

Regional strategy for the
elimination of
congenital syphilis



**World Health
Organization**

Regional Office for South-East Asia

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WHO Library Cataloguing-in-Publication data

World Health Organization, Regional Office for South-East Asia.

Regional strategy for the elimination of congenital syphilis.

1. Syphilis, Congenital – prevention and control - epidemiology. 2. Infant Mortality – prevention and control. 3. Syphilis Serodiagnosis – methods - statistics and numerical data. 4. International Agencies. 5. South-East Asia.

ISBN 978-92-9022-346-7

(NLM classification: WC 161)

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Printed in India

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Acronyms and abbreviations

ANC	antenatal care
CBO	community-based organization
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
ICS	immunochromatographic strip (test)
Ig	immunoglobulin
INGO	international nongovernmental organization
MCH	maternal and child health
MDG	Millennium Development Goal
MSM	men who have sex with men
MSW	male sex worker
MTCT	mother-to-child transmission (of HIV)
NGO	nongovernmental organization
PCR	polymerase chain reaction
PMTCT	prevention of mother-to-child transmission (of HIV)
RPR	rapid plasma reagin (test)
RTI	reproductive tract infection
SEAR	South-East Asia Region
SEARO	Regional Office for South-East Asia
SRH	sexual and reproductive health
STI	sexually transmitted infection
TPHA	<i>Treponema pallidum</i> haemagglutination assay
TPPA	<i>T. pallidum</i> particle agglutination assay
VDRL	Venereal Disease Research Laboratory (test)
WHO	World Health Organization

Preface

Every year, 12 million people are infected with syphilis globally. Pregnant women with syphilis can transmit the infection to their fetus, causing congenital syphilis. In addition, maternal syphilis can also lead to other serious adverse outcomes of pregnancy such as stillbirth or spontaneous abortion, low birth-weight babies or serious infections that are associated with an increased risk of perinatal death. The true global burden of congenital syphilis is not known. In the South-East Asia Region (SEAR), reliable data on maternal and congenital syphilis are not available due to inadequate surveillance and reporting.

Although congenital syphilis is a global health priority, very little attention is being paid to address this problem by countries. Around 70% of pregnant women in SEAR access antenatal services at least once. There are simple, inexpensive and reliable point-of-care diagnostic tests that can be used to screen pregnant women for syphilis. Penicillin, which is the drug of choice to treat syphilis in adults and children, is cheap, off-patent and is included in the WHO list of Essential Medicines. Scaling up of services for prevention of mother-to-child transmission of HIV in antenatal settings in SEAR countries provides an ideal opportunity for routine testing for both syphilis and HIV. It is, therefore, imperative that we use the available opportunities and tools to prevent and possibly eliminate congenital syphilis.

The Regional strategy for the elimination of congenital syphilis builds on the 2007 *Global elimination of congenital syphilis: rationale and strategy for action*. It outlines the guiding principles, and key strategies and interventions to achieve the goal of eliminating congenital syphilis. The *Regional strategy* also proposes initial targets and indicators both at the regional and country levels. It is possible that some targets and indicators may need revision as countries are due to launch elimination programmes at different times.

WHO will support Member countries to plan, implement, monitor and evaluate programmes for the elimination of congenital syphilis (ECS).

This publication is intended to provide technical guidance to ministries of health in Member countries to implement ECS programmes. I am confident that Member countries will find the *Regional strategy* both relevant and useful. The successful implementation of a programme to eliminate congenital syphilis would also contribute to achieving three important Millennium Development Goals – reduce child mortality, improve maternal health and combat HIV/AIDS.

Dr Jai. P. Narain
Director, Communicable Diseases
WHO SEARO



Regional strategy for the
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Introduction

Worldwide, sexually transmitted infections (STI) are one of the major causes of morbidity and mortality among men, women and children. They cause infertility, ectopic pregnancy, stillbirth, cancer and congenital infections. Globally, around 340 million cases of curable new STI occur every year.¹ Of these, syphilis accounts for an estimated 12 million cases, 2 million of them among pregnant women. However, due to the absence of active surveillance, an accurate assessment of the magnitude of syphilis in pregnancy has yet to be made.

The seroprevalence of maternal syphilis varies among the regions of the World Health Organization (WHO). Region-wise estimates are given below:

American Region	3.90%
African Region	1.98%
European Region	1.50%
South-East Asia Region	1.48%
Eastern Mediterranean Region	1.11%
Western Pacific Region	0.70%

Syphilis in pregnant women can result in adverse outcomes of pregnancy in up to 80% of cases, such as stillbirth and spontaneous abortion (40%), perinatal death (20%), and serious neonatal infections and low-birth-weight babies (20%).² There is a paucity of data on adverse outcomes due to untreated syphilis in pregnancy in the South-East Asia Region (SEAR). Similarly, data on the incidence of congenital syphilis among liveborn

infants are also limited due to many reasons, including difficulties in diagnosis, asymptomatic infections and absence of surveillance or reporting systems in the Region.

