The National Strategy & Operational Guidelines Towards Elimination of Congenital Syphils

2015

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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.

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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.

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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.

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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

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I would like to acknowledge the invaluable contributions made by the technical staff from the STI/RTI division of the National AIDS Control Organization, especially 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, NACO, Dr Vani Srinivas, Consultant Congenital Syphilis, WHO and Dr Raghuram Rao, NPO (ICTC), Basic Services Division, NACO for writing this document.

This strategy document has been developed under the able guidance and leadership of Dr S.D. Khaparde, Deputy Director General (STI and BTS), NACO and Dr Himanshu Bhushan, Deputy Commissioner (Maternal & Child Health), MoHFW. I highly appreciate the critical comments made by Dr Ashok Kumar, Additional Director General BSD, NACO and Dr Dinesh Baswal, Deputy Commissioner, Maternal Health, MoHFW. These comments guided the technical staff in improving the contents of the document.

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I am thankful to all the experts who attended the national expert consultation workshop for E-PTCT during 19–20 December 2013 in New Delhi. The contents of this document were further refined based on the deliberations and reviews of a group of experts.

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National Workshop for Elimination of Congenital Syphilis (ECS)

25 February 2015 | The Oberoi, New Delhi

WR's Message

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 intiative 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.

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 ? 95%
- coverage of syphilis testing of ANC attendees of ? 95%
- treatment of ANC attendees seroreactive to syphilis of ? 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 health-care 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
GoI	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 regain [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 attendees[5]

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 2010–11[7] 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 health-care 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 health-care 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 ≥ 95%
- coverage of syphilis testing of ANC attendees of ≥ 95%
- treatment of syphilis-reactive ANC attendees of ≥ 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 health-care 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 auxillary 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 health-care 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.	▫Information to pregnant women ▫Ensure every pregnant woman is screened for syphilis ▫Facilitate syphilis-reactive pregnant women to seek services from a health-care 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	▫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 health-care 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	▫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/dispensary/CHC/urban 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	▫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	▫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	Conduct quarterly ANC syphilis EQAS and provide feedback to the testing facilities
Private hospitals/nursing homes	Gynaecologists and obstetricians/ general practitioners/ AYUSH practitioners	Gynaecology/obstetrics clinics, ANC clinics, general OPD, AYUSH clinics	▫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 health-care services. The following is recommended to reach out to them:

- Use of outreach teams of the targeted intervention projects supported by NACO through health-care 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 (SACSs), 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 health-care facilities for further management as early as possible;
- Institutional deliveries of syphilis-reactive pregnant women at CHCs/first referral units (FRUs) and health-care 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 new borns 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 health-care 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 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 4: 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:
  - District reproductive and child health officer
  - District health and family welfare officer/chief medical officer/civil surgeon
  - District programme management unit
  - District AIDS prevention and control unit (DAPCU), wherever available.

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

- At national level:
  - Deputy Director General STI, NACO
  - DDG Basic Service Division, NACO
  - 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 health-care 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 4 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 health-care 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 health-care 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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PART B:

OPERATIONAL GUIDELINES

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Abbreviations (Part B)

ANC	antenatal care
ANM	auxiliary nurse midwife
ASHA	accredited social health activist
BSD	Basic Services Division
CDSCO	Central Drugs Standard Control Organisation
CHC	community health centre
CS	congenital syphilis
DFA-TP	direct fluorescent antibody detection of T. pallidum
DPMU	district project management unit
DSRC	designated STI/RTI clinic
DTC	district training centre
E-PTCT	elimination of parent-to-child transmission
EQAS	external quality assurance scheme
FEFO	first expiry first out
FRU	first referral unit
HFWTC	health and family welfare training centre
HIV	human immunodeficiency virus
HMIS	Health Management Information System
ICTC	integrated counselling and testing centre
IEC	information, education, communication
IgG	immunoglobulin G
IgM	immunoglobulin M
JSSK	Janani Shishu Suraksha Karyakram
M&E	monitoring and evaluation
MO	medical officer

MoHFW	Ministry of Health and Family Welfare
NACO	National AIDS Control Organization
NACP	National AIDS Control Programme
NGO	non-governmental organisation
NHM	National Health Mission
PHC	primary health centre
POC	point-of-care
PPTCT	prevention of parent-to-child transmission
PT	proficiency testing
PTCT	parent-to-child transmission
RCH	reproductive and child health
RCH II	Reproductive and Child Health Phase II
RCHO	reproductive and child health officer
RMNCH+A	reproductive, maternal, newborn, child and adolescent health
RPR	rapid plasma reagin
RSTRRL	regional STI training, research and reference laboratory
RTI	reproductive tract infection
SACS	state AIDS control society
SC	sub-centre
SIHFW	State Institute of Health and Family Welfare
SIMS	Strategic Information Management System
SOP	standard operating procedure
SPMU	state project management unit
SRC	state reference centre
STI	sexually transmitted infection
TPHA	Treponema pallidum hemagglutination assay
UHC	urban health centre
USFDA	U.S. Food and Drug Administration
VDRL	venereal disease research laboratory

Introduction

The Venereal Diseases Control Programme was launched by the MoHFW in 1946. The programme was further revitalized and is being currently implemented by the National AIDS Control Organization (NACO), Ministry of Health and Family Welfare (MoHFW). Management of pregnant women for syphilis has been incorporated in this programme.

A national strategy for India "Towards Elimination of Parent-to-Child Transmission (E-PTCT) of Syphilis" is being launched in February 2015 by MoHFW. This strategy emphasizes the management of syphilis among pregnant women through a functional convergence approach. This will be achieved through advocacy, political commitment, coordination and cooperation by the key stakeholders, i.e. managers of the sexually transmitted infection (STI)/reproductive tract infection (RTI) Programme, human immunodeficiency virus (HIV)/Prevention of Parent-to-Child Transmission (PPTCT) Programme and the Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCH+A) Programme of the National Health Mission (NHM).

The operational guidelines for E-PTCT of syphilis have been developed to provide standardised protocols for syphilis screening of pregnant women and management of maternal syphilis at different levels of health care within the health-care delivery services. These guidelines also provide protocols for the diagnosis of congenital syphilis (CS) and the management and follow-up of infants born to women infected with syphilis. Information, education, communication (IEC), supply chain management, training, quality assurance, roles and responsibilities and monitoring and evaluation are also addressed in these guidelines.

The programme for E-PTCT of syphilis needs to be implemented across all health-care facilities for ensuring universal screening of pregnant women for syphilis and treating all those found syphilis reactive. Universal coverage of testing and treatment will help to achieve the overall goal of E-PTCT of syphilis. This can be done by integrating the programme for eliminating parent-to-child transmission (PTCT) of syphilis together with PPTCT of HIV with the existing RMNCH+A Programme. This will help in reaching out to large numbers of pregnant women in India for screening/testing them, their partners and babies and in ensuring effective management of ANCs.

These operational guidelines aim to provide guidance to STI, Basic Services Division (BSD) Programme Managers of AIDS Societies and RMNCH+A programme managers at the national, state and district levels and their implementing staff at all levels and private health sector partners

Risk of transmission and impact of maternal syphilis on pregnancy outcomes

The likelihood of transmission from mother to child is directly related to the stage of maternal syphilis during pregnancy, or the stage of pregnancy at which infection is acquired. The concentration of spirochaetes in the blood is the highest during the first two years after acquiring the infection. Thereafter, it decreases slowly as a result of acquired immunity. In early maternal syphilis, the maternal–foetal transmission rate can be up to as much as 80%, whereas infectivity decreases in late syphilis. Although pregnant women can transmit the infection to the foetus as early as nine weeks of gestation, transmission usually takes place between the sixteenth and twenty-eighth week of pregnancy.[1]

The course of maternal infection does not seem to be altered by pregnancy.

Adverse outcomes of pregnancy in women infected with syphilis include early foetal loss, stillbirths, neonatal deaths, low birth weight or prematurity and neonatal infection with syphilis.

Clinical manifestations, diagnosis and management of maternal and congenital syphilis

3.1 Signs and symptoms of syphilis

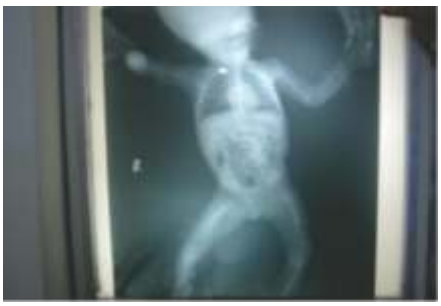
Syphilis has three stages:

- The primary stage usually starts after 21 days (range is 10–90 days) following the infection. The infected person develops a painless genital ulcer, which lasts for 2–6 weeks.
- The secondary stage is characterised by a skin rash all over the body, often with fever and muscular pain. This stage also lasts 2–6 weeks, and is followed by a latent phase of many years, when there are no signs or symptoms. However, even during the latent phase, spirochaetes may occasionally circulate in the blood, though this happens less frequently over time. As a result, virtually all the organs of the body may become infected.
- The tertiary stage occurs several years after infection, and can take the form of neuro-syphilis (in which the brain or spinal cord is affected), cardiovascular syphilis (involving the aorta and heart), or late benign syphilis (involving primarily the skin). These complications will develop in about 40% of people with latent infection, in the absence of antibiotic treatment.

3.2 Signs and symptoms of congenital syphilis

Congenital syphilis may be asymptomatic in about 50% of cases, especially in the first weeks of life. Usually, symptoms appear in the first months but the clinical manifestations may be delayed until the second year of life.

