant women for syphilis and HIV will help achieve dual elimination of parent-to-child transmission of both HIV and syphilis.

3.2 Challenges

- Lack of trained staff and guidelines on who can perform syphilis testing for routinisation of syphilis screening for all pregnant women;
- Poor awareness of burden of maternal syphilis-related adverse outcomes among providers and the community due to limited information, education and communication (IEC) activities on the subject, asymptomatic nature of infection, perception among healthcare providers that syphilis is no longer a problem in India, poor reporting and lack of surveillance;
- Late ANC attendance. According to HMIS 2012–13, only 57% of pregnant women register during the first trimester of pregnancy;
- Ineffective linkages and lack of clarity regarding roles, responsibilities and accountability between service delivery outlets among various programmes such as STI, HIV/AIDS and RMNCH+A;
- Missed opportunity for syphilis screening even when ANC coverage is high due to parallel service delivery of programmes;
- Despite the low cost of inj. benzathine penicillin and widespread availability of the drug, there is reluctance among healthcare providers to use penicillin for fear of serious adverse events;
- Lack of male involvement in RMNCH+A and STI services;
- Challenges in controlling and preventing syphilis amongst high-risk groups and their clients due to stigma and discrimination;
- Lack of monitoring to assess adverse outcomes of syphilis among pregnant women, including congenital syphilis.

National strategy for India

4.1 Guiding principles

- Public health approach to provide the best standards of care at scale, ensuring optimal use of limited resources;
- Functional convergence between the existing prevention of parent-to-child transmission (PPTCT) and STI programmes of NACO with RMNCH+A services under the National Health Mission;
- Rights- and gender-based approach to ensure that people get the necessary information about syphilis infection, including ways to protect themselves from infection and where to seek services. There is a need to proactively address issues such as stigma, discrimination and confidentiality.
- Partnership and collaboration with all partners and stakeholders working in the field of HIV, STI, family planning and maternal, child, and adolescent health to maximise synergies and minimise duplication.

4.2 Goal

To eliminate parent-to-child transmission (PTCT) of syphilis by 2017.

4.3 Target

To reduce the incidence of congenital syphilis to less than 0.3 cases per 1000 live births by 2017.

4.4 Objectives

The objectives are to:

- ensure universal registration of pregnant women at the first ANC visit in the first trimester;
- ensure screening of pregnant women for syphilis at least once during pregnancy;
- identify and provide prompt treatment to all syphilis-reactive pregnant women;
- ensure treatment of all infants born to syphilis-reactive women;
- reach partners of syphilis-reactive pregnant women, promote condom use, educate and counsel on risk reduction and safer sex practices to prevent infection/re-infection;
- monitor the core indicators of E-PTCT of syphilis initiative.

4.5 Programmatic targets

The programmatic targets to achieve the goal above are:

- ANC coverage (pregnant women having at least one ANC visit) of $\geq 95\%$
- coverage of syphilis testing of ANC attendees of $\geq 95\%$
- treatment of syphilis-reactive ANC attendees of $\geq 95\%$

treatment, follow-up and investigation of 100% of all infants born to syphilis-reactive mothers.

Strategic directions and key interventions for elimination of parent-to-child transmission of syphilis

5.1 Strategic direction 1 – ensuring sustained high-level commitment and advocacy

NACO, National Health Mission (NHM) and other key stakeholders such as development partners and programme managers of NACO and NHM will strive to ensure that the initiative receives adequate political, policy, financial and logistic support.

5.1.1 Key interventions

- Secure high-level political commitment and advocacy by working towards an enabling political and policy environment for adequate resource allocation.
- Raise awareness of decision-makers on the magnitude of the problem; feasibility, simplicity and cost-effectiveness of interventions for E-PTCT of syphilis; and potential for their easy functional integration into the RMNCH+A and HIV programmes.
- Include syphilis screening and management as an essential intervention and monitoring package within ANC services.
- Ensure resource allocation for diagnosis and management of syphilis in RMNCH+A programme settings.
- Build staff capacity for diagnosis and management of syphilis in all levels of healthcare facilities.
- Endorse the policy for introducing task shifting and delegation of screening of pregnant women with point-of-care tests from primary health centre (PHC) to sub-centre (SC) and from laboratory technician to auxiliary nurse midwife (ANM) to improve access to screening, especially in hard-to-reach areas.
- Establish policies to support functional convergence of PPTCT, STI and RMNCH+A programmes to enhance access to quality ANC services.