The 2000 Global Burden of Disease estimates attributed 1.3% of deaths among children under the age of 5 years to congenital syphilis.³ The annual global number of cases of congenital syphilis is estimated to be between 713 600 and 1 575 000.⁴ More newborn infants are affected by congenital syphilis than any other infection including human immunodeficiency virus (HIV) and tetanus. The morbidity and mortality due to congenital syphilis is much higher than that due to mother-to-child transmission (MTCT) of HIV, yet syphilis has not received the same attention as HIV. This is mainly due to inadequate political commitment and insufficient national and international awareness of the burden of congenital syphilis.

Laboratory tests are available for the diagnosis of syphilis and are not expensive. Syphilis can be treated with an effective drug, penicillin, which is also used for the prevention of congenital syphilis. Penicillin is off-patent, cheap and included in the WHO list of essential drugs.⁵ Resistance to penicillin is not a known problem. Yet, congenital syphilis remains a significant public health problem and causes a high burden of disease in many countries of the Region.

In order to eliminate congenital syphilis, increased awareness about the extent and gravity of syphilis is required at all levels of the health services, supported by high-level commitment. The community, especially pregnant women, needs to be made aware of the extent and consequences of syphilis and the need for early antenatal care (ANC) and treatment. Elimination of congenital syphilis (ECS) is feasible by:

- Providing ANC to pregnant women
- Screening pregnant women for syphilis
- Treating seropositive women and their partners, and
- Treating newborn infants of seropositive women.

ECS will reduce spontaneous abortions, miscarriages, stillbirths, pre-term and low-birth-weight infants, and perinatal deaths, and will thus reduce morbidity and mortality in women and children. However, the potential for congenital transmission remains high as long as syphilis is prevalent among adults. ECS will contribute to the achievement of the following three Millennium Development Goals (MDGs) on maternal and child health (MCH) and on HIV/AIDS:

MILLENNIUM DEVELOPMENT GOALS

Interventions for ECS will contribute to achieving the following three MDGs:

- **MDG 4—REDUCE CHILD MORTALITY**

Reduced incidence of low birth weight, perinatal deaths and congenital syphilis will help reduce the mortality rates among children below five years of age.

- **MDG 5—IMPROVE MATERNAL HEALTH**

Fewer stillbirths and spontaneous abortions will help improve maternal health. Increase in access to ANC will also improve maternal health in general. Education and counselling will help in controlling other STI including HIV, and treatment of partners will prevent reinfection, thus leading to improved maternal health.

- **MDG 6—COMBAT HIV/AIDS, MALARIA AND OTHER DISEASES**

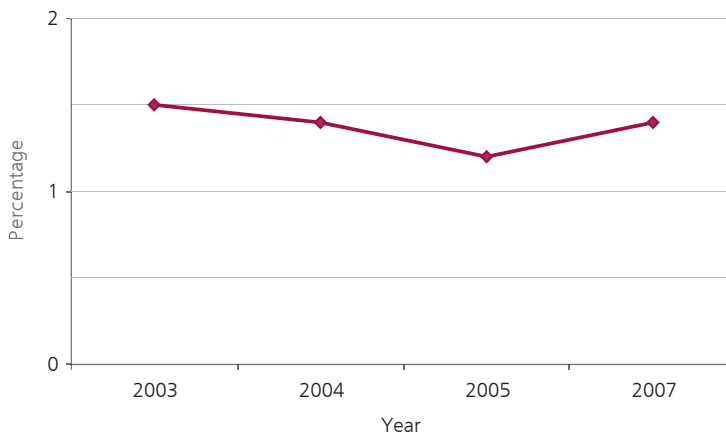
Women screened for syphilis can be counselled and tested for HIV and treated as necessary, thus helping in the prevention of mother-to-child transmission (PMTCT) of HIV. Treatment of syphilis and other STI in women will also reduce the risk of HIV transmission.

ECS is one of the initiatives envisaged in the *Regional strategy for the prevention and control of sexually transmitted infections, 2007–2015* of the WHO Regional Office for South-East Asia (SEARO).⁶ This Regional strategy for the elimination of congenital syphilis is a regional adaptation of WHO's *The global elimination of congenital syphilis: rationale and strategy for action*.⁷ Deliberations at an informal consultative meeting on ECS attended by national experts and WHO staff held at SEARO on 7–8 October 2008 have also contributed to the preparation of this Regional strategy.⁸ This document is aimed at various stakeholders concerned with ECS including national policy-makers, programme officials, nongovernmental organizations (NGOs), international nongovernmental organizations (INGOs), community-based organizations (CBOs), multilateral and bilateral donor agencies, and United Nations agencies.