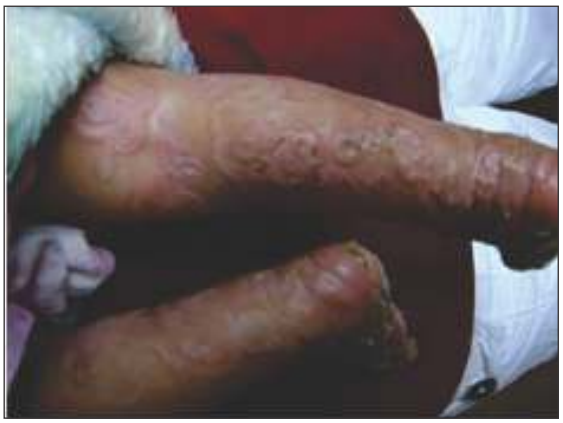
Fig. 3.1. Radiograph showing lower end of humerus (periostitis) and proximal ends of radius and ulna (metaphysitis)2,4



The most frequent clinical signs of congenital syphilis at birth are hepatosplenomegaly (33–100%), bone changes seen on X-ray (75–100%) (Figure 3.1), blistering skin rash especially over palms and soles (40%) (Figure 3.2), fever (16%), low birth weight (10–40%), bleeding (10%), swelling of the joints, abnormal faeces, snuffles, oedema, abdominal distension, pallor, respiratory distress and pseudoparalysis.2–4

An older child may have stigmata, e.g. interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson teeth, saddle nose, rhagades, or Clutton joints.[5]

Fig. 3.2. Blistering skin rash in noenates



3.3 Serological diagnosis of maternal syphilis in the programme for E-PTCT of syphilis

A number of serological tests are available for syphilis screening. These are classified into non-treponemal test and treponemal test. The tests used in the programme for E-PTCT of syphilis are:

– point-of-care treponemal test
– RPR or VDRL test
– TPHA test (when possible).

To achieve universal screening of pregnant women for syphilis, the tests used for syphilis screening depend on the level of services.

At health-care service points without laboratories, ANC attendees have to be screened using a point-of-care (POC) test (Flowchart 1 at Figure 3.3). At health-care service points with laboratory support, ANC attendees can be screened using the rapid plasma reagin (RPR) or venereal disease research laboratory (VDRL) test (Flowchart 2 at Figure 3.4). For women coming directly in labour, a POC test will be used. (Flowchart 3 at Figure 3.5).

The decision on the treatment to be administered for syphilis to a pregnant woman is based on the result of the screening test. After immediate treatment with one dose of inj. benzathine penicillin, a second test (RPR/VDRL test if screening test was a POC test) will be conducted to confirm active syphilis. When the screening test is an RPR/VDRL test, a treponema pallidum hemagglutination assay (TPHA) may be conducted, if available, to confirm active syphilis.

RPR/VDRL titre may be done to monitor the response to treatment, but this should not delay the start of treatment.

Following infection with syphilis, blood tests can take 10–45 days to become reactive, depending on the type of test. High-risk pregnant women can also be re-infected during the third trimester of pregnancy. Therefore, if the first test is negative, it should ideally be repeated during the third trimester or at the time of delivery, based on the criteria as given below.

3.3.1 Criteria for re-testing pregnant women in late pregnancy or at delivery6

– Pregnant women considered to be at high risk for acquiring STI, i.e. those with a current or past history of STI, women with more than one sexual partner, sex workers and injecting drug users;
– Pregnant woman with a history of repeated abortions, stillbirths, past history of delivery of premature babies and neonatal death/s;
– Testing at the time of delivery will also be required to detect re-infection, particularly in women whose partners were not treated.

All pregnant women should be tested for HIV, including those reactive for syphilis.
Partners of syphilis-reactive pregnant women should be treated for syphilis. While testing partners of syphilis-reactive pregnant women can be conducted, they have to be treated promptly, irrespective of test results.[7]

Risk-reduction counselling and condom provision enables modification of risk behaviour.

Table 3.1 gives information on the type of test to be used for pregnant women for syphilis in health-care facilities at different levels, and its management.

Table 3.1. Testing and management of pregnant women for syphilis

Level of Facility	Test to be conducted	Management
Sub-centre or cases coming directly in labour at any level – PHC/CHC/DH with non-functional laboratory	Rapid POC test for syphilis	Refer the reactive cases to a higher health-care facility for treatment and RPR/VDRL test
PHC with functional laboratory PHC/CHC/SDH/DH with functional laboratory DSRC and medical college facilities	RPR or VDRL test	Treat the reactive cases and perform TPHA in centres where TPHA is available

PHC – primary health centre; CHC – community health centre; SDH – sub-district hospital; DH – district hospital; DSRC – designated STI/RTI clinic

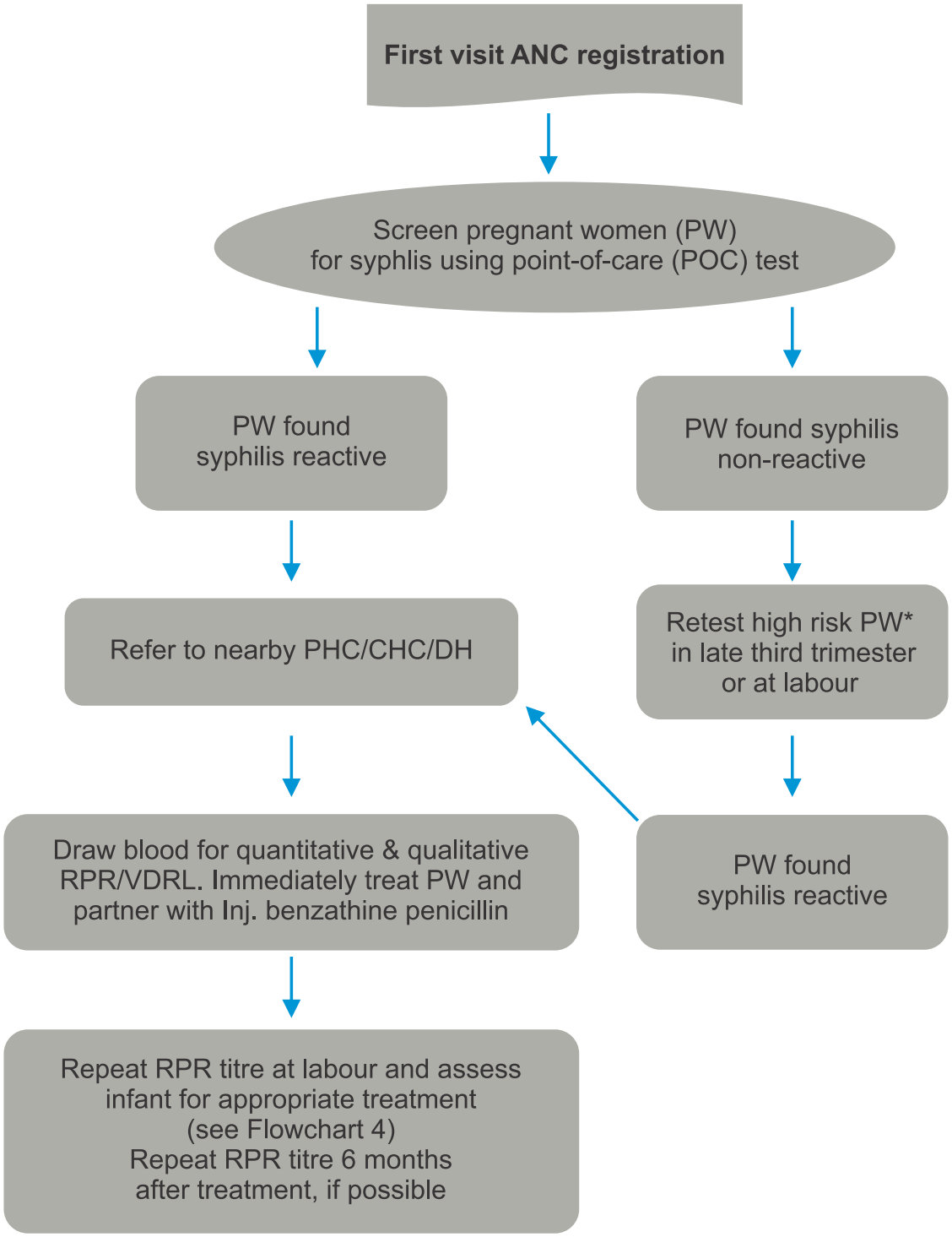
3.4 Management of syphilis in pregnant women

3.4.1. General guidelines for treatment of pregnant women with syphilis

– Treatment should be provided early in pregnancy, preferably during the first trimester but definitely before the third trimester.
– Treat as soon as the test for syphilis is found to be reactive (ideally at the first visit).
– All women who test reactive for syphilis with any test should be treated to avoid any case of congenital syphilis, although it may result in some over-treatment because of false-positive results. The risk of over-treatment does exist, but is outweighed by the benefits of preventing transmission to the infant (see Flowcharts 1 and 2).
– RPR/VDRL titre may be done to monitor the response to treatment, but this should not delay the start of treatment. Treatment can be provided at any titre of RPR/VDRL test and also when RPR titre is not available.

Partners of syphilis-reactive women should also be counselled and treated in order to prevent re-infection.

