



**SCREENING FOR**  
**SYPHILIS**  
**DURING PREGNANCY**

**Technical &  
Operational Guidelines**

**Maternal Health Division  
Ministry of Health & Family Welfare  
Government of India  
December 2014**

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December 2014





लव वर्मा  
सचिव

**Lov Verma**  
Secretary



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

## Preface

As part of national and international commitments, India is steadfast in its resolve to reduce the Maternal Mortality Ratio (MMR) by 75 percent of its 1990 levels i.e. about 560 deaths per 100,000 live births to 140 deaths per 100,000 live births by the year 2015. Going by the past trends in reduction of MMR, India seems to be on the right track, and we hope to reach the MDG-5 target for our country by the end of next year.

However, we need to capitalize on the ground gained and consolidate what we have achieved. Post 2015, the world will focus on achieving the Sustainable Development Goals (SDGs). International discussions on SDGs clearly bring out that not only do we need to continue working on reducing MMR to much lower levels; we also need to focus on maternal morbidities that have an adverse effect on not just the health of the mother but also on the foetus.

Infectious diseases such as Syphilis have the potential of being transmitted from mother to child and also increase the risk of perinatal and neonatal mortality. Congenital Syphilis can be eliminated by the sincere implementation of these guidelines.

These guidelines are being brought out at a very opportune moment, addressing a need that is being felt not just at the national but at the global level. I am confident that these guidelines will become an integral part of the antenatal care package and that states will take up the implementation of this initiative with full vigour and commitment.

Lov Verma



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## Foreword

India is witnessing significant changes in the health sector. Improvements in the health systems with respect to infrastructure, personnel, and financial allocations are already showing impact in terms of reductions in maternal and child mortality rates. The proportion of maternal deaths attributable to direct obstetric causes is declining, because interventions to tackle causes such as haemorrhage, pregnancy induced hypertension etc. are being implemented.

As we move forward toward achieving our national and international commitments, it becomes imperative to address the challenges of shifting burden of disease, where now we see a greater proportion of maternal deaths attributable to indirect causes such as infections. Whilst we need to continue our efforts for tackling obstetric complications, we also need to initiate work on managing indirect causes that put a substantial proportion of our mothers and children at risk.

Syphilis is one such infection for which mother to child transmission is one of the known routes for spread of the disease. Early and timely identification of pregnant women who have this infection, through use of simple diagnostic tests is important to initiate the needed management in positive cases. This will not only prevent congenital transmission of the infection, but will also improve the health of the mother.

I would like to congratulate the Maternal Health Division in framing these guidelines with the help of NACO, institutional experts and development partners.

These guidelines are the first step towards managing this infection which cause significant maternal and neonatal mortality and morbidity. I am hopeful that all health personnel will take cognizance of these new guidelines and incorporate screening for this infection as an integral component of the antenatal care package.

C.K. Mishra



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## Foreword

Persons affected with sexually transmitted infection like syphilis form a substantive proportion of our population, including pregnant women. These infections can easily be transmitted from mother to child. Their occurrence during pregnancy poses a risk to the health of not just the mother, but also that of the newborn child.

Pregnancies in many of the infected mothers end in spontaneous abortion, low birth weight babies or babies with severe infection. Unlike many neonatal infections, congenital syphilis is preventable. The WHO has set a goal of eliminating congenital syphilis and urges countries to undertake appropriate public health measures such as antenatal screening and treatment of infected pregnant women to prevent this transmission.

Diagnostic tests for syphilis screening are relatively simple and cost effective. Starting with point-of-care testing kits, these guidelines present detailed algorithms on the steps to be taken for confirmation and management of these infections once the pregnant woman is found to be positive on the basis of the screening tests. It is hoped that universal application of these simple screening tests will go a long way in reducing the burden of syphilis and soon eliminate it.

The guidelines have been prepared by Maternal Health Division with the active support of NACO, institutional experts and development partners. These guidelines aim to facilitate the State and District Programme Officers for effective implementation.

Dr. Rakesh Kumar



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## Programme Officer's Message

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In 2005, Ministry of Health and Family Welfare, Government of India, released the Guidelines for Skilled Attendance at Birth by ANMs and LHVs. This marked a paradigm shift in programming for improving maternal health as not only did we move away from the previous strategy of training traditional birth attendants, but, more importantly, ANMs and staff nurses were given the legal rights to perform certain life saving interventions and administer life saving drugs in clearly defined conditions and obstetric complications, which would otherwise have had an adverse impact on the mother's health, including causing death in extreme circumstances. These landmark changes, coupled with skill building of human resource on the same and improved infrastructure, has resulted in increasing numbers of safe deliveries at public health facilities and reductions in maternal mortality due to common obstetric complications.

Even though that work is far from over, and we need to continue to maintain focus on the direct obstetric causes of maternal mortality, data is beginning to show an increasing proportions of non-obstetric causes and pre-existing conditions as causes of maternal deaths. syphilis is one such infection which has an adverse impact on the health of the mother and the foetus. syphilis infection in the mother carries the risk of congenital transmission which can affect the health of the newborn, in the immediate and long-term.

I would like to express that these guidelines would not have been possible without the constant encouragement from Mr. C.K Mishra, AS & MD & Ms Anuradha Gupta, Ex AS & MD. Dr. Rakesh Kumar, Joint Secretary (RMNCH+A) headed the expert group meeting and gave valuable inputs in framing this guideline.

I would like to acknowledge the contribution of all members of the Expert Group in developing the content of these technical and operational guidelines. I would also like to acknowledge my colleagues in MH Division especially Dr. Dinesh Baswal, DC (MH) and development partners for their valuable efforts and inputs in developing this document.

I am extremely hopeful, that these guidelines, along with the others, will usher in a new era of maternal health care in the country, where in every pregnancy the mother and child is protected not just from potential mortality, but also from debilitating illnesses.