Data on the incidence and prevalence of STI in the South-East Asia Region (SEAR) are limited.⁸ Available data indicate a declining trend of some of the curable STI in a few countries of the Region.

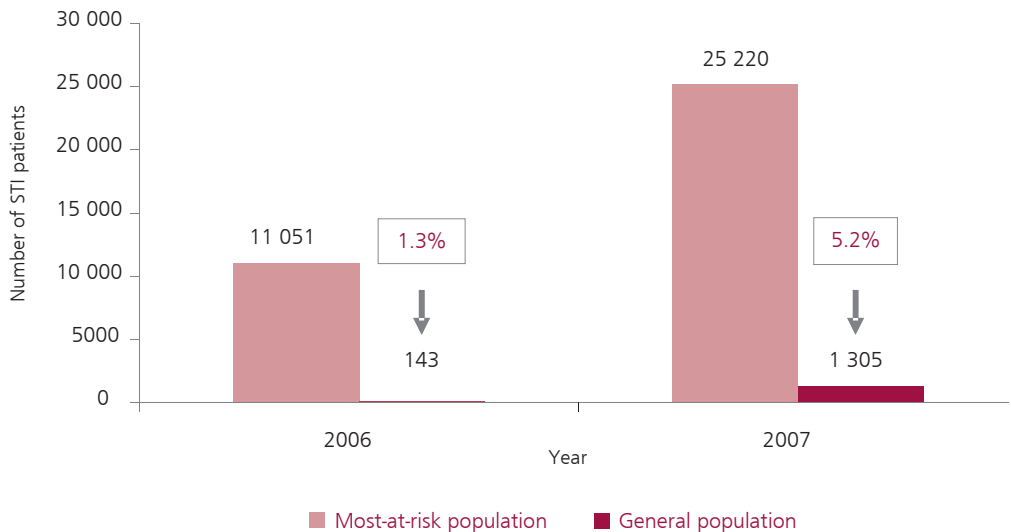
In India, there were an estimated 30 million episodes of STI/reproductive tract infections (RTI) in 2002. Youth 15–24 years of age accounted for 20% of these episodes. In 2007, approximately 1.82 million patients attended STI clinics in the public sector and about 523 000 were diagnosed with STI. A vast majority of patients with STI seek care from the private sector or non-formal sector leading to a gross underestimation of the actual number of cases in the country. There is routine screening of pregnant women for syphilis at the district and higher levels. Available information indicates that the prevalence of maternal syphilis has remained at around 1.5% from 2003 to 2007 (Figure 1).

Figure 1. Prevalence of syphilis among antenatal attendees, India, 2003–2007



In Indonesia, among 47 clinics in eight provinces, the number of STI cases among most-at-risk populations increased from 11 051 in 2006 to 25 220 in 2007 (Figure 2). The corresponding numbers for the general population were 143 and 1305. Syphilis accounted for about 7% of these cases. The policy of screening pregnant women for syphilis was revitalized after a gap of 10 years in 2008. In 2007, during a two-month trial in 15 health centres and three hospitals of four districts, 2805 pregnant women attended antenatal clinics during the first trimester. Of these, 2332 (83%) were offered testing for syphilis. Of these 2332 women, 1652 (71%) were actually tested and 24 (1.45%) were found to be positive. A further 6442 pregnant women attended the clinic for the first time during the later stages of pregnancy, of whom 988 were tested and 28 (2.83%) were found to be positive. Overall, 2640 pregnant women were tested and 52 (1.97%) were found to be positive. The syphilis positivity rate varied from 1.23% to 4.07% in the districts.

Figure 2. Number of STI patients from 47 clinics in eight provinces of Indonesia



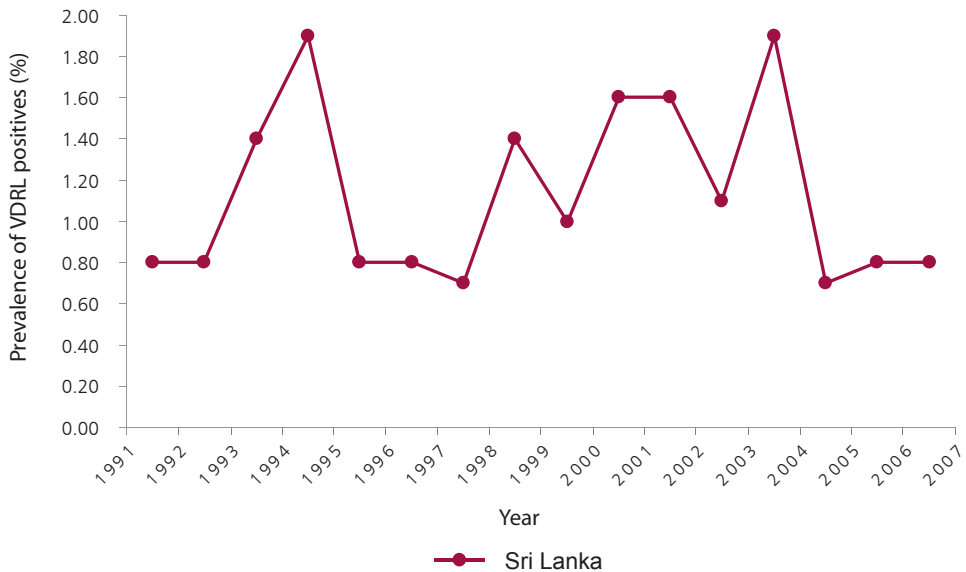
In Nepal, the prevalence of STI is much higher among female sex workers (FSW) and male sex workers (MSW) than among the general population. In a study carried out in 2004, the prevalence of syphilis was 2.4% among MSW and 1.5% among men who have sex with men (MSM). In another study carried out in 2006 among FSW in seven districts, the prevalence of syphilis ranged from 0% to 10.6%. The prevalence of syphilis among FSW seems to have declined over the past ten years. Nepal has one of the highest maternal mortality rates in the world (539 per 100 000 live births). About two thirds of these deaths occur during home deliveries. Approximately 90% of the deliveries take place at home and only 18% of these are assisted by a trained health worker.