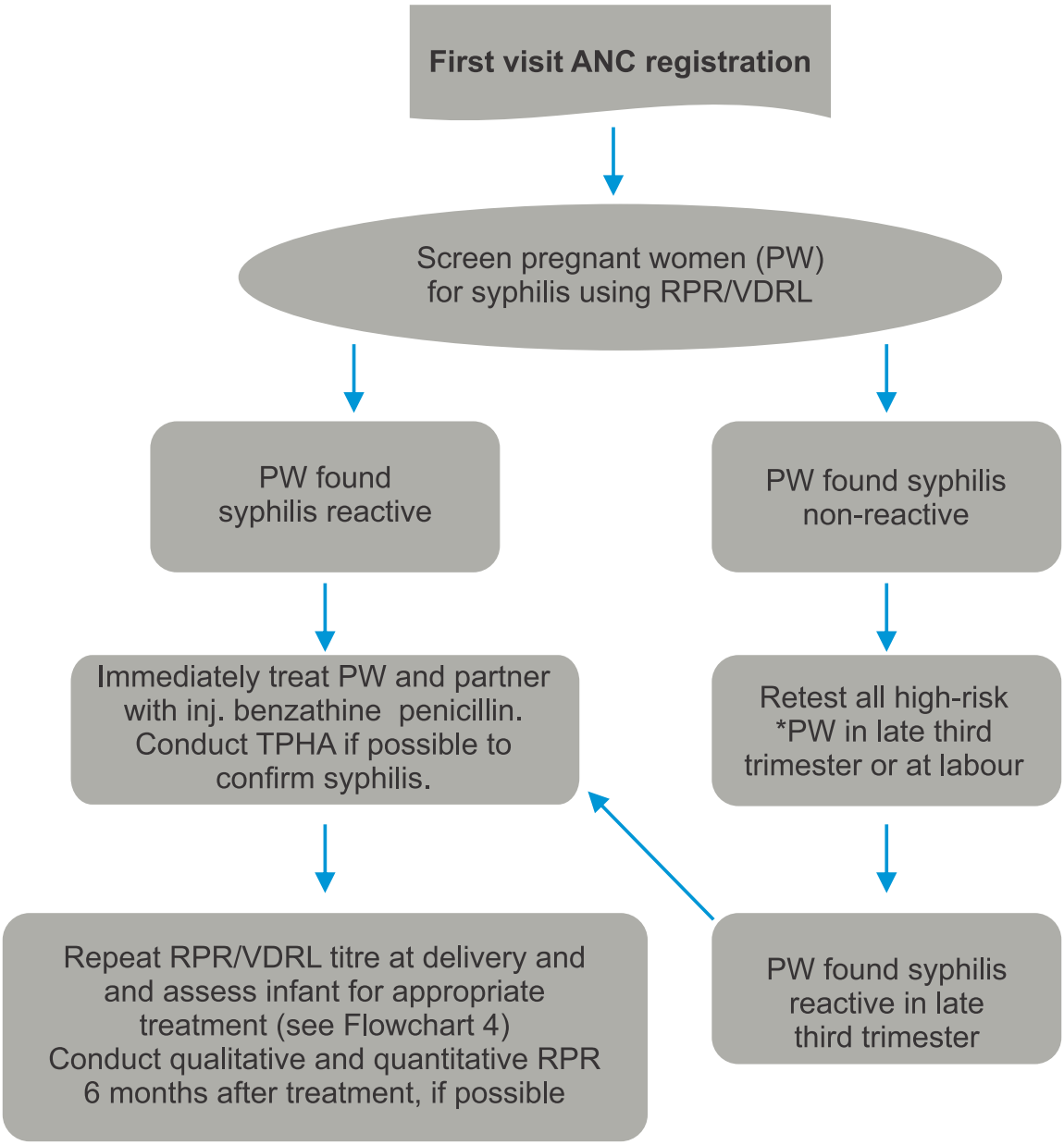
Fig 3.3 – Flowchart 1. Syphilis screening of pregnant women using point-of-care test and treatment of maternal syphilis at health-care service delivery points without laboratory



***Criteria for repeat test:**

i. Pregnant women considered to be at high risk for acquiring STI (those with current or past history of STI, women with more than one sexual partner, sex workers and injecting drug users)
ii. Pregnant women with history of repeated abortions, stillbirths, past history of delivery of premature baby and neonatal deaths
iii. Testing at the time of delivery will also be required to detect re-infection, particularly in women whose partners were not treated.

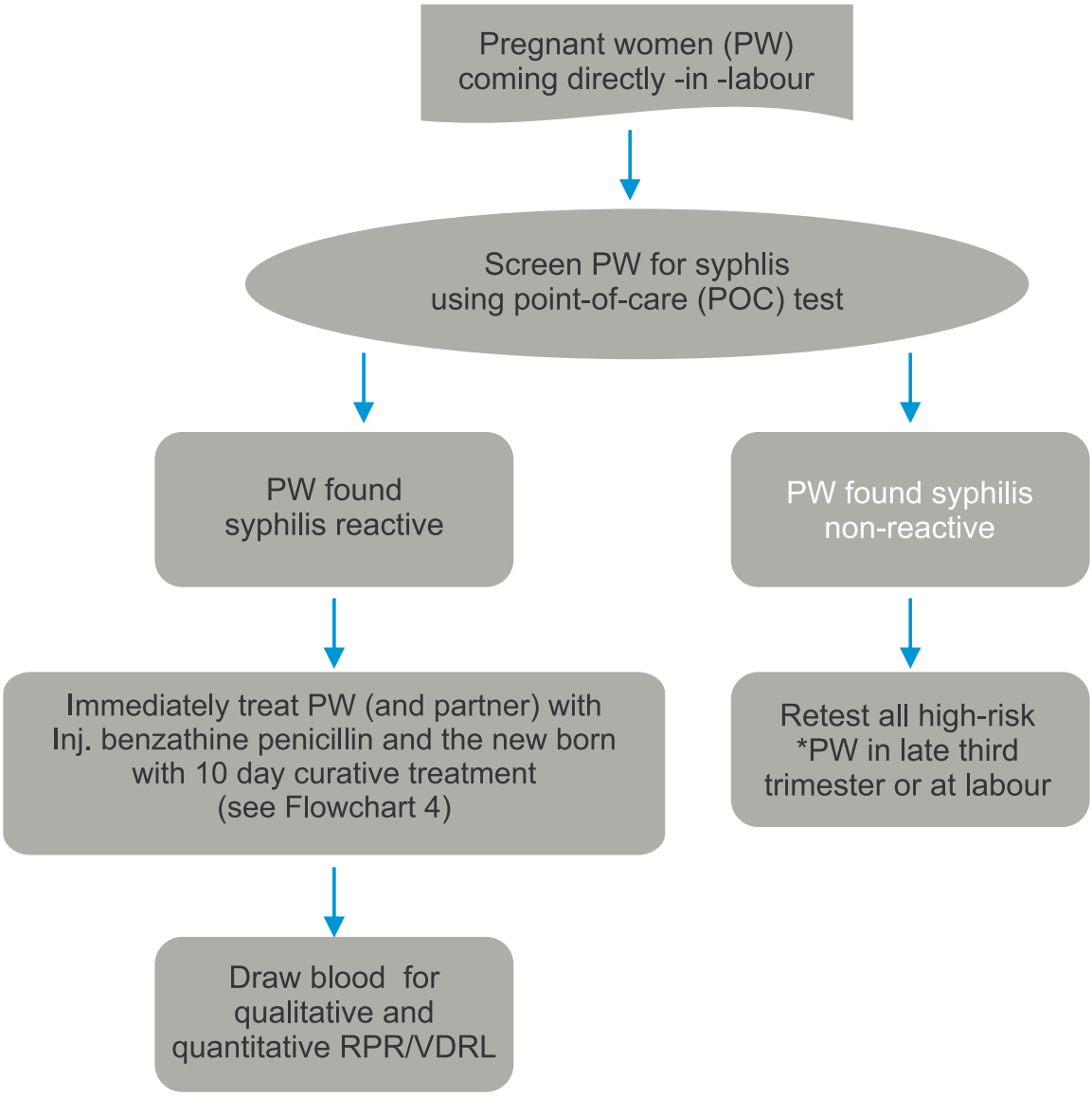
Fig. 3.4 – Flowchart 2. Syphilis screening of pregnant women and treatment of maternal syphilis at health-care service delivery points with laboratory support



*** Criteria for re-testing pregnant women in late pregnancy or delivery:**

i.Pregnant women considered to be at high risk for acquiring STI (those with current or past history of STI, women with more than one sexual partner, sex workers and injecting drug users)
ii. Pregnant women with history of repeated abortions, stillbirth, past history of delivery of premature baby, preterm baby and neonatal death.
iii.Testing at the time of delivery will also be required to detect re-infection, particularly in women whose partners were not treated.

Fig. 3.5 – Flowchart 3. Algorithm for syphilis screening of pregnant women coming directly- in-labour and treatment of maternal syphilis



* Criteria for re-testing pregnant women in late pregnancy or delivery:

i.Pregnant women considered to be at high risk for acquiring STI (those with current or past history of STI, women with more than one sexual partner, sex workers and injecting drug users)
ii. Pregnant women with history of repeated abortions, stillbirth, past history of delivery of premature baby, preterm baby and neonatal death.
iii.Testing at the time of delivery will also be required to detect re-infection, particularly in women whose partners were not treated.

3.4.2. Treatment protocol of maternal syphilis

Treatment providers should rule out history of severe allergy to inj. penicillin through oral history-taking before giving inj. penicillin. The emergency drugs for managing anaphylaxis should be kept ready prior to administrating penicillin (see anaphylaxis management in Annexure 4).

National STI guidelines[7] for the treatment of adult syphilis specify the following:

i. **In the early stage,** a single intramuscular injection of benzathine benzyl penicillin 2.4 million IU is sufficient.
ii. **In the late stage or if the duration is unknown,** three weekly intramuscular injections of 2.4 million IU benzathine benzyl penicillin are required.

Whatever the stage of infection, even a single dose of penicillin is generally sufficient to prevent infection in the foetus. Adequate treatment with penicillin will end infectivity within 24–48 h

Alternative regimen for penicillin allergic pregnant patients

Regimen 1:

a. Early stage syphilis: Erythromycin, 500 mg orally, 4 times daily for 15 days
b. Late stage syphilis: Erythromycin, 500 mg orally, 4 times daily for 30 days

OR

Regimen 2: Azithromycin 2 gm orally as a single dose.

Note:

- For the treatment of syphilis during pregnancy, no proven alternates to penicillin exist.
- Penicillin is a safe drug. Evidence suggests that anaphylaxis is extremely rare8
- All infants of pregnant women treated with a non-penicillin regimen should be treated at birth as if the mother was inadequately treated.
- Alternatives to penicillin should be considered for pregnant women who have a history of severe penicillin allergy, e.g. anaphylaxis.
- Erythromycin estolate is contraindicated because of drug-related hepatotoxicity. Only erythromycin base or erythromycin ethyl succinate should be used.

Treatment using a non-penicillin regimen is considered inadequate for the prevention of mother-to-child transmission of syphilis. Benzathine penicillin injection(s) administered less than 4 weeks before delivery is also considered inadequate for prevention of CS.

3.4.3. Follow-up of pregnant women treated for syphilis

– All syphilis-reactive pregnant women should be followed-up by an integrated counselling and testing centre (ICTC) counsellor at the closest facility. The ICTC counsellor will ensure that the planned interventions are received. He will facilitate referral for delivery and subsequent follow-up.