  
12.12.14

Dr Himanshu Bhushan

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## List of Acronyms

ANC	Antenatal Care
ART	Antiretroviral Therapy
ASHA	Accredited Social Health Activist
CBO	Community-based Organization
CMIS	Computerized Management Information System
CS	Congenital Syphilis
DSRC	Designated STI/RTI Clinics
ePTCT	Elimination of Parent-to-Child Transmission
ECS	Elimination of Congenital Syphilis
EIA	Enzyme Immunoassay
ELISA	Enzyme-linked Immunosorbent Assay
FSW	Female Sex Worker
FTA-ABS	Fluorescent Treponemal Antibody Absorption Test
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HRG	High Risk Groups (for HIV)
HSS	HIV Sentinel Surveillance
ICS/ICT	Immuno Chromatographic Strip (test)
ICTC	Integrated Counselling and Testing Centres
IEC	Information Education and Communication
Ig	Immunoglobulin
F-ICTC	Facility Integrated Counselling and Testing Centres
INGO	International Non-governmental Organization
JSSK	Janani Shishu Suraksha Karyakram

RMNCH+A	Reproductive, Maternal, New Born, Child Health and Adolescent Health
MCTS	Mother and Child Tracking System
MDGs	Millennium Development Goals
MSM	Men who have Sex with Men
MSW	Male Sex Worker
MTCT	Mother-to-Child Transmission
NGO	Non-governmental Organization
NACO	National AIDS Control Organisation
NACP	National AIDS Control Programme
NHM	National Health Mission
PCR	Polymerase Chain Reaction
PPTCT	Prevention of Parent-to-Child Transmission
RPR Test	Rapid Plasma Reagin (Test)
RTI	Reproductive Tract Infection
SEAR	South-East Asia Region
SEARO	South East Asia Regional Office (WHO)
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
TPHA	Treponema Pallidum Haemagglutination Assay
TP IgM	Treponema Pallidum IgM Enzyme-linked Immunosorbent Assay
TPPA	Treponema Pallidum Particle Agglutination Assay
VDRL	Venereal Disease Research Laboratory (Test)
WHO	World Health Organization



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## Introduction

Syphilis is a sexually transmitted infection caused by the spirochaete bacterium *Treponema Pallidum*, subspecies *Pallidum*. The primary route of transmission is through sexual contact; it may also be transmitted from mother to foetus during pregnancy or at birth resulting in congenital syphilis.

The signs and symptoms of syphilis vary depending on which of the four stages it presents (primary, secondary, latent and tertiary). The primary stage classically presents with a single chancre (a firm, painless, non-itchy skin ulceration); secondary syphilis with a diffuse rash which frequently involves the palms of the hands and soles of the feet; latent syphilis with little to no symptoms and tertiary syphilis with gummas, neurological or cardiac symptoms.

### 1.1 Disease Burden

Data on the incidence and prevalence of STI in the South-East Asia Region (SEAR) are limited. WHO estimates approximately 600,000 pregnant women are infected with syphilis and 230,000 associated adverse outcomes occur every year in the SEAR.

Syphilis in pregnancy is an under-recognized problem that carries a significant public health and economic burden. It is estimated that there are 12 million people infected worldwide, with more than 90% of these cases being from the developing countries. Each year nearly 1.5 million pregnant women around the world are infected with active syphilis. Due to widespread availability of Penicillin in the 1940s there was dramatic decrease in the rates of infection, which have again increased since the turn of the millennium in many countries, often in combination with HIV infection. This has been attributed partly to unsafe sexual practices and decreasing use of condoms.

In the 2010–11 round of HIV sentinel surveillance, the average serological prevalence of syphilis (qualitative test result) among ANC attendees of 696 selected ANC sites was 0.38%. Arunachal Pradesh (2.86%) has shown the highest prevalence of syphilis followed by West Bengal (1.91%), Rajasthan (1.17%), Punjab (0.95%), Meghalaya (0.90%), Madhya Pradesh (0.66%), Andaman Nicobar Island, Uttar Pradesh and Tripura (0.63%) and Odisha (0.62%).

## 1.2 Impact on the Millennium Development Goals (MDGs)

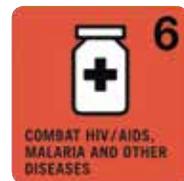
With 2015 approaching, international and national focus is on achieving the Millennium Development Goals (MDGs). Screening for and management of syphilis during pregnancy is the next step forward by the Government of India (GoI) in achieving MDGs 4, 5, 6.



Screening and management of syphilis will result in reduced incidence of low birth weight (LBW), perinatal deaths and congenital syphilis



Reduction in the incidence of stillbirth and spontaneous abortions will result in improved pregnancy outcomes and reduced maternal morbidity.



Reduction in comorbidities like HIV will occur due to improved behaviours following counselling

### **1.3 Consequences of Syphilis**

The global estimate of adverse outcomes of syphilis in pregnancy in 2008 was about 520,000. Of this large number, early foetal deaths/stillbirths are 215,000; neonatal deaths 90,000; pre-term/LBW 65,000 and congenital diseases 150,000. An estimated 96% of maternal syphilis infection 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 33%; however the pace of decline needs to be accelerated.

### **1.4 Need for National Guidelines**

As syphilis is known to cause adverse outcomes in pregnant women and newborns, these guidelines offer clear technical recommendations and operational framework for screening pregnant women and managing them when detected positive.

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## Technical Guidelines on Testing and Management of Syphilis During Pregnancy

### 2.1 Goal

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To reduce maternal and newborn morbidity and mortality and move towards detection and treatment of maternal syphilis and elimination of congenital syphilis.

### 2.2 Objectives

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- To ensure early screening of all pregnant women for syphilis, preferably in the first trimester;
- To detect and manage syphilis infection in pregnant women and their partners;
- To ensure institutional delivery at (FRUs/higher level institutions) of all syphilis-positive pregnant women;
- To prevent the transmission of syphilis from mother to child.

## 2.3 Target Population

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- All pregnant women and their newborns
- Partners of syphilis-positive pregnant women

## 2.4 Prerequisites for Testing and Management of Syphilis

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- Availability of Point-of-Care (POC) testing at Sub-centres (SC) and outreach sessions such as Village Health and Nutrition Days (VHNDs)
- Availability of POC test at any other facility where rapid plasma reagin (RPR) testing is not available, including at centres where deliveries are conducted
- Availability of RPR testing facility at all the health facilities above sub-centre
- All commodities and human resource for management of syphilis, relevant to the level of facility
  - » Availability of drugs, injectables and consumables required for the management of maternal and congenital syphilis
  - » An emergency kit containing essential drugs, injections and supplies for managing anaphylactic shock
  - » Trained human resource to provide the management to pregnant women after they test positive for syphilis
  - » Appropriate referral linkages to First Referral Units (FRU)/ Emergency Obstetric Care (EmOC) centers for conducting the delivery of syphilis-positive pregnant women
  - » Availability of Ob-Gyn and pediatrician is mandatory at such FRUs

## 2.5 Selection of Facilities

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- States are free to choose the number of districts where the programme will be implemented
- Once a district is chosen, implementation of the programme should be universal in all health care institutions in that district, right from the medical college to the sub-centre
- All health care facilities in the selected district should have all the relevant prerequisites in place
- The service providers and programme officer must be well oriented and trained regarding the programme

## 2.6 Steps for Implementation

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- A Government order/policy decision on implementation of the programme should be issued by the State
- Testing and treatment for syphilis to be declared as an integral part of the essential ANC package
- Orientation and training of all programme officers and service providers involved in the programme
- Availability of test kits, consumables, drugs and other logistics, as relevant at health care facilities in the district identified for rolling out the programme
- Adequate information education and communication (IEC) /interpersonal communication (IPC) for generating awareness
- Availability of different formats, records, registers and other requisite Monitoring and Evaluation (M&E) tools for documentation, data collection, collation and for review and evaluation of the programme
- Provision of adequate budget and timely release to the implementing institutions