About three quarters of pregnant women seek ANC at least once during pregnancy. In urban areas, only 16% of pregnant women attend antenatal clinics four times during pregnancy. Routine screening of pregnant women for syphilis is limited to a few hospitals where about 15% of the women are screened. The prevalence of syphilis among pregnant women ranged from 1% to 4% in these hospitals. Very few of the patients who test positive for syphilis are treated with an injection of benzathine penicillin owing to the lack of trained staff who can test for allergy and manage anaphylaxis. Spontaneous abortion and stillbirth are not uncommon in rural areas.

In Sri Lanka, due to sustained efforts, the prevalence of STI has declined significantly and has remained low over the years. Routine screening of pregnant women for syphilis began in 1951. Nearly 60% of pregnant women get their Venereal Disease Research Laboratory (VDRL) tests done in the private sector. Irrespective of the source of VDRL testing, the coverage of screening for syphilis among pregnant women is over 90%. The prevalence of maternal syphilis has remained low and varied from 0.06% to 0.6% during the period 2002–2007. The VDRL positivity rate among pregnant women varied between 0.8% and 1.8% (Figure 3). The reported number of cases of congenital syphilis has remained low over the past ten

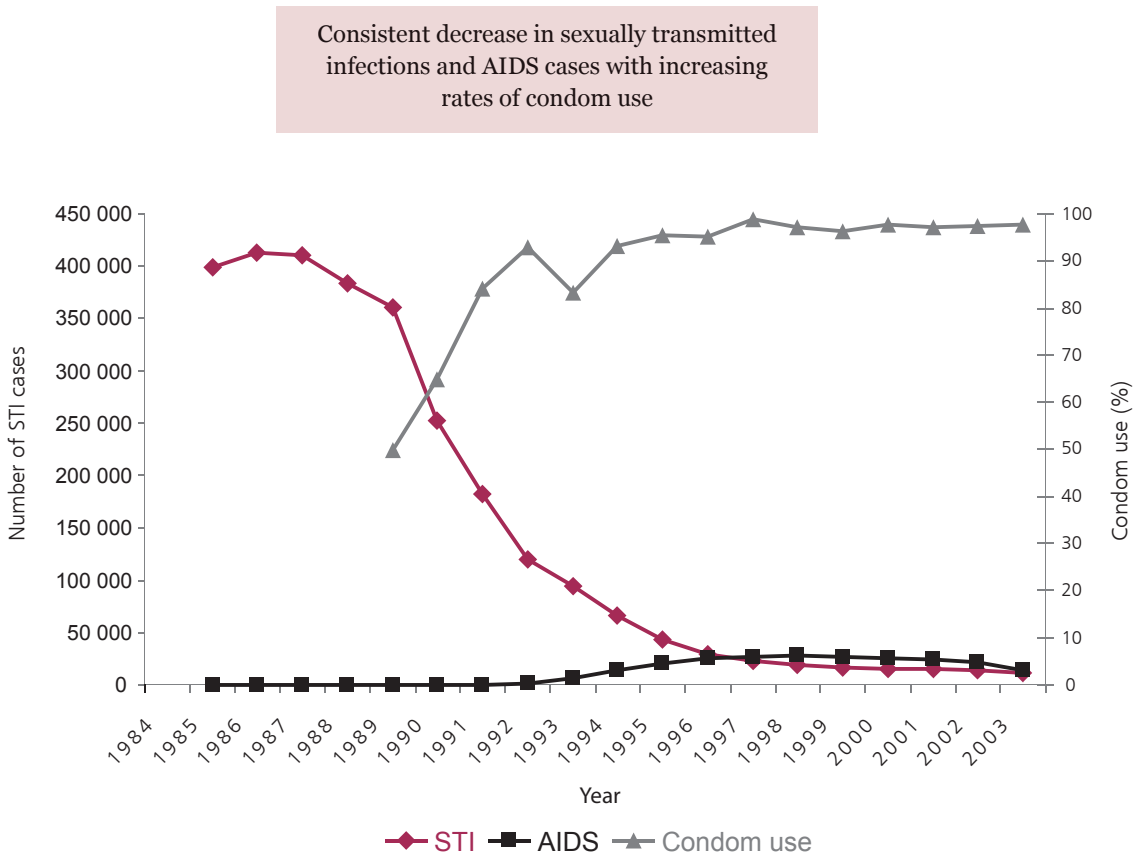
years (1997–2007) at less than 25 cases per year, but it is believed that this might not reflect the true number of cases because of underdiagnosis, underreporting and incomplete reporting.