- Following treatment, high-risk women (those with a current or past history of STI, women with more than one sexual partner, sex workers and injecting drug users) should receive a qualitative and quantitative RPR/VDRL test again during the third trimester of pregnancy. Re-treatment should be undertaken if there is serological evidence of reinfection or relapse.
- Wherever feasible, syphilis-reactive pregnant women should be referred for delivery to a facility where a paediatrician is available (community health centre [CHC]/first referral unit [FRU] level) for drawing a sample of venous blood from the baby together with the mother's blood for quantitative and qualitative RPR or VDRL test.
- Syphilis-reactive pregnant women should also have a qualitative and quantitative RPR/VDRL test 6 months after their treatment to assess if they are cured.
- To ensure that results are comparable, follow-up tests should be performed by using the same RPR/VDRL test that was used initially.
- The RPR/VDRL titre is expected to decrease four-fold by six months. The rate of sero-reversion depends on the pretreatment titre and stage of disease.

The ICTC counsellor will liaise with auxiliary nurse midwives (ANMs) of the sub-centre (SC) and ensure counselling, testing and treatment of syphilis-reactive pregnant women and their partners. The counsellor will also ensure that the treatment provided is adequate treatment and that follow-up is done after treatment.

3.5 Management of infants born to syphilis-reactive mothers

All infants born to syphilis-reactive mothers should be examined for clinical evidence of congenital syphilis (see signs and symptoms of congenital syphilis at Section 3.2).

3.5.1 Confirmatory test for congenital syphilis

Wherever feasible, quantitative and qualitative RPR or VDRL test should be performed on both the mother and infant at birth. This is why syphilis-reactive pregnant women should be referred for delivery at a facility where a paediatrician is available (CHC/FRU level). At the time of birth, the paediatrician will collect 2 ml of venous blood from the newborn together with a sample from the mother for conducting a qualitative and quantitative RPR/VDRL test. This is the preferred specimen, since cord blood may give false positive results.

A RPR/VDRL titre, which is four times greater in an infant than that in the mother, suggests congenital syphilis.

3.5.2 Management of infants born to syphilis infected mothers (Flowchart 4 at Figure 3.6)

The availability of RPR/VDRL test should not delay the decision for treatment. All newborns born to syphilis-reactive pregnant women should receive either a prophylactic treatment (Regimen 1) or a curative treatment (Regimen 2).

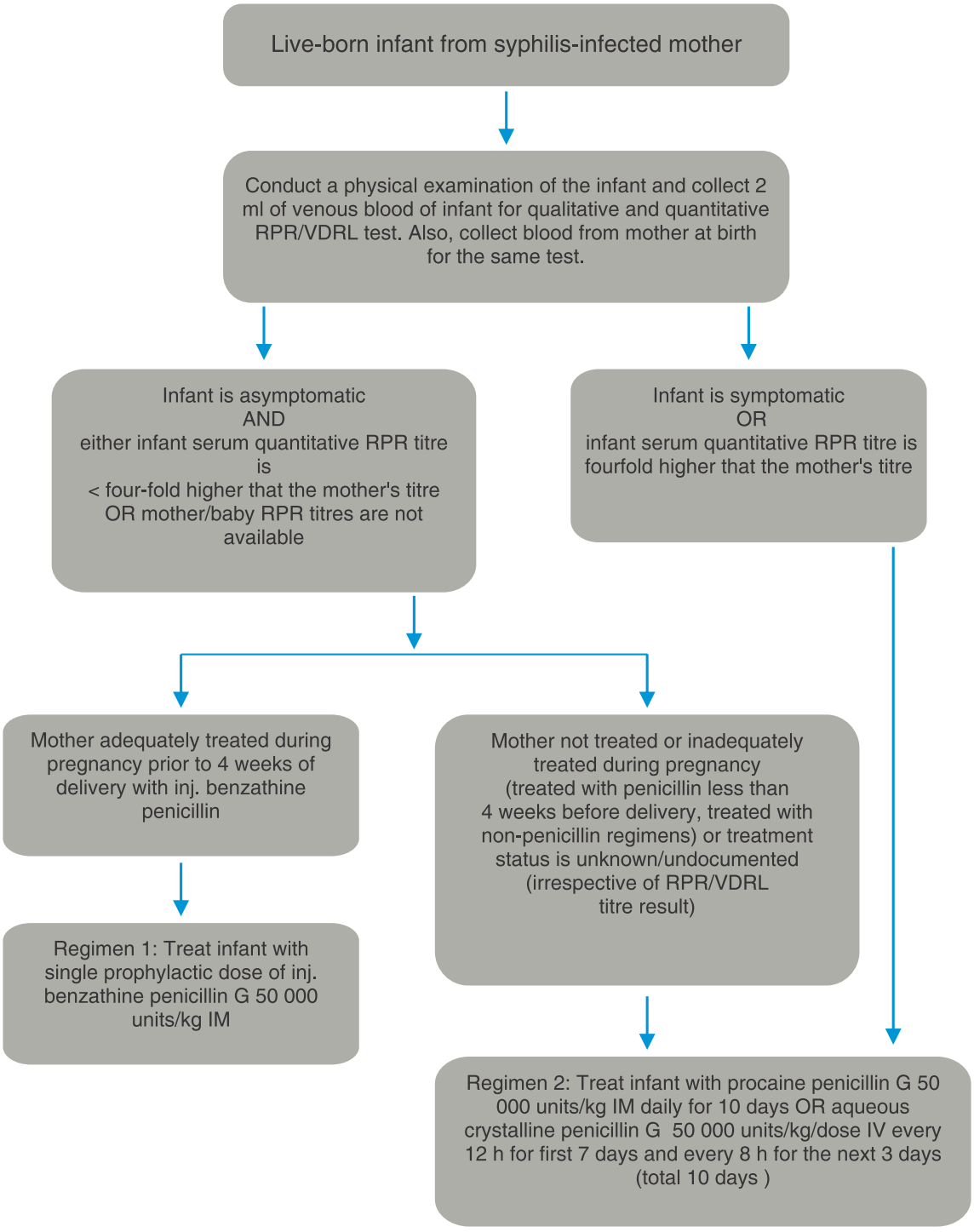
Regimen 1 (prophylactic treatment)[a]

All asymptomatic infants, who have no serological evidence of syphilis and are born to mothers who were adequately treated for maternal syphilis with inj. benzathine penicillin during the current pregnancy 4 weeks prior to delivery, should be treated with a single dose of prophylactic penicillin, i.e. benzathine penicillin G 50 000 units/kg given as a single intramuscular injection.[9]

Babies are never allergic to penicillin.

[a]The prophylactic dose of inj. benzathine penicillin G is recommended in the 2003 WHO STI Treatment Guidelines.8 The reasons for this are that (a) the mother's treatment could have failed, or (b) she may have been re-infected.

Fig. 3.6 – Flow chart 4. Management of infant born to syphilis-positive mother



Regimen 2 (curative treatment)

Regimen 2 should be given to:

– All symptomatic infants (see signs and symptoms of congenital syphilis at Section 3.2)
– All asymptomatic newborns fulfilling anyone of the following criteria:
  - Born to mothers who were treated with penicillin less than 4 weeks before delivery;
  - Born to mothers who were treated with non-penicillin regimens (erythromycin or azithromycin) during pregnancy;
  - Born to mothers whose treatment status is unknown or undocumented.
– All infants/children fulfilling anyone of the following criteria:
  - Whose RPR/VDRL titre is four-fold higher than that of the mother at delivery;
  - Born to mothers with clinical evidence of syphilis;
  - Born to mothers who did not complete the recommended course of inj. penicillin during pregnancy;
  - Born to mothers whose RPR/VDRL titre had not dropped fourfold;
  - Having a rising RPR/VDRL titre.

Regimen 2 can be provided either in intramuscular or intravenous route.

Intravenous treatment regimen
Aqueous crystalline penicillin G 100 000–150 000 million units/kg/day intravenously. It could be given as 50 000 units/kg/dose IV every 12 hours during the first 7 days of life and thereafter every 8 hours for 3 days to complete a total of 10 days of treatment.

OR

Intramuscular treatment regimen
Procaine penicillin 50 000 units/kg body weight intramuscularly daily for 10 days.

Hospitalisation of the infant should be considered in order to ensure the full course of treatment. If more than one day of treatment is missed, the entire course of treatment should be restarted.

Infant follow-up
With appropriate treatment of symptomatic infants, clinical features such as hepatosplenomegaly, jaundice and bone changes on X-ray usually resolve within three months of birth.

As far as possible, infants should be followed up at 6 and 24 months by a paediatrician at an FRU/CHC. During each follow-up visit, a clinical examination and qualitative and quantitative RPR/VDRL test should be performed. To ensure that results are comparable, follow-up tests should be performed using the same RPR/VDRL test that was used initially. The follow-up tests should preferably be conducted in the same laboratory as earlier. At 24 months, a bone X-ray should be performed.

The ICTC counsellor who is already in charge of counselling and tracking events of syphilis-reactive pregnant women should also ensure that the babies receive their follow-up visits at 6 months and 24 months.

3.6 Congenital syphilis case definition

Suspected cases of congenital syphilis infants born to syphilis-reactive mothers who have not been adequately treated have to be considered as suspected cases of congenital syphilis.

It is very difficult to provide microbiological evidence of congenital syphilis through identification of T. pallidum by dark field microscopy or direct fluorescent antibody detection of T. pallidum (DFA-TP) specific IGM in the umbilical cord, placenta, nasal discharge or skin lesion material. There is also no commercial immuoglobulin (IgM) test available in India.

It is therefore recommended that a qualitative and quantitative RPR/VDRL test be performed at the time of birth on the venous blood of the newborn, born to a syphilis-reactive mother, together with the same test on the mother.

The box below provides the case definitions for suspected and confirmed congenital syphilis. These definitions are for reporting purposes only and not for case management.

A team comprising of a paediatrician, obstetrician, ICTC counsellor and a laboratory technician will collect and compile all information available to define and report CS cases.

Congenital syphilis 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 four-fold higher that the mother's titre.

OR

A child within 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 a non-penicillin regimen.
***At least 2 of the following: swelling of joints, snuffles, bullous skin lesions, hepatosplenomegaly, jaundice, anemia, radiological changes in the long bones.

Information, education and communication for E-PTCT

4.1 IEC messages for E-PTCT of syphilis

IEC messages for E-PTCT of syphilis should include the following:

- Details of transmission of maternal syphilis to the foetus, treatment of syphilis and prevention methods;
- Referral of syphilis-reactive pregnant women to a higher level health-care facilities for further management as early as possible;
- Institutional delivery of syphilis-reactive pregnant women at PHC and higher facilities;
- Regular follow-up as per schedule.