---

## Protocol for Investigation and Management of Syphilis

- All pregnant women should be tested for syphilis in the first ANC visit itself, which should be as early as possible, by a POC test at the sub-centre level or at any other facility where the woman visits for ANC, where laboratory facilities for RPR are not available, irrespective of her previous syphilitic status.
- Those women who go for ANC check-up at health care facilities where testing for RPR is available should be tested by RPR method (qualitative and quantitative).
- Ideally, all women who test positive for syphilis through POC should undergo testing by RPR also for confirmation of diagnosis and assessment of the antibody titres. The latter is important not just for ensuring appropriate treatment for the woman but also for deciding on the line of treatment for the newborn.
- Those found positive either by POC or RPR should be treated for maternal syphilis as per the defined treatment protocol explained in this guideline.
- Women who are at high risk for syphilis (*see box on the adjacent page*), those who live in areas of high prevalence of syphilis, those who have had adverse outcomes of pregnancy previously or those who were untested earlier, should be screened again in the third trimester or at the time of delivery.
- Testing of spouse/partner of syphilis-positive women should be mandatory followed by treatment as per protocol for those found positive.

- For all syphilis-positive women detected during ANC by either POC or RPR, their newborns should be tested by RPR.
- All newborns showing four-fold rise in titre compared to that of mother's titre need to be hospitalized to initiate penicillin treatment for 10 days.

**Pregnant women considered to be at high risk for acquiring STIs, including Syphilis:**

- Women with current or past history of STI
- Women with more than one sexual partner
- Sex workers
- Injecting drug users

### 3.1 Treatment Regimen for Syphilis-positive Pregnant Women and their Partners

#### 3.1.1 Treatment of maternal syphilis

Although severe allergy to penicillin is rare, the provider should rule out history of allergy before administering penicillin. The emergency drugs for managing anaphylaxis should be kept ready prior to administering penicillin (*see Anaphylaxis Management at Annexure 1*).

- In the early stage (primary and secondary syphilis of <2 years' duration; RPR titre < 1:8 approximately), a single intramuscular injection of 2.4 million IU benzathine benzyl penicillin is sufficient.
- In the late stage (tertiary > 2 years or unknown duration, RPR titre > 1:8 approximately), a total of three intramuscular injections of 2.4 million IU benzathine benzyl penicillin once a week for 3 weeks need to be given.

**Ensure readiness of emergency tray for management of anaphylactic reactions:**

- The tray should be kept in the day-care room.
- Every morning the tray should be checked for replenishment of used drugs and for expiry dates of drugs on the tray.
- List of drugs and consumables that should always be available on the tray: Inj Adrenaline, Inj Chlorpheniramine Maleate, Inj Dexamethasone, Inj Hydrocortisone succinate, Inj Deriphylline, Inj Furosemide, Inj Dopamine, Inj Sodium bicarbonate, Oxygen, Ringer Lactate, disposable needles, gloves, cotton swabs.

## Alternative Regimen for Penicillin-allergic Pregnant women

### Regimen 1

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

OR

### Regimen 2

Primary syphilis (syphilitic chancre): Azithromycin, 2 g orally as a single dose

### Important facts about penicillin use:

Facts about benzathine penicillin injection:

- Benzathine penicillin injection is the only effective treatment for preventing congenital syphilis, perinatal deaths, stillbirths and preterm deliveries in pregnant women with syphilis.
- A study undertaken by Tais F Galvio, Lori M. Newman et al. (Feb 2013 Journal PLOS ONE) states that no case of serious adverse reactions to benzathine penicillin injection was reported in pregnant women and the incidence was very low in the general population.
- Incidence of adverse reactions in pregnant women treated with benzathine penicillin injection for preventing congenital syphilis in studies conducted between 1954 and 2012 have shown only one case of skin rash.
- Benefits of benzathine penicillin injection outweigh the risks of adverse reactions.

Therefore, fears regarding use of benzathine penicillin injection among doctors should be dispelled.

### Key points:

- For the treatment of syphilis during pregnancy, NO PROVEN ALTERNATIVES TO PENICILLIN exist.
- All infants of pregnant women treated with a non-penicillin regimen should be treated at birth as if mother was not sufficiently treated.
- Alternative to penicillin should be considered ONLY for those syphilis-positive 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.

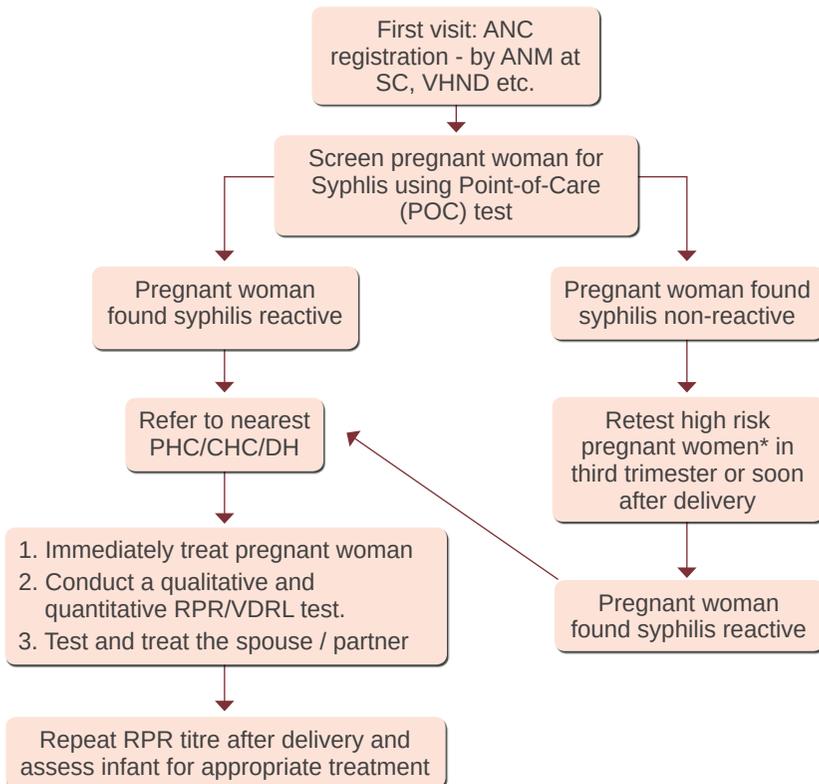
The partner or spouse should be treated with the same regimen.