5.2 Strategic direction 2 – increasing access to, and improving the quality of RMNCH+A and other relevant services

Maternal and newborn health services provide a unique opportunity to screen and treat pregnant women for syphilis. Accessibility, use and quality of these services are hence critical for reducing adverse outcomes due to maternal syphilis and E-PTCT of syphilis.

5.2.1 Key interventions

- Develop and strengthen existing health systems for service delivery for providing qualitative antenatal, natal, post-natal and newborn care, availability of requisite infrastructure, supply of test kits and consumables and capacity building of the health staff.
- Improve provision of comprehensive linked services through an integrated and client-centred package of RMNCH+A/HIV/STI and family planning services.
- Provide for HIV and syphilis testing using point-of-care (POC) for all pregnant women, STI/RTI attendees, high-risk groups and their clients.
- Train healthcare service providers regarding the safety of inj. benzathine penicillin in adults and inj. crystalline penicillin in new borns.
- Include syphilis testing, management and reporting as part of the essential package of services in ANC.
- Introduce POC tests or other simple tests at PHCs and hard to reach areas where laboratory facilities and trained manpower are not available.
- Raise awareness levels and community engagement for early ANC registration and care, preferably in the first trimester, through public health communication channels customised to the local context.
- Develop functional linkages of ANC services with other relevant services such as STI, family planning and clinical and paediatric care services to ensure screening and treatment of syphilis-reactive women, their partners and newborn infants.
- Ensure inclusion of syphilis screening as part of the workup for women with bad obstetric history (BOH) or history of spontaneous abortions, stillbirths, neonatal deaths, prematurity or preterm babies.
- Enhance community involvement to improve uptake of services through meaningful involvement of accredited social health activists (ASHAs), anganwadi workers, panchayat raj institutions, non-governmental organizations (NGOs), community-based organizations (CBOs), etc.

5.3 Strategic direction 3 – screening pregnant women and treating syphilis-reactive women, their partners and newborn infants

Early detection and treatment of syphilis among pregnant women, their sexual partners and babies are crucial elements of the strategy for E-PTCT of syphilis.

5.3.1 Key interventions

- Screen all pregnant women for syphilis during their first visit, preferably in the first trimester. Make the results available promptly; testing and handing over of test results should preferably be done on the same day.
- Test all pregnant women at least once during the antenatal period. For those who were not tested earlier, testing needs to be done at the time of delivery.
- Counsel and treat all syphilis-reactive women on the same day of being tested as stipulated in the operational guidelines.¹⁰
- Enhance male involvement, including treating all sexual partners of syphilis-reactive pregnant women.
- Ensure that women are not re-infected through education, counselling, use of condoms and treatment of partners.
- Retest high-risk pregnant women who had tested negative earlier during late pregnancy as per operational guidelines.⁹

- Screen all patients attending STI clinics for syphilis and treat those found to be reactive.
- Conduct bi-annual syphilis screening of high-risk groups (HRGs) and prompt referral and treatment of those found reactive.
- Carefully examine all infants of syphilis-reactive women for clinical evidence of congenital syphilis. Manage all syphilis-exposed infants as per the operational guidelines.¹⁰

5.4 Strategic direction 4 – surveillance, monitoring and evaluation

Surveillance and monitoring are essential to accurately assess the magnitude of maternal and congenital syphilis cases and to plan and evaluate the effectiveness of the interventions.

5.4.1 Key interventions

- Incorporate E-PTCT of syphilis indicators in the existing monitoring systems of RMNCH+A and HIV/STI programmes.
- Strengthen existing reporting systems under NACO and RMNCH+A through simplified recording and reporting formats.
- Conduct investigation of infants born to syphilis-reactive mothers in accordance with the operational guidelines.¹⁰
- Analyse and compile data routinely at national/state levels and provide feedback to the reporting units. This initiative should be evaluated in 2017 for its effectiveness, using identified core indicators and targets.

5.5 E-PTCT of syphilis at various levels of care

Service delivery packages for various levels of care, specifying the service provider and the modalities of care, are tabulated in Table 5.1.

Table 5.1. Service delivery packages for E-PTCT of syphilis at various levels of care