Health workers need orientation towards E-PTCT of syphilis. This will enable them to pass on information about the disease and educate pregnant women to screen for syphilis and understand how to prevent transmission of infection to their foetus. A toolkit should be developed for healthcare workers, covering these aspects by the State AIDS control society (SACS) in collaboration with State Reproductive and Child Health (RCH) Officer and State Health Mission.

4.2 Target groups for IEC

Health workers: There is a need to incorporate messages related to E-PTCT of syphilis in all antenatal care services together with PPTCT of HIV. Health-care workers should be encouraged to promote early ANC registration and syphilis testing in the first trimester. IEC materials emphasizing this should be prepared to impart education to health-care workers.

Community health workers (Accredited Social Health Activists [ASHAs]): IEC materials should include basic information about syphilis, early ANC registration and syphilis testing in the first trimester. ASHAs should be involved in creating awareness regarding syphilis screening in ANCs in the community at the village level.

Treating physician: IEC materials should include the diagnosis, treatment and management of maternal and congenital syphilis.

Pregnant women: Messages should include early ANC registration and testing for syphilis during the first trimester, and institutional delivery.

4.3 IEC Materials to be developed for E-PTCT of Syphilis

- TV spots
- Print advertisements
- Leaflets
- Hoardings
- Flipcharts
- Brochures
- Posters.

4.4 Demand generation for E-PTCT of syphilis

- E-PTCT of syphilis services delivered in ANC clinics should be widely publicised so as to generate adequate demand. This should be jointly undertaken by SACS and RCH division of the state health missions and non-governmental organizations (NGOs) working for maternal and child health.

- Publicise E-PTCT services through public service announcements/advertisement spots on radio and TV.
- Develop products specifically designed for E-PTCT of syphilis, including pamphlets, videos, hoardings and brochures.
- Conduct advocacy workshops for journalists on syphilis, and particularly its adverse outcomes on pregnancy.
- Conduct interviews with administrators, those in charge of ANC clinics or counsellors on radio/TV/print media to explain the strategy towards E-PTCT of syphilis and the importance of testing and treating.
- Remove fears and misconceptions related to syphilis in the public mind.
- Promote POC testing for syphilis, immediate availability of test results as well as confidentiality of results.

4.5 Large and small IEC interventions to promote E-PTCT services

- Within a facility that provides E-PTCT of syphilis services, sign-boards and posters should be placed at prominent locations to publicise such services.
- Signages must be put up at all facilities to help clients easily locate laboratory facilities for syphilis testing and counselling facilities.
- ANC clinics should display posters in bold letters in the local language giving information on the importance of screening for syphilis and treatment during pregnancy for E-PTCT of syphilis.
- Ensure that all IEC materials such as posters, etc. are displayed prominently in the ANC clinic.
- Ensure that communication aids in the form of flip charts, condom demonstration models, fliers, etc. are available in the DSRCs and ANC clinics for providing counselling.

Supply-chain management system for tests and drugs

5.1 For designated STI/RTI clinics (DSRCs)

NACO will procure and distribute RPR test kits for DSRCs through state AIDS control societies (SACS). Joint Director/Deputy Director STI should closely monitor the supply of RPR test kits to all district DSRCs under the STI/RTI prevention and control programme. Estimates for RPR test kits should be based on estimated number of pregnant women accessing the facility.

5.2 For NHM health facilities (primary health centre [PHC]/CHC/block PHC/sub-divisional hospital/urban health centre [UHC])

States should procure the RPR test kits and POC test for syphilis screening through NHM funds. The expected budget should be proposed in the Programme Implementation Plan of the NHM. This will be closely coordinated and monitored by the state and district project management units under the NHM. Items directly supplied to district level consignees under Janani Shishu Suraksha Karyakram (JSSK) programme are to be further distributed to sub-divisional hospitals, FRUs, CHCs, block PHCs and PHCs.

State and district Reproductive and Child Health Phase II (RCH II) officers, procurement officers and NHM programme managers in the state project management units (SPMUs) and district project management units (DPMUs) should closely monitor the supply chain management with all health-care facilities. They need to streamline the process and develop a warning system through regular inspections to facilitate avoidance of excess of stocks or stock outs of RPR test kits and POC test kits for syphilis. They have also to ensure the availability of inj. benzathine penicillin and erythromycin or azithromycin in all the facilities.

States will plan for adequate supply of POC test kits and RPR test kits based on the estimated number of pregnancies.

5.3 Guidelines for state programme managers

– State programme managers should ensure inclusion of inj. benzathine penicillin and inj. erythromycin or inj. azithromycin as drugs in the essential drug list. State programme managers under the NHM should ensure the availability of drugs at all the sub-district NHM-supported health facilities (sub-divisional hospitals, FRUs, CHCs and PHCs in the district).

- Three months' supply of syphilis test kits should be available at all PHCs/CHCs and other health-care facilities.
- The three month supply should be calculated for drugs and kits as per the consumption pattern of the PHCs/CHCs and other health-care facilities.
- The Health Management Information System (HMIS)/Strategic Information Management System (SIMS) STI modules (for DSRCs) data and field visit observations should be used to monitor the requirement, distribution and consumption of drugs and syphilis test kits.
  - There should not be a mismatch between the number of syphilis-reactive reported cases in HMIS and SIMS STI modules (for DSRCs).
  - The requirements of syphilis test kits varies with the patient load and level of facility, e.g. sub-divisional hospital/CHC/PHC. This aspect should be considered by the RCH officer at district level before distributing the test kits. The SCs should be supplied only with POC test kits. Facilities higher than the PHCs should receive RPR/VDRL test kits. The number of RPR/VDRL test kits should be calculated based on the number of syphilis-reactive pregnant women.
- Supplies should be distributed against signed indents from the facilities. All records of receipt, indent, issue, stock status, consumption and balance should be maintained as per the standard formats for the same at the district stores and all health-care facilities. The manufacturing and expiry date details and batch number of kits should be recorded. The expiry date should be recorded in red colour. District RCH II officers should oversee the same through regular inspections.
- First expiry first out (FEFO) principle should be followed in distributing and utilising the supplies. Expiry date should be monitored closely and State RCH II officers and procurement officers should be kept informed of any stock due to expire in the next six months.
- All supplies should be stored in accordance with the manufacturer's instructions. The stock of drugs and test kits remaining after distribution should be stored ensuring prevention of loss or pilferage at district stores. District stores should ensure at least 3 months of buffer stock in their stores based on the average quarterly consumption at all the facilities.
- The District RCH focal person should maintain a register for drugs and syphilis test kits recording the details of indent, receipt, release, consumption and balance at the end of month at each facility.
- The district RCH officer should furnish the details of availability of syphilis kits to the state RCH officer/procurement officer on the seventh of every month as per the given format.
- The State RCH II officer/procurement officer should be informed of excess stock, impending stock-out or stock due for expiry well in advance so as to plan for re-distribution from one district to another as per usage and need pattern. The remaining stock of drugs and test kits, after distribution, should be stored at the state level to ensure prevention of loss or pilferage.

The medical officers (MOs) in charge of STI/RTI clinics (facilities with DSRC)/ANC clinics are primarily responsible for proper utilisation of syphilis test kits and ensuring that there is no misuse or pilferage. The STI/RTI focal person at SACS and supervisory teams will

closely monitor the utilisation of kits and ensure prevention of stock-outs and wastage. The STI/RTI clinic counsellor (at facilities with DSRC) and ANMs/staff nurses (at facilities with no DSRC) will keep a close watch on the kit utilisation and inform the STI/RTI focal person of SACS in a timely manner to prevent stock-outs. STI/RTI mentors would also visit the ICTCs during their supportive supervisory visits.

Training on E- PTCT of syphilis

The objectives of training are to:

- Introduce strategic and operational guidelines of E-PTCT of syphilis so as to enhance the capacity of state and district officials to train health workers in its implementation;
- Create awareness among community health workers regarding E-PTCT of syphilis;
- Build capacity of ANMs at SCs to screen for syphilis using POC test kits;
- Build capacity of health staff to adequately treat syphilis-reactive pregnant women and infants born to syphilis-reactive mothers, and to investigate these infants to detect congenital syphilis in them.

The state and the district officials involved in the STI/RTI programme and PPTCT of HIV are responsible for training of health-care workers. The state nodal officers for STI/RTI and Basic Service Division from the SACS and State Health Mission should undertake the training programme effectively in their respective states. The training should be incorporated with HIV PPTCT training.

As state nodal officers, they have to ensure that the health workers do not consider the above activities as additional workload but an integral part of their routine maternal and child health activities. It is important to have role clarity. Training should be planned for the entire state and developed using a case-based approach for health-care workers. State and district nodal officers should use this strategic document for the orientation of their health workers. States should use the technical contents of these guidelines for treatment and follow-up schedules.

States will be able to build the capacity of the grassroots level health workers such as ASHAs and ANMs on the E-PTCT of syphilis initiative. To achieve this, states should develop appropriate training manuals and IEC materials, which can be used by the health workers and be displayed at the various health-care facilities.

Quality assurance of testing

Laboratory technicians should ensure the highest standards of quality while processing samples for syphilis testing. They will be held personally accountable for any substandard testing services. The technical specifications of RPR, TPHA and POC tests are given in Annexures 1, 2, and 3, respectively. All facilities providing syphilis testing of ANC attendees, including those providing POC tests, should participate in syphilis serology external quality assurance scheme (EQAS) or proficiency testing (PT) programmes.

EQAS will be supported by a three-tier pyramidal structure, with an apex laboratory at the national level, regional STI training, research and reference laboratories (RSTRRL) at the regional level through the state reference centres (SRCs) down to the DSRC/PHC/CHC/SDH/DH.

7.1 Proficiency testing

Proficiency of testing services will be evaluated by a designated reference laboratory, i.e. the proficiency testing of the DSRC/PHC/CHC/SDH/DH will be conducted by the SRCs and in turn the proficiency testing of the SRCs will be conducted by the RSTRRL. Similarly, the proficiency testing of the RSTRRL will be undertaken by the apex laboratory which in turn participates in an international EQAS. This will be carried out using a proficiency panel of five “coded” samples once a year. A proficiency panel will comprise of a set of predefined and validated specimens, which will include reactive and nonreactive serum samples in non treponemal and treponemal tests. The PT samples will be examined using the same procedures as those used for patient samples and by the same personnel who routinely examine the patient samples. Facilities conducting POC testing will participate in this exercise.