### 3.1.2 Follow-up

Follow-up should be done during postnatal care (PNC) visits and in addition, at 6 months and 24 months after the treatment is administered.

#### Flowchart 1

**Syphilis screening of pregnant women using POC test and treatment of maternal syphilis at health care settings without laboratory support**

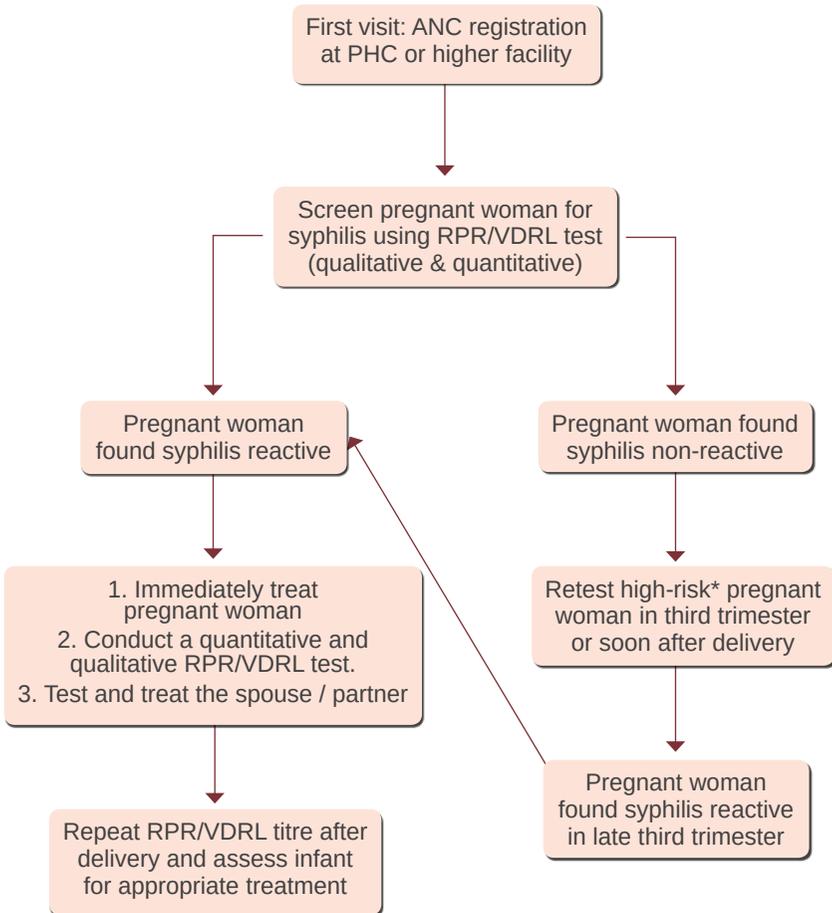


#### Criteria for repeat test:

- 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);
- Pregnant women with history of repeated abortions, stillbirths, past history of delivery of premature babies, preterm babies and neonatal deaths;
- Women living in areas of high prevalence of syphilis;
- Testing at the time of delivery will also be required to detect re-infection, particularly in those syphilis-positive women whose partners were not treated;

## Flowchart 2

### Algorithm for syphilis screening of pregnant women and treatment of maternal syphilis at health care settings with laboratory support

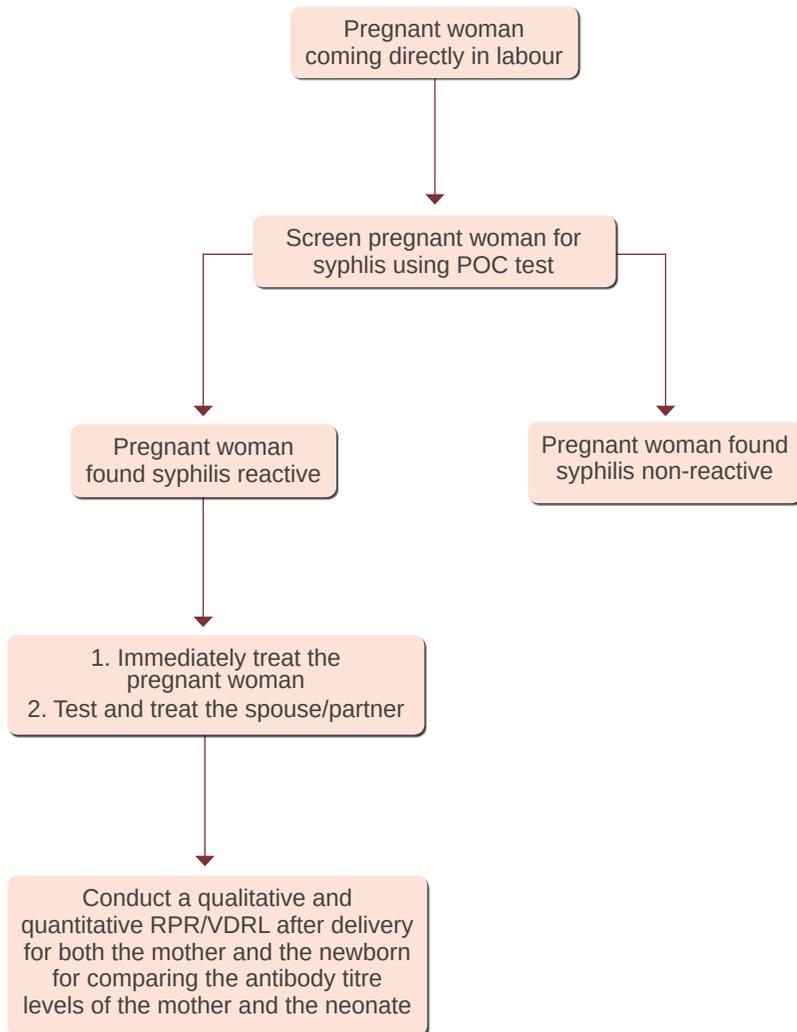


#### Criteria for repeat test:

- 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)
- Pregnant women with history of repeated abortions, stillbirths, past history of delivery of premature babies, preterm babies and neonatal deaths
- Women living in areas of high prevalence of syphilis
- Testing at the time of delivery will also be required to detect re-infection, particularly in those syphilis-positive women whose partners were not treated.

### Flowchart 3

Algorithm for syphilis screening of pregnant women coming directly in labour and treatment of maternal syphilis



## 3.2 Neonatal Syphilis

### 3.2.1 Case Definitions

#### Suspected case of congenital syphilis

A stillborn or live-born baby of syphilis-reactive mother who has been inadequately treated

#### Confirmed case of congenital syphilis

A live born child with serum quantitative RPR titre that is four-fold higher than the mother's titre

OR

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

### 3.2.2 Signs and Symptoms of Congenital Syphilis

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

The most frequent clinical signs of congenital syphilis at birth are hepatosplenomegaly (33%–100%), bone changes seen on x-ray (75%–100%) (Fig.1), blistering skin rash especially on palms and soles (40%) (Fig.2), fever (16%), low birth weight (10%–40%), bleeding (10%), swelling of the joints, abnormal facies, snuffles, oedema, abdominal distension, pallor, respiratory distress and pseudo-paralysis.