Level of care	Service provider	Modalities	Package of services
Village	ASHA	While observing the village health and nutrition day (VHND) each month, ASHAs should create awareness about syphilis and the importance of screening for syphilis during early pregnancy.	<ul style="list-style-type: none"> • Information to pregnant women • Ensure every pregnant woman is screened for syphilis • Facilitate syphilis-reactive pregnant women to seek services from a healthcare facility for confirmation and treatment • Facilitate treatment and follow-up of a syphilis-reactive mother, her baby and partner.
Sub-centre (SC)	ANM/health worker	Through ANC clinics, group meetings and household contacts	<ul style="list-style-type: none"> • In addition to the above, provide counselling • Screen for syphilis using point-of-care (POC) test • Referral of syphilis-reactive pregnant woman and her partner to a nearby PHC or a higher healthcare facility for confirmation and adequate treatment • Facilitate effective treatment of syphilis-reactive pregnant women and follow-up of syphilis-exposed babies at 6 months and 24 months.
PHC/24 x 7 PHC/ F-ICTC /mobile medical unit/dispensary/CHC/urban health post/rural hospital/sub-divisional hospital (facilities with no DSRCs and no stand-alone ICTCs)	Medical officer/staff nurse/LHV/general laboratory technician	Routine OPD at ANC clinics/camps	<ul style="list-style-type: none"> • In addition to the above, ensure RPR/VDRL test (qualitative and quantitative) for those tested reactive for syphilis at SC • Delivery of syphilis-reactive pregnant women and management of their newborns • Provide adequate treatment to syphilis-reactive pregnant women, their partners and newborns. • Reporting in HMIS.

ICTC – integrated counselling and testing centre; F-ICTC – facility integrated counselling and testing centre; LHV – lady health visitor; EQAS – external quality assurance scheme

Level of care	Service provider	Modalities	Package of services
PHC/24 x 7 PHC/ /mobile medical unit/dispens ary/CHC/urb an health post/rural hospital/sub- divisional hospital (with stand- alone ICTC but no DSRC)	Medical officer, ICTC counsellor, ICTC laboratory technician	Gynaecology/obstetric clinics, ANC clinics, general OPD	<ul style="list-style-type: none"> • In addition to the above, ensure syphilis screening of all pregnant women at ICTC and general laboratory. • ICTC and PPTCT counsellor to provide counselling to all ANC attendees and their partners • Maintain a line- list of all ANC attendees reactive for syphilis and ensure their and their babies effective follow-up .
Designated STI/RTI clinic (district hospital, medical college hospitals, selected rural hospital/sub divisional hospital), Suraksha clinics	Medical officer, staff nurse, DSRC counsellor, laboratory technician of ICTC	Gynaecology/obstetric clinics, ANC clinics, general OPD	<ul style="list-style-type: none"> • In addition to the above, the STI Counsellor of the DSRC will coordinate with the ICTC counsellor. • S/he will provide counselling to all ANC attendees and partners coming to the ANC clinic and refer them to the laboratory for screening and confirmation of syphilis. • Will also maintain a line- list of all ANC attendees reactive for syphilis and ensure effective follow-up for them and their babies.
Regional STI training research and reference laboratories and state reference centres	Microbiologist, laboratory technician, experts from other departments	Referral of samples from all the linked DSRCs and health facilities	<ul style="list-style-type: none"> • Conduct quarterly ANC syphilis EQAS and provide feedback to the testing facilities
Private hospitals/nur sing homes	Gynaecologists and obstetricians/ general practitioners/ AYUSH practitioners	Gynaecology/obstetrics clinics, ANC clinics, general OPD, AYUSH clinics	<ul style="list-style-type: none"> • Ensure syphilis screening of all pregnant women • Provide effective treatment to syphilis-reactive pregnant women, their partners and newborns • Ensure RPR/VDRL test (qualitative and quantitative) • Report to district RCH officer • Participate in quarterly EQAS with the linked state reference laboratory.

5.6 Reaching the mobile population

Mobile populations face a huge challenge to access healthcare services. The following is recommended to reach out to them:

- Use of outreach teams of the targeted intervention projects supported by NACO through healthcare facilities of public sector undertakings such as mines, railways, defence, ports and shipping, surface transport, ESI corporations, small-, medium- and large-scale industries and the private health sector;
- Linking with professional associations such as the Indian Medical Association (IMA), Federation of Obstetric and Gynaecological Societies of India (FOGSI), Indian Academy of Paediatrics (IAP) and Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) to orient and sensitise their members and reach out to mobile populations;
- Existing strategies to reach the mobile population under NHM such as mass vaccination campaigns/mobile medical units (MMUs); announcing VHNDs for them to access services.

IEC and social mobilization for E-PTCT of syphilis

6.1 Communication for E-PTCT of syphilis

The aim of communication is to increase awareness in the community regarding basic information about syphilis and its adverse impact on pregnancy. This will help to improve health-seeking behaviour among pregnant women, leading to improved uptake of syphilis testing and treatment during the first trimester of pregnancy.