In this programme, each of the RSTRRLs will prepare a panel of 5 specimens and will send the proficiency panel to the apex laboratory for validation before distribution to the linked SRCs. The designated RSTRRL will distribute the panel to the linked SRCs for their proficiency testing and a bulk panel will be given to the SRCs for aliquoting and distributing to their linked laboratories (DSRC/PHC/CHC/SDH/DH). The participating laboratories/services will test the panel along with the routine test samples and communicate the results in the prescribed format to the reference laboratory (DSRC/PHC/CHC/SDH/DH to SRC, SRC to RSTRRL and RSTRRL to apex laboratory) for analysis within the specified time, i.e. 7 working days.

The reference laboratory will provide a feedback to the participating laboratories/services after analysing their results and will assist in trouble-shooting and corrective action in case of discordance. The PT report will be reviewed by the laboratory in charge within 7 days. The participating laboratory/service will take corrective action wherever needed, depending on the feedback of results. The limitations of PT are that they are spot checks in time. They represent the upper performance level and usually involve a small number of samples. Moreover, there are a limited number of assessments per year. Therefore, the test results frequently do not represent the daily, routine test performance since great care is taken in testing PT samples.

7.2 Re-checking of samples

The DSRC/PHC/CHC/SDH/DH will send 20% of syphilis serology positive sera and 5% negative sera (0.5 ml) tested in the first week of each quarter of the year (January, April, July, and October) to the designated SRC by the tenth of the respective month. The samples will be selected systematically, e.g. for 20% positive samples, select the fifth, tenth, fifteenth, twentieth, etc. and the last sample. The samples should be stored at 2–8 0C till they are transported. Serum samples will be packaged and transported maintaining cold-chain conditions (2–8 0C) along with the requisition form. An aliquot of the samples sent for rechecking should be kept back in the freezer compartment of the refrigerator till the results are obtained. A record of the samples sent will be maintained by the concerned DSRC/PHC/CHC/SDH/DH.

The SRC will test these serum samples as per the algorithm followed by the DSRC/PHC/CHC/SDH/DH. The results from re-checking will be conveyed to the respective DSRC/PHC/CHC/SDH/DH within 7 days of receiving the samples. If there are any discordant results, the SRC will advise the participating laboratory and help the DSRC/PHC/CHC/SDH/DH so that appropriate corrective action can be taken and documented. If the discordance persists, the SRC will send the sample to the designated RSTRRL for confirmation. The SRC will prepare a consolidated report for sending to the RSTRRL.

High-quality syphilis testing services can be maintained by:

- use of test kits that have not expired
- not mixing components from different kits
- adherence to standard operating procedures (SOPs)
- correct interpretation of results
- availability of laboratory internal quality control
- adherence to recommended temperatures
- proper dropper use and proper pipette tips
- regular calibration, monitoring and maintenance of equipment
- proper documentation.

Roles and responsibilities

8.1 Steering committee

Members will comprise of Deputy Director General STI as Chairperson; Assistant Director General STI, senior officers from STI Division NACO, Deputy Commissioners Maternal Health, MoHFW, one representative from Basic Services Division (BSD) Division of NACO, development partners WHO and UNICEF, and one member each from Technical Resource Group of STI and Apex Regional STI Centre.

The Steering Committee will meet once a quarter.
Roles and responsibilities of the Steering Committee

– To review the progress of the E-PTCT of syphilis activities, take policy decisions and expedite the process for implementing the national strategy. Review the action-taken report of the previous steering committee.
– The Chair as well as the members will ensure that the officers responsible for the different activities own the programme and ensure functional convergence between National AIDS Control Programme (NACP) and NHM. They will ensure that systems are in place with regard to the filling up of vacancies, building capacities of health staff, equipment procurement, availability of syphilis test kits including POC tests, drugs at all levels of health-care delivery services and that the monitoring and evaluation (M&E) system is functioning.

8.2 Project management cells in states

The project management cells in the states will include the following members:

i) State STI focal person from SACS
ii) State BSD Officer and M&E officer from SACS
iii) State Reproductive and Child Health Officer (RCHO)
iv) Director, State Institute of Health and Family Welfare (SIHFW)
v) Deputy Director, Maternal Health, NHM.

Roles and responsibilities of the project management cell at state HQ

- Advocacy with top-level officers to ensure commitment;
- Administrative functions;
- Vacancies to be filled-up; ensure availability of equipment, test kits, consumables and reagents round the year at all health-care facilities;
- Budget allocation and submission of Statement of Expenditures (SoEs): Ensure that both NACP and NHM budgets are effectively committed with no duplication of resources for the same activity;

- Capacity building: Address the capacity-building needs of different categories of staff. Conduct sensitisation, induction and refresher training. Training criteria and training programmes of State Institute of Health and Family Welfare, Health and Family Welfare Training Centre (HFWTC), DTCs, ANMs and ASHAs to be undertaken under one umbrella and ensuring funds transfer;
- Developing comprehensive IEC development plans jointly by MCH and NACP for disseminating information on new programmes;
- Monitoring, and supervisory activities: monthly review of the programme for E-PTCT of syphilis and feedback to district RCHO.

Roles and responsibilities of different categories of staff from NACP and MCH involved in E-PTCT of syphilis

ANM of the SC

- Testing and referral for treatment:
  - Conduct POC testing for syphilis for all ANC attendees registered with her, enter the numbers tested in the register and report them to the concerned MO and ICTC counsellor;
  - Ensure that all ANC attendees screened and found reactive for syphilis are accompanied to the MO PHC for treatment;
  - Ensure that the partner/s of the syphilis-reactive pregnant woman is/are tested and treated immediately whenever possible.

- Follow-up of syphilis-reactive women:
  - Follow-up women who are reactive for syphilis;
  - Ensure routine ANC check-ups and report any abortion, premature labour, low birth weight, stillbirth (adverse outcomes of pregnancy) to the MO PHC;
  - Undertake birth-planning with the syphilis reactive ANC attendee for motivating her to have her delivery in a FRU/CHC or a higher level institution. This is to ensure the presence of a paediatrician at birth to draw a sample of venous blood, to know and compare RPR titre] with that of the mother, especially in women who did not receive adequate treatment for syphilis .

- Follow-up of babies born to syphilis-reactive mothers:
  - Refer syphilis-reactive mothers and their babies to CHCs to ensure follow-up of babies at 6 months and 24 months.

MO at the PHC

Testing and treatment:

- Ensure that the POC test kits are available at SCs and RPR/VDRL test kits at PHCs round the year, especially during the follow-up period of 3 months; indent for the same from the DSRC MOs from time to time;
- Ensure all cases tested and found reactive are treated immediately and reported in the records, registers and HMIS;
- Ensure that all women screened reactive for syphilis by ANMs using POC tests are confirmed at the PHCs/CHCs using RPR/VDRL test;
- Ensure that all spouses/partners of ANC attendees who are syphilis-reactive are tested; and if found reactive, adequately treated using inj. benzathine penicillin;

- Do birth-planning along with the syphilis-reactive pregnant women and ANMs/ASHAs and ensure that they have their delivery in an FRU/CHC or a higher level institution where a paediatrician is available, especially if they were not adequately treated;
- Ensure that all ANC attendees are followed up until delivery, and report any adverse outcome of pregnancy ;
- Ensure that all infants born to syphilis-reactive mothers undergo a physical examination by a paediatrician and either prophylactic or curative treatment is administered following the recommended algorithm, preferably at a CHC level Institution.

MO in charge of DSRC

DSRCs are mainly located in the district hospitals. MOs are responsible for follow-up.

- Test kits and drugs procurement and supply:
  - Ensure that POC and RPR/VDRL test kits are supplied to all the PHCs/SCs;
  - Ensure that inj. benzathine penicillin/inj. procaine penicillin G are procured and supplied;
  - Maintain the inventory and stock registers of drugs and test kits.

- Capacity building:
  - Build capacities of all new STI counsellors;
  - Sensitise the PHC MOs, ANMS/ASHAs on updates to the programme whenever new guidelines/updates are released.

STI counsellor of DSRC

- Counselling and lab referral for testing:
  - Responsible for counselling all ANC attendees and their spouses/partners coming to the STI clinic and referring them to the laboratory for screening/confirmation of syphilis.

- Follow-up of syphilis-reactive pregnant women:
  - Maintain the line-lists of all ANC attendees reactive for syphilis and ensure their effective follow-up and that of their babies.

ICTC counsellor (wherever STI counsellor of DSRC is unavailable)

- Counselling and laboratory referral for testing:
  - Responsible for counselling of all ANC attendees coming to the ICTCs and referring them to the laboratory for screening/confirmation of syphilis;

- Follow- up of syphilis-reactive pregnant women:
  - Maintain positive line-lists of all ANC attendees reactive for syphilis and ensure their and their babies effective follow-up .

District RCH officer

- Procurement and supply:
  - Ensure that there are no stock-outs of test kits, drugs and other consumables/equipment critical for the success of the programme.

- Training and supervision:
  - Conduct training needs assessment and ensure that all the staff are trained appropriately;
  - Will be the nodal officer of the district who will supervise the DSRCs;
  - Supervise the implementation of the programme and ensure that all gaps are filled up as soon as possible.

Monitoring and evaluation

Currently, the STI/RTI Division at NACO receives data from 1138 DSRCs which are located in district hospitals and tertiary-care centres. The programme for E-PTCT of syphilis should capture the data on the number of ANC attendees registered, screened for syphilis and treated at all levels of health-care facilities, as well as the number of cases of congenital syphilis detected. Therefore, the core indicators to monitor the programme will be integrated into the general health system recording and reporting systems.

9.1 M&E indicators

The list of indicators for the E-PTCT of syphilis programme is summarised in Table 9.1.
The five core indicators required by WHO for validation of E-PTCT of syphilis are:[10]

1. Percentage of pregnant women visiting ANC clinics at least once;
2. Percentage of ANC attendees tested for syphilis;
3. Percentage of ANC attendees tested for syphilis who are reactive for syphilis;
4. Percentage of syphilis-reactive ANC attendees who received adequate treatment;
5. Incidence of confirmed cases of congenital syphilis (as per national case-definition).