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).

Fig. 1: Radiograph showing lower end of humerus (with periostitis) and proximal ends of radius and ulna (with metaphysitis)



Fig. 2: Blistering skin rash in neonates



### 3.3.3 Management of Congenital Syphilis

#### Regimen 1 (Prophylactic Treatment)

All asymptomatic babies who meet ALL the following criteria:

- Have no serological evidence of syphilis and
- Are born to mothers who were adequately treated for maternal syphilis with penicillin during the current pregnancy and
- The mother has received the treatment at least 4 weeks prior to delivery

Should be treated with a single dose of prophylactic penicillin:  
Benzathine penicillin G 50,000 units/kg given as a single intramuscular injection.

#### Regimen 2 (Curative Treatment)

This should be given to

- All symptomatic babies (newborns and older)
- All asymptomatic babies-

##### Asymptomatic newborns

- 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

**Asymptomatic infant/child**

- Whose RPR/VDRL titre is four-fold higher than that of the mother at or after delivery
- Born to mothers with clinical evidence of syphilis
- With a reactive syphilis IgM antibody test
- Born to mothers who did not complete the recommended course of penicillin during pregnancy
- Born to mothers whose RPR/VDRL titres had not dropped four-fold

**Intravenous (IV) 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, and thereafter every 8 hours for 3 days to complete a total of 10 days of treatment.

OR

**Intramuscular (IM) treatment regimen**

- Procaine penicillin 50,000 units/kg body weight intramuscularly as a single daily dose for 10 days;
- Alternatively, benzathine penicillin G 50,000 units/kg IM in a single dose

Hospitalization 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.**

**3.3.4 Follow-up**

Follow-up should be done during PNC visits as well as at 6 months and 24 months after the treatment is received.

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## Operational Plan for Investigation and Management of Syphilis

- The programme manager for the state should collect the data for the estimated number of pregnancies from each of the districts and direct the district programme manager to ensure that all pregnant women attending ANC clinics at government health care facilities receive screening for syphilis, preferably as part of the first ANC visit itself.
- In the district, about 60% to 70% of the total estimated pregnancies will avail ANC screening from government health care facilities (Sub-centre, PHC, CHC, Sub-divisional Hospital, District Hospital, Medical College, etc.).
- The programme manager at the district will estimate the caseloads per health care facility based on HMIS data.
- The programme manager will ensure that kits and consumables for syphilis screening are available based on the type of health care facility.
- Pregnant women will be screened as mentioned in the algorithm charts.

## 4.1 Awareness Generation at the Community Level

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All health care workers and professionals should generate awareness in the community about the importance of screening for syphilis in the antenatal period by using various IEC methods and strategies including IPC.

## 4.2 Human Resources Involved

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Specialists, medical officers, laboratory technicians and other health care workers across different levels of health care facilities; no additional human resources need to be recruited to implementing these guidelines.

## 4.3 Role and Responsibilities – Defined by Levels of Health Care Facilities

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### 4.3.1 Village:

- Generate awareness among pregnant women regarding the importance of routine ANC highlighting the importance of screening for syphilis during early pregnancy.
- Mobilize pregnant women to attend VHND/sub-centre as per the ANC registrations list for getting routine ANC and investigations.
- If the pregnant woman is syphilis-positive, ASHA should ensure her treatment, testing and treatment of spouse/partner, delivery in an FRU or higher facility through birth planning and prompt investigation and treatment of the newborn.
- Enlist family support as it is required for testing and for ensuring treatment if the woman is found to be syphilis-positive.

### 4.3.2 Level I: Sub-centre/VHND

- Conduct ANC and testing for syphilis by POC test along with other mandatory tests during ANC.
- If the pregnant woman is reactive to the POC test, she should be referred to PHC/CHC/Sub-divisional Hospital/District Hospital for treatment and RPR.
- Her spouse/partner should be encouraged to get tested and seek treatment if found positive.
- The ANM will record the test results in the MCP card and RCH register.
- All positive cases should be followed up for treatment.
- The test kit should be kept in the refrigerator to maintain the temperature at 2°C to 8°C.

- If a refrigerator is not available at the sub-centre, then the kits should be kept at the PHC to maintain cold chain, and be brought to the VHND or outreach sessions while ensuring that cold chain is maintained.

#### **4.3.3 Level II: PHC/Corresponding urban centre**

All the jobs assigned above plus the following:

- RPR test has to be performed by the laboratory technician. In the absence of a laboratory technician, a staff nurse will do the POC test and refer syphilis-positive pregnant woman to the Medical Officer or to a higher centre for treatment and RPR test.
- The MO will provide treatment by using the standard treatment protocol for syphilis.
- The MO will also monitor the treatment/investigation required for syphilis-positive cases and refer to an FRU/higher level centre for further medical management, if required and conduction of delivery by the specialist.

#### **4.3.4 Level III**

A) DH and All CEmOC Centres

All jobs as defined under Level II plus the following:

- Ob-Gyn to conduct the delivery of syphilis-positive pregnant women
- Paediatricians to provide care to the newborn of a syphilis-positive mother

B) Medical College and Other Super-speciality Centres

Comprehensive management of all cases needing treatment of syphilis including all referral cases

### **4.4 Roles and Responsibilities Defined by Cadre of Health Worker**

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#### **4.4.1 District RCH Officer/State RCH Officer**

- Plan the roll-out of syphilis testing among pregnant women
- Ensure that all facilities have adequate supply of test kits, consumables and drugs for at least 3 months
- Calculate the health facility-wise case load for sending the supplies in advance as per consumption pattern

- Coordinate with CMHO/Civil surgeon, State RCH Officer, DPMU and DAPCU to strengthen service delivery in the field
- Monitor the programme to ensure:
  - » The storage of all supplies is in accordance with the manufacturer's instructions
  - » The required drugs are part of the Essential Drugs List (EML)
  - » Training of all the health staff
  - » All the reporting units provide report on screening and treatment of pregnant women for syphilis in HMIS

#### **4.4.2 ANM/Staff Nurse**

- Increase awareness among pregnant women regarding syphilis screening
- Register all pregnant women for ANC and screen for syphilis using the POC test during first ANC visit
- Maintain the ANC register, including record of syphilis test results.
- Refer syphilis-positive pregnant women to higher health care facility for confirmation and treatment
- Follow-up syphilis-positive women and their newborns for treatment
- Assist/prepare HMIS and other relevant reports