Figure 3. VDRL positivity rate among antenatal attendees, Sri Lanka, 1991–2007



In Thailand, intensive prevention and control efforts began in the early 1990s. Interventions such as counselling and testing, treatment, and promotion and use of condoms have resulted in a remarkable decline in the incidence of STI. New cases of STI decreased from 200 000 to less than 10 000 per year (Figure 4). However, among youth, the incidence of STI has increased from 1–2% to up to 10%. This is supported by the findings of behavioural surveillance surveys. Nearly half of the students and one third of the girls reported having had sex. Only about 50% of them had used condoms during sex. About 98–99% of pregnant women attend antenatal clinics. They are routinely screened for syphilis and are offered counselling and testing for HIV under the PMTCT programme, and about 85% return for the test results. The prevalence of maternal syphilis has also decreased from 2% to 0.1–0.2%.

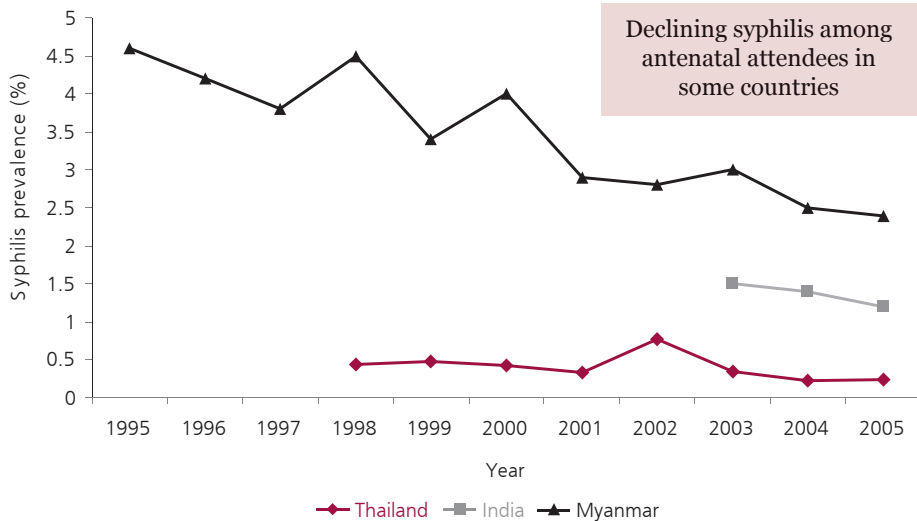
Figure 4. Impact of implementation of the 100% Condom Use Programme on the incidence of sexually transmitted infections (STI) and AIDS, Thailand, 1985–2003



Reliable data on maternal and congenital syphilis are limited to a few countries in the Region.⁸ Based on the available information, the number of pregnant women seeking ANC at least once during pregnancy ranges from 50% to over 95% in the countries of the Region. Screening of pregnant women for syphilis varies from 5% to 95%. According to available data, the prevalence of maternal syphilis is estimated to vary from 0.2% to 4.3% with an overall prevalence of 1.48%, and there are an estimated 446 900 cases of congenital syphilis every year. While maternal syphilis is showing a declining trend in a few countries of the Region (Figure 5), the number

of seropositive women treated varies from 10% to 60%. The number of partners of seropositive women treated varies from 10% to 20% and there are no data on the treatment of babies born to seropositive women.

Figure 5. Syphilis prevalence among antenatal attendees, South-East Asia, 1995–2005



All countries in SEAR have a national STI control plan and two countries, Myanmar and Sri Lanka, have a national ECS plan. Universal screening of pregnant women for syphilis has been promoted in a number of countries but actual implementation is variable and reports are incomplete in many countries. Rapid tests for syphilis are available in Myanmar, Sri Lanka and Thailand. Confirmatory tests are done in Sri Lanka and Thailand, and the result of the confirmatory test is required for treatment only in Sri Lanka. On-site treatment is available in India and Myanmar. However, same-day treatment is not available in any country of the Region.