These core indicators will be reported through the HMIS.

Additional indicators listed in Table 9.1 will be collected through the HMIS or through line-lists of syphilis-reactive pregnant women and their babies.

Table 9.1. List of indicators for the E-PTCT of syphilis programme

S.No	Indicator	Numerator	Denominator	Method of measurement	Periodicity
1*	**Programme indicators**				
1.1	Percentage of pregnant women visiting ANC clinics at least once*	No. of pregnant women visiting ANC clinics 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	
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 congenital syphilis* cases	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				

9.2 M&E tools

The M&E tools at the field level for calculating the desired indicators are:

- RCH register
- HMIS – existing recording and reporting tools
- Congenital syphilis case investigation form – newly recommended.

9.2.1 HMIS

HMIS format

As of now, with the existing formats available in the HMIS, only the following indicators can be generated:

- percentage of pregnant women visiting ANC clinics at least once
- percentage of ANC attendees tested for syphilis in the first trimester
- stillbirths rate.

In order to generate the five core indicators and most additional indicators proposed in the E-PTCT of syphilis M&E framework (Table 9.1), some data fields will be added to the existing input screens in HMIS and the reporting tools will be used.

Reporting into HMIS at various levels

– At the SC, the ANM has to record information into the RCH register (number of ANC attendees tested and found reactive) and report the following details in the HMIS monthly reporting input screen:
  - Number of ANC attendees who were tested for syphilis using POC tests;
  - Of the above, numbers reactive to the POC tests.

– At the PHC level, it is the responsibility of the MO to ensure that accurate data regarding the following details are collected and entered in the HMIS monthly reporting form:
  - Number of female ANC attendees tested with RPR/VDRL test;
  - Number of female ANC attendees reactive with RPR/VDRL test;
  - Number of RPR/VDRL reactive ANC attendees adequately treated with inj. benzathine penicillin;
  - Number of suspected cases of congenital syphilis.

– At the CHC/SDH/DH level, all of whom use the common HMIS data entry forms, it is the responsibility of the MO in charge/hospital superintendent to ensure that accurate data regarding the following details are collected and entered in the HMIS monthly reporting form:
  - Number of female ANC attendees tested with VDRL/RPR test;
  - Number of female ANC attendees reactive with VDRL/RPR test
  - Number of RPR/VDRL reactive ANC attendees adequately treated with inj. benzathine penicillin;
  - Number of confirmed cases of congenital syphilis.

– At the district headquarters, it is the responsibility of the district RCH officer to ensure that accurate data is collected regarding the test kits and drugs and stock details are entered in the monthly HMIS reporting form.

– The district RCH officer will also be responsible for validating and consolidating the entire district data on E-PTCT of syphilis.

– At DSRCs, it is the responsibility of the officer in charge of DSRC and the STI counsellor to fill Section 5 of the monthly STI Strategic Information Management System (SIMS) format.

9.2.2 Syphilis-reactive mother and child electronic line-list

Line-list format (see Annexure 5)
The line-list has five sections: general and demography; antenatal care – syphilis testing, treatment, pregnancy outcomes; spouse details; infant details (treatment, testing); and follow-up.

The primary objective of this line list is to ensure the follow-up of pregnant women found reactive for syphilis, document that they have been adequately treated and that their babies have also received the appropriate intervention.

The secondary objective of the line-list is to provide information necessary to determine the suspected and confirmed CS cases and to provide data that needs to be entered into the HMIS.

Recording and reporting in the line-lists
The primary responsibility of entering data and updating details in the line-lists at each facility right from a PHC to a higher level health-care institution is that of the ANM, counsellor of ICTC or STI. The ANM will maintain and update the line-list at the facilities where there is no ICTC and STI counsellor. The ICTC counsellor will interact with the ANMs and the laboratory technicians regularly to find out the numbers of syphilis-reactive pregnant women, collect their details and enter them in the line-lists.

In addition to counselling syphilis-reactive pregnant women for treatment, they are also counselled for delivery through birth-planning and treatment of their infants. ICTC counsellors should also follow them up as is routinely done for HIV-positive pregnant women in the PPTCT programme. At the end of each month, the ICTC counsellor will submit the updated line-lists of syphilis-reactive pregnant women through the MO in charge of the STI clinic to the superintendent of the hospital, the taluk health officer and the RCHO and District AIDS Prevention & Control Unit Officers (DAPCUOs) programme officer HIV/AIDS. Similarly, the STI counsellors will maintain a line-list at all the DSRCs and coordinate with the ICTC counsellor for updating.

The superintendent/administrative MO of the hospital will collect the line-lists from the ANMs, ICTCs and STI counsellors on a monthly basis. He will compare and verify the details in the line-lists with that of the collected data to be reported through HMIS. Based on the line-list details, he will give appropriate instructions to the staff for birth-planning, adequate treatment and follow-up of the mothers and babies.

The district RCH officer will collect all the facilities' line-lists, compile the data and compare and verify the same with the data from the HMIS. Upon necessary verification of the line-lists, the same are to be sent to the district Chief MO and to the state RCH officer/project director RCH and the demographer or statistician of the state/Deputy Director, STI, SACS.

9.2.3 Congenital syphilis case investigation form (Annex 6)

CS investigation form

- This form will be used by the CS case investigation team to report information on each infant born to a syphilis-reactive mother, in order to determine if the infant is a suspected or confirmed case of CS or otherwise.
- The line-list information will be very useful in compiling the data required for the CS case investigation.
- A decision-making tree (Annex 7) has been designed to facilitate the detection of a confirmed CS case based on the national case definitions.

Reporting confirmed CS cases

The Chief MO/superintendent/administrative MO at all levels of health-care facilities is responsible for reporting the suspected and confirmed CS cases into the HMIS on a monthly basis based on the filled in investigation form of a CS case.

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Annexures

Annex 1: Technical specifications of rapid plasma reagin (RPR) test kit

1. The indigenous rapid plasma reagin (RPR) test kits should have been manufactured under manufacturing license issued by the state licensing authority under the Drugs and Cosmetics Act, 1940 (as amended). The imported kits should have been imported under import license issued by the DCG(I) under the Drugs and Cosmetics Act.

2. The assay should allow for qualitative and semi-quantitative determination of reagin antibodies in the serum of plasma for sero-diagnosis of syphilis based on flocculation principle using non-treponemal antigens.

3. The assay should be suitable to perform with either serum or plasma.

4. The assay should have sensitivity of 80% or more in primary syphilis and a specificity of 90% or more.

5. The assay should be calibrated to WHO reference serum and the same should be supported by statements in the kit insert and a certificate from the manufacturer.

6. The test should be able to yield results within 20 minutes.

7. The pack size of the RPR test kit should be less than or equal to 50 tests per kit.

8. The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls).

9. The kit should have all essential accessories required for the test such as cards, droppers, applicator, etc. in adequate quantities for the number of tests to be performed.

10. The kit should have more than 60% residual shelf-life or 12 months (whichever is more) at the time of dispatch to the consignee.

11. The kit should have a storage temperature of 2^{0}C to 8^{0}C and the supplier/local agent should have the facility to store kits at 2^{0}C to 8 C.

12. Cumulative time temperature indicator should be part of the kit and the indicator technology used should be pre-qualified by WHO.

13. Literature detailing the components, methodologies, validity criteria, performance characteristics, storage conditions and manufacturing and expiry dates should be provided with each kit.

Annex 2: Technical specifications of Treponema pallidum haemagglutination assay (TPHA), Treponemal specific diagnostic test for syphilis

1.	The assay should have avian erythrocytes coated with synthetic or recombinant type of Treponema pallidum antigens.
2.	The assay should be based upon the principle of passive haemagglutination method.
3.	The assay should be able to perform qualitative and quantitative determination of anti-treponemal antibody in human serum, plasma and CSF for serodiagnosis of syphilis.
4.	The assay should be able to detect treponemal antibody in all stages of infection.
5.	The assay should have U-well micro titration plates, unsensitised erythrocytes, diluent, reactive and non-reactive control sera with each kit in adequate volume.
6.	The kit should have a minimum shelf life of 60% of residual life or a shelf life of 12 months at the time of dispatch to the consignee, whichever is more.
7.	Adequate literature detailing the principle, components, methodologies, validity criteria, interpretation of results, bio-safety, performance characteristics, storage conditions, limitation of assay, manufacturing and expiry dates should be provided with each kit.
8.	The imported kit should have got the approval of the statutory authority in its country of origin. The imported kits should have been registered and licensed in India by the Central Drugs Standard Control Organization (CDSCO).
9.	In case of indigenous manufacturers, they should have a valid license issued by the competent authority defined under Drugs and Cosmetics Act, 1940 after appropriate evaluation by the centres approved by the CDSCO.
10.	The assay should have sensitivity of 98.5% or more and specificity of 99% or more.
11.	The pack size of test kits should not be more than 100 tests per kit.
12.	The manufacturer/authorised agent should ensure maintenance of cold-chain during storage and transport of kits at 2^0C to 8^0C.
13.	Regulatory requirements: ISO 13485:2003 certified; registered for in vitro diagnostic use.

Specific requirements:
1. The supplier should supply 200 tests x 2 sets free of cost from each batch for random evaluation at the identified laboratories for pre-dispatch lot verification. Protocol of each batch is to be attached.
2. A "cold-chain indicator" is to be supplied with the kits with the following specification: • A cumulative time/temperature indicator to indicate the exposure to high temperatures above 8 C; • Should be mounted on a card with clear instructions for interpretation; • The card should be self-adhesive and be placed on each kit box to monitor heat exposure during transit and storage of the kit till its expiry. • The cumulative time-temperature indicator technology used should be qualified by the U.S. Food and Drug Administration (USFDA) and/or prequalified by WHO. • The indicator should change colour uniformly, irreversibly and the rate of reaction should be predictable by appropriate kinetic parameters. • The colour change should have a well-defined start point and end point that can be correlated to the heat stability of the kit.