#### **4.4.3 Laboratory Technician**

- Conduct syphilis testing test for all pregnant women visiting the PHC and higher centres for ANC
- Maintain the laboratory register
- Store test kits as per guidelines
- Refer syphilis-positive pregnant women for treatment
- Keep records
- Testing blood of newborns

#### **4.4.4 Medical Officer**

- Provide treatment to all the syphilis-positive women,
- Test and treat their spouse/partner
- Refer the syphilis-positive pregnant women to an FRU for delivery, and further testing

- Conduct follow-up test after treatment as per guidelines
- Follow-up of patient management
- Manage the cases of anaphylaxis if any occur
- Check for correctness of reporting

#### **4.4.5 In-charge of DSRC (Designated STI/RTI Clinic)**

DSRCs are mainly located at district hospitals

- Maintain the inventory and stock registers of drugs and test kits
- Build capacity of all new STI counsellors
- Sensitize the PHC- MOs and ANMs/ASHAs on updates of the programme
- Provide mentoring and supportive supervisory visits to health facilities
- At the STI clinic counselling of pregnant women and laboratory referral for testing
- Counselling all ANC attendees and partners coming to the ANC clinic and referring to the laboratory for screening/confirmation of syphilis

#### **4.4.6 Paediatrician/Gynaecologist**

- Provide delivery services to all pregnant women who test positive for syphilis
- Help in assessing the antibody titres in the newborn's blood by drawing blood from the neonate's cubital vein and sending it to the laboratory technician for testing by RPR
- Provide treatment for the newborn and infant of a syphilis-positive mother
- Provide comprehensive care to a syphilis-positive mother and her newborn

## 4.5 Capacity Building of Human Resource

### 4.5.1 Training Needs for Different Cadres

Cadre of Health Care Functionary	Type of Training	Content of Training
ASHA	General orientation about the programme	Orientation on <ul style="list-style-type: none"> <li>▪ Syphilis disease burden, consequences for pregnant women and neonates</li> <li>▪ IEC material on awareness</li> </ul>
ANM/LHV/SN	Knowledge and skills about POC screening test for syphilis	The training for ASHAs, plus <ul style="list-style-type: none"> <li>▪ POC testing technique</li> <li>▪ Interpreting POC test results</li> <li>▪ Referral required when the test is positive</li> <li>▪ Technique of testing sensitivity of penicillin</li> <li>▪ Maintenance of records and different reporting formats</li> </ul>
Laboratory technician	Knowledge and skills about RPR and POC test for syphilis	The training for ANMs plus <ul style="list-style-type: none"> <li>▪ POC testing techniques</li> <li>▪ RPR testing techniques – qualitative and quantitative</li> <li>▪ Interpreting POC and RPR test results</li> <li>▪ Referral required when the test is positive</li> </ul>
Medical Officer	Medical management of a syphilis-positive pregnant woman	<ul style="list-style-type: none"> <li>▪ Interpretation of RPR test results</li> <li>▪ Technique of administration of penicillin injection through the proper site and route</li> <li>▪ Medical management of syphilis, including alternative (to penicillin) therapies</li> <li>▪ Referral to FRU for delivery and management of newborn</li> </ul>
Specialists (Ob-Gyn, Paediatrician)	Special obstetric care of syphilis-positive pregnant women	The training for medical officers, plus <ul style="list-style-type: none"> <li>▪ Special obstetric care: ante-partum, intra-partum and postpartum</li> <li>▪ Comprehensive medical management of syphilis-positive pregnant women</li> <li>▪ Technique of drawing venous blood from newborn from the cubital vein for RPR test (by paediatrician only)</li> <li>▪ Management of the neonate of a syphilis-positive mother</li> </ul>

#### 4.5.2 Structure of Training for Syphilis Programme

- A one-day training will be organized for syphilis programme in every district
- All participants (programme managers and medical officers [MOs] in-charge of STI Clinics/DSRCs/District AIDS Prevention & Control Units/Integrated Counselling and Testing centres/HFWTC/DTC faculty, Principals, ANMTC/LHVTC; School/s of Nursing; DNOs/ HEOs/ASHA Mentors/ANMs/ SNs/ LHVs/LTs/MOs/Specialists (Obstetricians; Paediatricians, Dermatologists) will attend
- ASHAs will have a separate batch and 1-day training programme can be incorporated either into their existing module or a separate orientation programme at block level can be organized

#### 4.5.3 Batch Size

- All health care facilities in a district will be mapped
- Health personnel of all health care service delivery points need to be oriented/ trained on a rotational basis
- One batch can have 40 to 60 trainees from all cadres (heterogeneous group)
- One batch of trainees will comprise
  - Programme managers: 3–5
  - ANM/SN/LHV: 20–25
  - LT: 5–10
  - MO/ Ob-Gyn/Paediatrician and dermatologist/ pathologist or microbiologist: 10–15
- Once the health personnel of the designated delivery points in the district have been trained on a priority basis, other health personnel involved in ANC care can be oriented
- District Training In-charge will prepare a training plan and calendar accordingly

#### 4.5.4 Training Sites

Prerequisites:

- Seminar/Conference room with capacity of 50–60 participants
- Audio-visual and other training aids
- At least two in-house Ob-Gyn and one paediatrician
- Availability of in-house counsellor, pathologist/ microbiologist, community medicine faculty is desirable
- Any medical college/district hospital having the above prerequisites can be chosen as a training site/venue

#### 4.5.5 Trainers

- MO, Ob-Gyn, paediatrician and dermatologist/pathologist or microbiologist/specialist in Community Medicine to be included as trainers as per their availability and area of expertise
- One-day training of trainers should be organized for 20–25 trainers at medical college level

#### 4.5.6 Training Material

- GoI guidelines on syphilis
- Any other teaching or training material synchronized with GoI guidelines
- Job aids/Posters/Handouts/Flipcharts
- Presentations
- POC testing strips/cards

### 4.6 Monitoring and Evaluation Framework

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This initiative envisages a focused and robust monitoring and evaluation system with specific indicators mentioned below to monitor progress of the initiative across states so as to take appropriate programmatic responses. NACO and the Maternal Health Division of MoHFW will monitor indicators identified as critical for monitoring at national level. States and districts will be responsible for monitoring of these indicators and for ensuring quality of data collection from the facilities.