6.2 Responsibility for developing the IEC

State AIDS control societies (SACs), Sexually Transmitted Infection Division and Information, Education and Communication (IEC) Division, of NACO in collaboration with IEC and Reproductive and Child Health (RCH) Divisions of state health missions will develop IEC for E-PTCT of syphilis. SACs will review the existing IEC material on maternal health and incorporate the HIV and syphilis testing messages in the same. Technical support for IEC will be provided by the STI Division of SACs.

6.3 IEC Messages for E-PTCT of syphilis

- Details of transmission of maternal syphilis to the foetus; need for early screening in pregnancy; treatment of syphilis; treatment of partner and the newborn; prevention methods;
- Referral of syphilis-reactive pregnant women to higher level healthcare facilities for further management as early as possible;
- Institutional deliveries of syphilis-reactive pregnant women at CHCs/first referral units (FRUs) and healthcare facilities;
- Regular follow-up as per schedule.

6.4 Community involvement and social mobilisation for E-PTCT of syphilis

Given the large number of pregnant women to be screened for syphilis in a diverse country like India, the role of community based grassroot level workers (ANMs and ASHAs) is crucial to make the E-PTCT of syphilis a reality.

- Home visits: Prioritise the home visits of syphilis-reactive pregnant women or newborns born to syphilis-reactive pregnant women. Home visits to these households should take place at least monthly.

- Attending the VHND: Promote attendance at the monthly VHND by those who need anganwadi or ANM services and help with counselling for early pregnancy registration, health education on screening for syphilis and access to services.
- Visits to the healthcare facility: Accompanying a syphilis-reactive pregnant woman, or accompanying her child for the management of syphilis and follow-up visits. ASHAs are expected to attend the monthly review meetings held at the PHCs regularly.
- Maintain records: Maintain records of syphilis-reactive pregnant women and the follow-up schedule of mothers, babies and partners for necessary action.

Monitoring and evaluation framework of E-PTCT of syphilis

The E-PTCT of syphilis initiative envisages a focused monitoring and evaluation (M&E) system with specific indicators (Table 7.1) to monitor the progress of the initiative across states so as to take appropriate programmatic responses. NACO and NHM will monitor indicators identified as critical for monitoring at a national level. States and districts will also be encouraged to monitor these indicators and to ensure good quality of data collected from the facilities.

7.1 Case definitions

- Suspected case of congenital syphilis: A stillborn* or live-born baby of a syphilis-reactive mother who has been inadequately** treated.
- Confirmed case of congenital syphilis: A live birth with serum quantitative RPR titre that is fourfold higher than that of the mother's titre.

OR

A child within the first 2 years of life with clinical evidence*** of syphilis and reactive syphilis serology, irrespective of the mother's serology.

**A stillbirth is a baby born with no signs of life at or after 28 weeks' gestation.*

*** Treated with penicillin <4 weeks before delivery or treated with non-penicillin regimen.*

****At least two of the following: Swelling of joints, snuffles, bullous skin lesions, hepatosplenomegaly, jaundice, anaemia, radiological changes in the long bones.*

Table 7.1: Indicators for monitoring E-PTCT of syphilis in India

S.No	Indicator	Numerator	Denominator	Method of measurement	Periodicity
1*	Programme indicators				
1.1	Percentage of pregnant women visiting ANC clinic at least once*	No. of pregnant women visiting ANC clinic at least once	Total estimated number of pregnancies	Numerator –HMIS Denominator –National estimations	Annually
1.2	Percentage of ANC attendees tested for syphilis	No. of ANC attendees tested for syphilis at any point in time during pregnancy	Number of ANC attendees	Numerator –HMIS Denominator –HMIS	Monthly
1.3	Percentage of ANC attendees tested for syphilis who are reactive for syphilis*	No. of ANC attendees found reactive for syphilis	Number of ANC attendees screened for syphilis at least once	Numerator – HMIS Denominator – HMIS	Monthly
1.4	Percentage of syphilis-reactive ANC attendees who received adequate treatment*	Number of ANC attendees reactive for syphilis who received adequate treatment	Number of ANC attendees reactive for syphilis	Numerator- – HMIS Denominator – HMIS	Monthly
1.5	Percentage of infants born to syphilis-reactive mothers who received adequate treatment	Number of infants born to syphilis-reactive mothers who received adequate treatment	Number of babies born to syphilis-reactive mothers	Numerator – Line list Denominator – Line List	Monthly
2*	Impact indicators				
2.1	Incidence of cases of congenital syphilis*	No. of reported cases of congenital syphilis (as per case definition)	Total number of live births	Numerator – HMIS Denominator – HMIS	Annually
	* WHO required indicators for validation of E-PTCT of syphilis				

Roles and responsibilities for M&E and reporting formats are given in the operational guidelines for E-PTCT of syphilis.