STI programme indicators are collected in Myanmar and Sri Lanka. In Myanmar, the indicator used is the number of pregnant women with a reactive VDRL test. The indicators used in Sri Lanka are: (i) VDRL coverage among pregnant mothers, (ii) number reported as VDRL positive, and (iii) number of antenatal clinics collecting blood for VDRL.

Although diagnostic tests are available to screen women for syphilis, and an effective and inexpensive drug for treatment, adequate attention has not been paid to ECS. As a consequence, congenital syphilis remains a public health problem. Several factors are responsible for this state of affairs.

- In resource-constrained countries, there is usually very low or no priority accorded to surveillance for maternal and congenital syphilis, leading to underrecognition of the magnitude of the problem and consequent lack of policy and inadequate allocation of resources for ECS.
- There is a lack of adherence to policy even where it exists, leading to poor coverage of pregnant women with screening.
- There is a lack of clarity regarding roles, responsibilities and accountability for ECS among various programmes such as STI, HIV/AIDS and MCH.
- There is poor coverage and late attendance of pregnant women for ANC, and poor coverage of newborn care in many developing countries. Only about 68% of pregnant women attend antenatal clinics in developing countries and many of them seek care late in pregnancy, the average time at first attendance being five to six months.⁹ Lack of resources for screening and treatment, and lack of awareness among the community

about the need for screening contribute to non-seeking or delayed seeking of ANC by pregnant women.

- There is a lack of male participation in improving MCH.
- The health system is not well developed at the primary health-care level in many countries, leading to poor quality of services in health-care facilities. Lack of trained staff, guidelines, drugs and equipment, and awareness among health-care providers about the importance of routine screening of pregnant women and the consequences of maternal syphilis are factors that contribute to the poor coverage.
- Many seropositive women are reluctant to divulge the names of their partners for fear of retribution. Even when the partners are known, there is usually no system in place to trace and treat them. In many cultures, women do not like to talk about pregnancy, especially during the early period. Stigma attached to STI and lack of confidentiality in the clinics further compound the issue.
- There is often a lack of monitoring and evaluation, which are essential for planning/replanning and implementing interventions.

Cost-effectiveness

Though there are challenges to eliminating congenital syphilis, it has been shown that it is feasible and cost-effective. A number of studies have been carried out to assess the cost-effectiveness of screening pregnant women for syphilis.^{10–12} These studies indicate that screening is cost-effective and cost-saving even when the prevalence of syphilis is considerably lower than 1%. This is true for developed countries as well, where the cost of providing care for congenital syphilis is very high. Economic analysis studies carried out in sub-Saharan Africa indicated that screening is highly cost-effective even at a relatively low level of prevalence, e.g. 1%;^{11–13} the cost of averting a case of congenital syphilis ranged from US\$ 50 to US\$ 177.¹³ In Thailand, a cost-benefit ratio of 2.8 has been estimated even at a prevalence of 0.07%.¹⁴

The tests for syphilis are inexpensive and affordable in most countries of the world. The new rapid tests have made screening even more cost-

effective and cost-efficient. For example, in South Africa where the prevalence of syphilis is 6.3%, the cost of averting a case of congenital syphilis was US\$ 37 with the immunochromatographic strip (ICS) test, US\$ 43 with on-site rapid plasma reagin (RPR) test and US\$ 111 with referral of specimens to the laboratory.¹⁵ The ICS test was the most preferred by both staff and patients. In settings with a high prevalence of maternal syphilis, on-site screening with the ICS test is a cost-effective approach to reduce the incidence of congenital syphilis.

Screening for syphilis could be combined with screening for other infections such as HIV and malaria, thus complementing each other and reducing the cost of counselling, drawing blood and performing tests. In particular, programmes for the prevention of congenital syphilis should be integrated with those for PMTCT of HIV. As long as syphilis is prevalent among adults, the potential for congenital transmission remains high. Therefore, attention should also be paid to the prevention and control of syphilis in adults. Synergy between programmes would consolidate resources, and help strengthen and improve ANC as well.

Goals for the elimination of congenital syphilis

The goal of ECS will be considered to have been achieved when the incidence of congenital syphilis falls below 0.5 per 1000 live births in a country where syphilis screening covers more than 90% of pregnant women. Elimination should be based on evidence, which will require an effective surveillance system supported by adequate diagnostic services.

4.1 Overall goal

The overall goal of the ECS initiative is to ensure that congenital syphilis is no longer a public health problem.

4.2 Specific goal

The specific goal of the ECS initiative is to prevent transmission of syphilis from mother to child and thereby reduce the incidence of congenital syphilis. This can be achieved by the following:

- Early ANC for and universal screening of all pregnant women, and prompt treatment of all seropositive women;
- Treatment of partners of seropositive women, promotion of condom use, and education and counselling to prevent infection/reinfection;
- Prophylactic treatment of all infants born to seropositive women.