#### 4.6.1 Key performance indicators for Syphilis Screening (KPI)

- Number of pregnant women tested for syphilis out of total ANC's registered
- Total number of syphilis-positive pregnant women detected out of those tested
- Total number of pregnant women adequately treated (i.e. received one dose of benzathine penicillin injection) for syphilis
- Total number of confirmed cases of congenital syphilis
- Total number of babies born to syphilis-positive mothers who received treatment

### 4.7 Budget

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- Infrastructure: No additional infrastructure required
- Human resource: No separate human resource required
- Equipment/Instruments: No additional equipment or infrastructure required
- Testing kits, consumables and drugs required for this programme need to be budgeted for

While estimating the budget required for rolling out this initiative, the following need to be considered

#### 4.7.1 Estimated Case Loads

- All pregnant women availing ANC at public health care facilities will be screened for syphilis by strip/card test, or by RPR depending on where they access ANC services
- The pregnant women who test positive for syphilis by the POC test will need to be tested by RPR also (both qualitative and quantitative)
- The pregnant women who test positive for syphilis by POC test will need benzathine penicillin injection treatment
- All spouses / partners of syphilis-positive women should ideally be tested for syphilis too, and if found positive, then they too will need to be treated

- Newborns with congenital syphilis or where mothers were inadequately treated will need to be treated with benzathine penicillin

Estimating these proportions from existing data or from reported data following initial roll-out will assist in budgeting for this initiative.

#### **4.7.2 Records/Registers and Formats**

The following records and registers need to be printed and made available to the relevant service provider(s)

- Monthly syphilis reporting formats for state and district programme managers (*Annexure 6*)
- Monthly syphilis reporting formats for health care facility (*Annexure 7*)
- Referral slip (*Annexure 4*)
- Migration form for Pregnant Women with syphilis (*Annexure 5*)

#### **4.7.3 Drugs Consumables and Other Logistics**

- Estimate the requirement of test kits, drugs, consumables like lancets, gloves, swabs, etc. and ensure supplies of the same

#### **4.7.4 Training**

- One-day training will be organized for syphilis programme at the state level
- One-day training will be organized for syphilis programme in every district. ProgrammeManagers/ANMs/SNs/LHVs/LTs/MOs/OB-GYN/ Paediatricians/Pathologists/Microbiologists will attend

## Budget: Training for Syphilis

### 1-day Training at State Level for Syphilis - Batch of 50

Sr. No.	Head	Unit Cost (Rs.)	Number of Participants	Days	Total (Rs.)
1	TA for participants (to and fro) – to be given as per actuals	3,000	50		1,50,000
2	DA to trainees	700	50	1	35,000
3	Lunch and tea	200	50	1	10,000
4	Per diem/Honorarium for trainers**	1,000	2	1	2,000
5	Logistic expenses such as for study material, course material, photocopying, job aids, flip charts, LCD etc. (Rate x days of training x number of participants)	200	50	1	10,000
	Sub-total				2,07,000
	Incidental overheads (10% of sub-total)				20,000
	<b>Total for one batch of 50 candidates for 1-day training</b>				<b>2,27,000</b>

### 1-day Training of District-level Officers for Syphilis - Batch of 50

Sr. No.	Head	Unit Cost (Rs.)	Number of Participants	Days	Total (Rs.)
	TA as per state norms				
1	DA to District-level Programme Officers	700	10	1	7,000
2	DA to Staff Nurses/ANM/LHV	400	25	1	20,000
3	DA to Medical Officers/Ob-Gyn	700	15	1	10,500
4.	Lunch and tea	200	50	1	10,000
5	Honorarium to State-level Faculty**	1,000	2	1	2,000
6	Logistic expenses such as for study material, course material, photocopying, job aids, flip charts, audio-visuals etc. (Rate x number of participants)	200	50	-	10,000
	Sub-total				49,500
	Incidental overheads (10% of sub-total)				5,000
	<b>Total for batch of 50</b>				<b>54,500</b>

Note:

\*\* TA to be given as per state norms

The state needs to adjust the training norms as per the training load of the district and state

**Note:**

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- Every district programme officer needs to undertake advance planning and budget estimates for universal screening of syphilis in the district.
- The state programme officer needs to reflect the budgetary requirement in the state/ NHM Programme Implementation Plan (PIP).
- State/district accounts manager needs to ensure timely submission of utilisation certificates and statements of expenditure.
- Necessary equipment/supplies either cash or in kind need to be made available in advance to all the health care facilities in the district.
- Similarly, training institutes also need to be provided with the training budget as per the estimates in advance.
- Any procurement that needs to be done should be through competitive and transparent bidding process.

# Annexures

## Annexure – 1

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### Anaphylaxis Management

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

### Signs of possible Anaphylaxis

- Shock
- Difficulty in breathing
- Itchy rash or hives (urticarial)

### Management of Anaphylaxis

- Call for help
- Check
  - » Airway
  - » Breathing: Give mouth-to-mouth respiration, if necessary
  - » Circulation: Perform cardiopulmonary resuscitation, if necessary
- If Anaphylaxis, give Adrenaline intramuscularly (IM)
  - » Dosage: Adult 0.5 mL (if elderly, 0.3 mL), repeat every 5–10 minutes until adequate response
  - » Check blood pressure and pulse every 5–10 minutes
- Give Hydrocortisone. Dosage: Adult 250 mg IM
- Give Chlorpheniramine. Dosage: 10–20 mg or Diphenhydramine 50–100 mg IM
- Transfer patient to hospital
  - » Repeat Adrenaline injection if necessary. Take extra doses with you
  - » Record all details of treatment. Give a copy to the hospital as well as to the patient
  - » Stay with the patient until another doctor takes over care in person

## Annexure – 2

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### Technical Specifications of Rapid Plasma Reagin (RPR) Test Kits for Syphilis Testing

- The indigenous RPR kits should have been manufactured under manufacturing licence issued by the State Licensing Authority under the Drugs and Cosmetics Act. The imported kits should have been imported under import licence issued by the DCG (I) under the Drugs and Cosmetics Act.
- The assay should allow for qualitative and semi-quantitative determination of reagin antibodies in serum or plasma for serological diagnosis of syphilis based on flocculation principle using non-treponemal antigens.
- The assay should be suitable to perform with either serum or plasma.
- The assay should have sensitivity of 80% or more in primary syphilis and a specificity of 90% or more.
- The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit inserts and certificate from manufacturer.
- The test should be able to yield results within 20 minutes.
- The pack size of RPR test kit should be less than or equal to 50 tests per kit.
- The assay components should include positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls).
- The kit should have all essential accessories required for the test such as cards, dropper, accelerator, etc., in adequate quantities for the number of tests to be performed.
- The kit should have 5/6th of the shelf life or 12 months before expiry (whichever is more) at the time of receipt by the consignee.
- The kit should have a storage temperature of 2°C to 8°C and supplier/ local agent should have the facility to store kits at 2°C to 8°C.
- Cumulative Time Temperature Indicator should be part of the kit and the indicator technology used should be prequalified by WHO.
- Literature detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing and expiry dates should be provided with each kit.