7.2 Monitoring implementation

Programme managers and officers of Maternal and Child Health of the National Health Mission, Ministry of Health, Government of India (GoI) and the programme managers and officers of the STI Programme of NACO/SACS will oversee implementation of the programme for the elimination of congenital syphilis.

7.3 Programme monitoring

The following officials are responsible for programme monitoring:

- At district level:
 - o District reproductive and child health officer
 - o District health and family welfare officer/chief medical officer/civil surgeon
 - o District programme management unit
 - o District AIDS prevention and control unit (DAPCU), wherever available.

- At state level:
 - o State reproductive and child health officer
 - o State programme management unit (SPMU)
 - o SACS: Joint director STI/deputy director STI/assistant director STI/joint director basic services division/programme officer sexually transmitted infections.

- At national level:
 - o Deputy Director General STI, NACO
 - o DDG Basic Service Division, NACO
 - o Deputy Commissioner, Maternal Health Division, Ministry of Health and Family Welfare (MoHFW).

Roles and responsibilities

8.1 NACO through state AIDS control societies

- To formulate a national policy for E-PTCT of syphilis and HIV with sustained commitment at all levels of health services;
- To prepare guidelines on the prevention, management and care of maternal and congenital syphilis;
- To conduct a baseline situational analysis to assess the problem of syphilis during pregnancy and monitor progress of the initiative;
- To supervise and ensure reporting for routine surveillance, monitoring and evaluation of the E-PTCT of syphilis initiative;
- To define strategic information on the epidemiological situation of maternal and congenital syphilis and interventions to prevent and control syphilis;
- To conduct advocacy at all levels and garner support and necessary resource allocation;
- To manage the programme effectively through convergence with HIV PPTCT and RMNCH+A Programmes;
- To standardise specifications of diagnostic tests for syphilis;
- To incorporate standardised E-PTCT of syphilis content in training material;
- To support operations research on E-PTCT of syphilis implementation;
- To provide technical support to the Maternal and Child Health Divisions of MoH for implementing E-PTCT strategy.

8.2 Maternal and child health divisions through the national and state health missions

- To ensure that maternal syphilis screening, diagnosis, treatment and prevention is included in the RMNCH+A programme as an essential component of comprehensive antenatal-care services;
- To allocate resources for screening and treatment of all pregnant women, partners and newborn for syphilis in the state project implementation plan (PIP);
- To provide directions to all the states to implement the E-PTCT initiative;

- To introduce POC test for syphilis at SC level ANC clinics, hard to reach facilities and other facilities where laboratories are non-functional;
- To support task and role shifting for syphilis screening through lab technicians at PHCs and ANMs at the SC level;
- To ensure supply chain management of drugs and test kits across all levels of health care;
- To build capacity of healthcare providers and field staff on E-PTCT of syphilis;
- To ensure that indicators for monitoring the programme are incorporated in the existing HMIS and other systems.

National Steering Committee

The National Steering Committee will review the implementation of E-PTCT and troubleshoot issues through regular meetings held once every four months. The Committee will consist of the following:

- Deputy Director General (STI Programme), NACO
- Deputy Director General (Basic Services Division), NACO
- Deputy Commissioner (Maternal Health Division), NHM
- Nodal officers from microbiology departments and from apex regional STI training, research and reference laboratories
- Development partners (WHO and UNICEF)
- Member from Technical Resource Group of STI Programme

Engagement with the private sector

Professional bodies and accredited private healthcare providers can contribute to augment the effort of government agencies for reporting and treating maternal syphilis.

The Clinical Establishments (Registration and Regulation) Act, 2010 was notified by the Union Government on 28 February 2012. It has been enforced in many states and all union territories since March 2012.¹⁰

The Act makes it mandatory for all clinical establishments to

- provide necessary medical care and treatment
- undertake mandatory registration of all clinical establishments
- develop standard treatment guidelines for common disease conditions
- maintain standards for electronic records maintenance systems to be adopted in hospitals.

Professional bodies such as the IAP, FOGSI, Indian Association of Preventive and Social Medicine (IAPSM), Indian Public Health Association (IPHA) and IMA, to name a few, can play a key role in implementing the E-PTCT of syphilis strategy by screening ANC attendees for syphilis, treating those found reactive and submitting their monthly reports. These organisations can also assist the Government in training human resources for E-PTCT of syphilis in the public health system.

Accredited private healthcare providers can play a critical role in filling the gap in essential RMNCH+A services, including comprehensive abortion care, family planning procedures and emergency obstetric care which may be required by syphilis-reactive pregnant women.

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