Annex 3: Technical specifications of Treponemal specific rapid (point-of-care) diagnostic test for syphilis

1.	The assay should have solid phase coated with synthetic or recombinant type of Treponema pallidum antigens.
2.	The assay may be based on any of the rapid test principles - immune concentration/dot blot immunoassay (vertical flow), dip stick or comb assay.
3.	The assay should quantitatively detect total anti-treponemal antibody (immunoglobulin G [Ig G] and immunoglobulin M [Ig M]) in whole blood, serum or plasma for serodiagnosis of syphilis in all stages of infection.
4.	The assay should have an inbuilt positive and negative control for testing validity of the test kits.
5.	The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10 % of pack size).
6.	The kit should have a minimum shelf- life of 60 % of residual life or a shelf -life of 12 months at the time of dispatch to the consignee, whichever is more.
7.	Adequate literature detailing the principle's components, methodologies, validity criteria, bio-safety, performance characteristics, storage conditions, limitations of assay, manufacturing and expiry dates and methods of disposal should be provided with each kit.
8.	The imported rapid kit should have gotten the approval of the statutory authority in its country of origin. The imported kits should have been registered and licensed in India by CDSCO.
9.	In case of indigenous manufacturers, they should have a valid license issued by the competent authority defined under Drugs and Cosmetics Act, 1940, after appropriate evaluation by the centres approved by the CDSCO.
10.	The assay should have sensitivity of 90% or more and specificity of 95% or more and the same should be supported by statements in the kit insert and a certificate from National Institute of Biologicals.
11.	The assay should be calibrated to WHO reference serum and the same should be supported by statements in the kit insert and certificate from the manufacturer.
12.	The manufacturer should ensure that: • The test kit is packed such that there is a provision to conduct a single test at a time. " The pack size of test kits is in 50 (for peripheral healthcare institutions) and 100 tests per kit (for secondary and tertiary health care institution) but not more than 100 tests per kit.
13.	The manufacturer/authorised agent should ensure maintenance of cold-chain during storage and transportation of kits at temperatures of 2^{0}C to 8^{0}C.
14.	The total procedure time should not be more than 30 minutes.

Specific requirements
1. The supplier should supply adequate kits free of cost from each batch for random evaluation at the National Institute of Biologicals, NOIDA for pre-dispatch lot verification. Protocol of each batch is to be attached.
2. A “cold- chain indicator” is to be supplied with the kits with the following specification: • A cumulative time/temperature indicator to indicate the exposure to high temperature above 8^{0}C. • Should be mounted on a card with clear instructions of interpretation. • The card should be self-adhesive and be placed on each kit box to monitor heat exposure during transit and storage of the kits till its expiry. • The cumulative time-temperature indicator technology used should be qualified by FDA and/or prequalified by WHO. • The indicator should change colour uniformly, irreversibly and the rate of reaction should be predictable by appropriate kinetic parameters. • The colour change should have a well-defined start point and end point that can be correlated to the heat stability of the kit.

Annex 4: Anaphylaxis management

Before administrating penicillin drugs or injections, ask the patient about previous allergies to penicillin.

– Signs of possible anaphylaxis
- Shock
- Difficulty in breathing
- Itchy rash or hives.

– Management of anaphylaxis
- Call for help, preferably a doctor
- Check
  - o Airway
  - o Breathing – give mouth-to-mouth respiration
  - o Circulation

Perform cardio-pulmonary resuscitation, if necessary.

- If anaphylaxis, give adrenaline intramuscularly:
  - o Dosage: adult 0.5 ml (if elderly, 0 3 ml), repeat every 5 to 10 minutes until there is adequate response
  - o Check blood pressure and pulse at 5 to 10 minute intervals.
- Give hydrocortisone IM. Dosage: adult 250 mg
- Give chlorpheniramine 10–20 mg or diphenhydramine 50–100 mg IM
- Transfer patient to hospital
  - o Repeat adrenaline if necessary. Take extra doses with you
  - o Record all details of treatment. Give copy to the hospital with patient
  - o Stay with the patient until another doctor takes over the care in person.

Annex 5: Syphilis-reactive mother and child electronic line-list

General and demography								
S.No. 1.	**Date (dd/mm/yy) 2**	**PID/Reg number 3**	**AADHAR Card No. 4**	**Name 5**	**Age 6**	**Current address 7**	**Contact number 8**	**Name of husband/father 9**

Antenatal care, syphilis testing, treatment and pregnancy outcome										
LMP 10	**EDD 11**	**Date of antenatal registration 12**	**Bad Obstetric history 13.** Select one – 1.Stillbirth 2. IUD 3. Miscarriage	**Date of syphilis test 14.**	**Syphilis Test type 15.** Select one – 1. POC 2.RPR 3.VDRL 4.TPHA	**Gestational age (in weeks) during diagnosis 16.**	**History of allergy to penicillin 17.** Select one – 1. Yes 2. No 3.Unknown	**Syphilis treatment 18.** Select one – 1. Single dose inj. benzathine penicillin 2. Three doses of inj. benzathine penicillin 3. Tab. Erythromycin for 15 days 4.Tab. Erythromycin for 30 days 5. Tab. Azithromycin 2mg single dose	**Whether adequately treated 19.** Select one – 1. Yes 2. No	**Date of treatment 20.**

Antenatal care, syphilis testing, treatment and pregnancy outcome		
Date of delivery 21.	**Pregnancy outcome 22.** Select one – 1. Live birth – normal 2. Live birth – premature 3. Live birth – low birth weight 4.Stillbirth 5. Neonatal death 6.IUD 7. Miscarriage	**Place of delivery 23.** Select one – 1.HSC 2.PHC 3.CHC 4. SDH 5.DH 6. MCH 7. Private 8. Home Delivery

Spouse/partner details			
Date of spouse's/Partner's Testing (Mention the date if spouse is tested or else write "NT" for not tested) 24.	**Spouse/partner syphilis testing type 25.** Select one – 1. VDRL 2.RPR 3.TPHA	**Spouse/partner syphilis test result 26.** Select one – 1. Reactive 2. Non-reactive	**Spouse/partner provided treatment 27.** Select one – 1. Yes 2. No 3. Unknown

Infant details							
Infant symptoms 28. Select one – 1. Symptomatic 2. Asymptomatic	**Date of syphilis test 29.**	**Syphilis test type 30.** Select one – 1. VDRL 2. RPR	**Name of the test kit used 31.**	**Syphilis test result- titre value 32.**	**Confirmatory syphilis testing using TPHA 33.** Select one – 1. Done 2. Not done	**Date of confirmatory testing dd/mm/yyyy format 34.**	**Treatment provided 35.** Select one – 1. Single dose Inj. benzathine penicillin 2.Inj. procaine penicillin for 10 days 3. IV aqueous crystalline penicillin G

Follow-up of baby							
At 6 months				At 24 months			
Testing of infant/child at 6 months using one of the following Test kit 36. Select one – 1. VDRL 2. RPR	**Date of the testing at 6 months 37.**	**Result at 6 months 38.**	**Name of the test kit used at 6 months 39.**	**Testing of infant/child at 24 months using one of the following test kit 40.** Select one – 1. VDRL 2. RPR	**Date of the testing at 24 months 41.**	**Result at 24 months 42.**	**Name of the test kit used at 24 months 43.**

Annex 6: Congenital syphilis case investigation form

CONGENITAL SYPHILIS CASE INVESTIGATION FORM						
Part A	**Facility information**					
1.	Name of the facility:					
2.	Name of the block:		3. Name of the district:			
4.	Name of the state :					
Part B	**Maternal information**					
1.	Name					
2.	Age in years					
3.	Address					
4.	Date of first ANC registration					
5.	First antenatal visit during which trimester	1. FIrst trimester	2. Second trimester	3. Third trimester		
6.	Date of first syphilis test and corresponding trimester	In dd/mm/yyyy	_____ trimester	During labour		
7.	Syphilis screening test	Type	Date of first test	Result (reactive/ non-reactive)	Date of recent test	Result (reactive/non-reactive)
		i. POC				
		ii. RPR				
		iii. VDRL				
8.	Clinical stage of syphilis	a) Early syphilis	b) Late syphilis			
9.	Bad obstetric history	a) Previous stillbirth	b) Previous premature baby	c) Previous miscarriage		
		d) Previous neonatal death				
10.	History of allergy to penicillin	a) Yes	b) No	c) Not known		
11.	Syphilis treatment			Yes/No	Date	
	Single IM dose of benzathine penicillin					
	Three IM doses of benzathine penicillin					
	Tablet Erythromycin 500 mg qid for 15 days					
	Tablet Erythromycin 500 mg qid for 30 days					
	Tablet Azithromycin 2mg single dose					
12	Place of delivery			Date of delivery		
PART C	**Partner information**					
1.	Name					
2.	Age					
3.	Occupation					

4.	Syphilis test	Type	Date of first test	Result (reactive/non-reactive)	Date of recent test	Result (reactive/non-reactive)
		POC				
		RPR				
		VDRL				

5.	Adequately treated	Yes (date)	No

Part D	**Infant/child information**

1.	Date of Delivery				
2.	Vital Status	a) Livebirth Normal Preterm Low birth-weight	b) Born alive, then died	c) Stillbirth	d) IUD
3.	Infant/cchild	a) Symptomatic		b) Asymptomatic	

4.	Signs	*a)* Condyloma lata	b) Snuffles	*c)* Syphilitic skin rash	d) Hepatosplenomegaly	e) Jaundice/hepatitis
		f) Pseudo paralysis	g) Oedema	h) Interstitial keratitis	i) Nerve deafness	j) Anterior bowing of shins
		k) Frontal bossing	l) Mulberry molars	m) Hutchinson's teeth	n) Saddle nose	o) Rhagades
		p) Cluttons joints	q) Any other			

5.	Syphilis test	Type	Date	Result
		RPR		
		VDRL		
6.	Congenital syphilis Confirmatory test	Type	Date	results
		RPR titre at birth four-fold higher that the mother's titre		

7.	Treatment provided		Date
		Prophylactic treatment with single dose inj. benzathine penicillin	
		Intravenous aqueous crystalline penicillin for 10 days	
		IM procaine penicillin G for 10 days	

PART E	**Congenital syphilis case classification**		
	Suspected case	Confirmed case	Not a case

Annex 7: Decision- tree for determining congenital syphilis cases