## Annexure – 3

### Technical Specifications of Treponemal-specific Rapid (Point-of-Care) Diagnostic Test for Syphilis

- The assay should have solid phase coated with synthetic or recombinant type of Treponema Pallidum antigens.
- The assay may be based on any of the rapid test principles: (Immunoconcentration/Dot blot immunoassay (vertical flow), dip stick and comb assay).
- The assay should quantitatively detect total anti-treponemal antibody (IgG and IgM) in whole blood, serum or plasma for serological diagnosis of syphilis in all stages of infection.
- The assay should have an in-built positive and negative control for testing the validity of the test kits.
- The assay should have reactive and non-reactive controls with each kit in adequate volume (minimum 10% of pack size).
- The kit should have 5/6<sup>th</sup> of the shelf life or 12 months before expiry (whichever is more) at the time of receipt by the consignee.
- Adequate literature detailing the principle, components, methodologies, validity criteria, bio-safety, performance characteristics, storage conditions, limitation of assay, manufacture and expiry dates and methods of disposal should be provided with each kit.
- The imported rapid kit should have 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).
- In case of indigenous manufacturers they should have a valid licence issued by the competent authority defined under Drugs and Cosmetics Act, 1940, after appropriate evaluation by the centres approved by the CDSCO.
- The assay should have sensitivity of 90% or more and specificity of 95% or more and the same should be supported by statements in kit insert and certificate from National Institute of Biological Sciences.
- The assay should be calibrated to WHO reference serum and the same should be supported by statements in kit insert and certificate from the manufacturer.

- The manufacturer should ensure the following:
  - » The test should be packed such that there is a provision to conduct single test at a time.
  - » The pack size of test kits should be in 50 (for peripheral health levels) and 100 tests per kit (for secondary and tertiary health care level) but not more than 100 tests per kit.
- The manufacturer/authorized agent should ensure maintenance of cold chain during storage and transport of kits at 2°C to 8°C.
- Total procedure time should not be more than 30 minutes.

## Annexure – 4

### Referral Slip

Name of referring facility: \_\_\_\_\_

Address: \_\_\_\_\_ Telephone: \_\_\_\_\_

Name of the patient: \_\_\_\_\_

Father's/Husband's name: \_\_\_\_\_

Contact no.: \_\_\_\_\_

Address: \_\_\_\_\_

Referred on \_\_\_/\_\_\_/\_\_\_ (dd/mm/yy) \_\_\_\_\_ (time) to \_\_\_\_\_  
\_\_\_\_\_ (name of the facility) for management.

Provisional diagnosis: \_\_\_\_\_

Summary of management: \_\_\_\_\_

Blood group: \_\_\_\_\_ Hb: \_\_\_\_\_

Status of Syphilis: \_\_\_\_\_

Other investigations: \_\_\_\_\_

### Procedures and critical interventions carried out

Treatment given: \_\_\_\_\_

Dose of penicillin: \_\_\_\_\_ Duration: \_\_\_\_\_

Condition at time of referral: \_\_\_\_\_

Consciousness: Temp: \_\_\_\_\_ Pulse: \_\_\_\_\_ BP: \_\_\_\_\_

Reason for referral: \_\_\_\_\_

Mode of transport for referral: Govt./PPP/Vehicle arranged by patient

Telephonic information on referral provided to the institution referred to: No/

Name of the person spoken to: \_\_\_\_\_

Signature of referring physician/health functionary: \_\_\_\_\_

Name/Designation/Stamp: \_\_\_\_\_

**Annexure – 5****Migration Form for Pregnant Women with Syphilis**

Name: \_\_\_\_\_

Husband's/Father's name: \_\_\_\_\_

Present address: \_\_\_\_\_  
\_\_\_\_\_

Name of Health Facility attended: \_\_\_\_\_

Migration address: \_\_\_\_\_  
\_\_\_\_\_Address of health facility to be attended: \_\_\_\_\_  
\_\_\_\_\_

Diagnosis of Syphilis: \_\_\_\_\_ Date: \_\_\_\_\_

Period of gestation: \_\_\_\_\_ weeks \_\_\_\_\_

Treatment given: \_\_\_\_\_  
\_\_\_\_\_

Information about migration given to:

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

Mobile no./Telephone no: \_\_\_\_\_

Place of work: \_\_\_\_\_

Signature of Doctor

## Annexure – 6

### Monthly Syphilis Reporting Format for State & District Programme Managers for month of .....year.....

Name of State: \_\_\_\_\_ Name of District: \_\_\_\_\_

Estimated number of pregnant women: \_\_\_\_\_

Estimated number of deliveries: \_\_\_\_\_

- Total number of ANC conducted (including all 4 ANC visits) in reporting month: \_\_\_\_\_
- Number of syphilis-positive pregnant women diagnosed out of total number of ANC conducted in the reporting month: \_\_\_\_\_
- Total number of pregnant women who received adequate treatment (i.e. received one dose of benzathine penicillin injection) for syphilis out of total number of syphilis-positive women diagnosed in reporting month: \_\_\_\_\_
- Number of confirmed cases of congenital syphilis out of total number of syphilis-positive pregnant women who delivered in the reporting month: \_\_\_\_\_
- Number of babies who received treatment who are born to syphilis-positive mothers out of total number of syphilis-positive pregnant women diagnosed in reporting month: \_\_\_\_\_

Note:

- Districts will report to their states.
- Information will be compiled at state level to forward to GOI.

## Annexure – 7

### Monthly Syphilis Reporting Format for Health Facility for Month of ....., Year.....

Name of State: \_\_\_\_\_ Name of District: \_\_\_\_\_

Name of Health Facility: \_\_\_\_\_

Estimated number of pregnant women: \_\_\_\_\_

Estimated number of deliveries: \_\_\_\_\_

- Total number of ANC conducted (including all 4 ANC visits) in reporting month: \_\_\_\_\_
- Number of syphilis-positive pregnant women diagnosed out of total number of ANC conducted in the reporting month: \_\_\_\_\_
- Total number of pregnant women received adequate treatment (i.e. received one dose of benzathine penicillin injection) for syphilis out of total number of syphilis-positive women diagnosed in reporting month: \_\_\_\_\_
- Number of confirmed cases of congenital syphilis out of total number of syphilis-positive pregnant women who delivered at the facility in the reporting month: \_\_\_\_\_
- Number of babies who received treatment who are born to syphilis-positive mothers out of total number of syphilis-positive pregnant women who delivered in reporting month: \_\_\_\_\_

Note:

- Health facility will report to District.
- Information will be compiled at district level for forwarding to state.

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Ministry of Health & Family Welfare  
Government of India  
Nirman Bhawan, New Delhi-110011  
Website: [www.mohfw.gov.in](http://www.mohfw.gov.in) & [www.nhm.gov.in](http://www.nhm.gov.in)