Screening is more effective if it is performed on-site early in pregnancy and treatment provided immediately to seropositive women. There is also a

need to prevent reinfection by treating sexual partners and re-screening in late pregnancy.

The ECS programme in countries should be based on the following guiding principles:

Country-based approach

The programme should be based on the perceived needs of the country after considering its sociocultural, epidemiological, and health and ANC situation. The programme should be flexible and adaptable to the local situation.

Integrated approach

The programme should not be vertical. It should be integrated into the existing services, mainly ANC and primary health care. Where appropriate, it can be added on to services for family planning, STI control, adolescent care, and sexual and reproductive health (SRH). Activities for ECS could be combined with those for PMTCT of HIV infection and treatment for malaria, thus complementing each other and improving cost-effectiveness. ECS will also contribute to the control of syphilis in the general population. All stakeholders should be consulted while developing the ECS programme.

Rights-based approach

The ECS programme should ensure the rights of people to information about syphilis infection, including ways to protect themselves from infection, and where to seek services and care. The programme should also

ensure the right of people to seek care and treatment, and to confidentiality of the test results and care.

Partnership and collaboration

There is a need to involve a number of stakeholders in the ECS programme, particularly in situations where resources are limited. They include the health, education, and women and social welfare sectors, NGOs, CBOs and the community. Within the health sector, a number of programmes – STI control, MCH, primary health care, SRH and family planning will have their roles, responsibilities and accountability clearly defined to ensure successful implementation of interventions. Bilateral and multilateral donors including WHO and United Nations agencies will also play a role in the ECS programme. The programme should be developed and implemented in close collaboration with all these partners.

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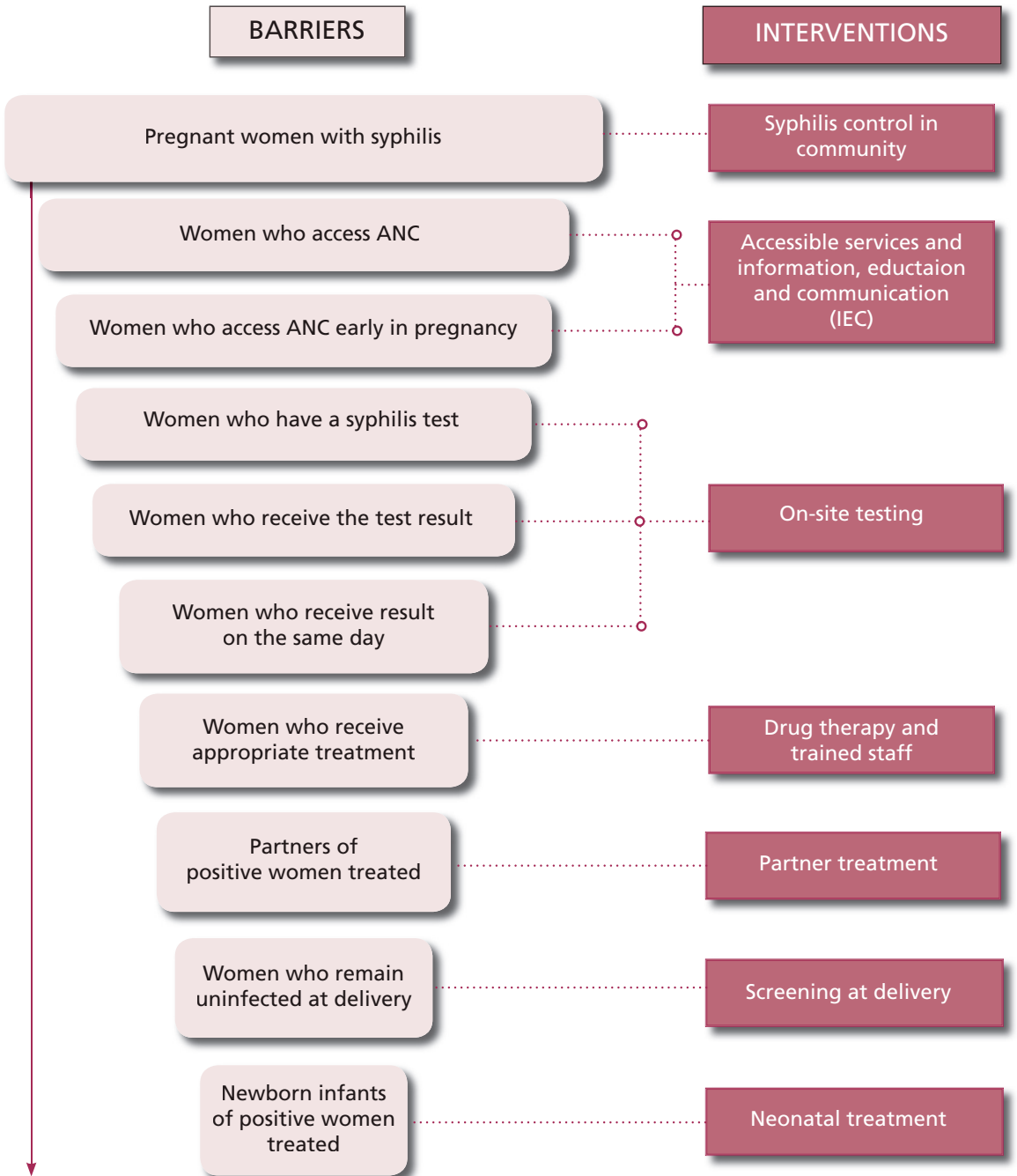
Strategies and interventions

Barriers to implementation of the ECS programme and interventions to remove these barriers are presented in [Figure 6](#). Each box represents a subset of women from the box above it, as there is a barrier that needs to be overcome between each box. The number of women represented in each box varies between countries and medical care settings. Intervention options targeting each of the barriers are listed on the right.

Key elements for an effective ECS programme include advocacy, political commitment and leadership, an adequate workforce, sufficient physical facilities, strengthened system of care, an effective logistics system, community involvement including education to improve ANC-seeking behaviour, advertising the available antenatal services and their benefits to the mother and child, and donor management.

The issue for developing countries is not whether to screen but how to screen most efficiently. This can be done through high-level commitment with allocation of adequate resources and advocacy at all levels. Congenital syphilis can be reduced significantly through ANC early in pregnancy, point-of-care screening of pregnant women for syphilis and treatment of positive women, and presumptive treatment of their partners. Screening and treatment of seropositive women, their partners and newborn infants should be integrated into the ANC services.

Figure 6. Barriers to ECS and interventions to overcome them



The proposed interventions for achieving the goals and objectives of ECS are grouped under the following four key strategies:

1. Ensuring sustained high-level commitment and advocacy
2. Increasing access to, and improving the quality of, MCH services
3. Screening pregnant women and treating seropositive women, their partners and newborn infants
4. Establishing surveillance, and monitoring and evaluation systems.

Strategy 1

Ensuring sustained high-level commitment and advocacy

The commitment of health policy decision-makers and other key stakeholders, such as programme managers, is necessary to ensure that the programme receives adequate political, financial and logistical support.

The main interventions are as follows:

- Secure high-level political commitment and advocacy in order to give high priority to the programme and allocate adequate resources.
- Raise the awareness of decision-makers about the magnitude of the problem of syphilis in pregnant women, and particularly of the adverse outcomes.
- Outline the cost-effectiveness and benefits of the ECS programme, and the importance of early care-seeking in the antenatal period.
- Highlight the importance of integrating the ECS programme with those for ANC, MCH, PMTCT of HIV infection, and STI prevention and control.

National policies, strategies and programmes need to be developed and implemented to eliminate congenital syphilis, supported by commitment at all levels.

Strategy 2

Increasing access to, and improving the quality of, MCH services

Maternal and newborn health services often provide the only opportunity to screen pregnant women for syphilis. Hence, accessibility, use and quality of services are critical if programmes to eliminate congenital syphilis are to succeed.

The main interventions are as follows:

- Increase the awareness of communities regarding syphilis, congenital syphilis and STI, and propagate clear messages regarding the benefits of seeking ANC early in pregnancy, thereby increasing the percentage of pregnant women seeking early ANC. Increase coverage with the involvement of NGOs and CBOs. Target programmes at men to get their support for effective partner management to prevent reinfection.
- Ensure that all pregnant women are screened for syphilis during the first visit and the results of the tests are given promptly.
- Ensure that all seropositive women are treated promptly, and that their partners and newborn infants are also treated.
- Ensure that all women with spontaneous abortion or stillbirth are screened for syphilis, as these events could be adverse outcomes of maternal syphilis during pregnancy.
- Improve the quality of care by training health care and laboratory staff, and making adequate provision for drugs and other supplies.
- Integrate the ECS programme with those for PMTCT of HIV infection, STI prevention and control, and malaria treatment.

In areas where there are no MCH services, a rapid assessment of the situation will be required and a minimum package of interventions identified to prevent congenital syphilis.

Strategy 3

Screening pregnant women and treating seropositive women, their partners and newborn infants

Early detection and treatment of syphilis among pregnant women, their sexual partners and babies are important elements of an ECS programme.

The main interventions are as follows:

- Screen all pregnant women for syphilis during the first visit early in pregnancy, preferably before 16 weeks of gestation, and make the results available promptly.
- Test all pregnant women in high-risk areas at the time of delivery, especially those who were not tested earlier.
- Treat all seropositive women on the same day with at least one single dose of 2.4 million IU of benzathine benzylpenicillin given intramuscularly after excluding allergy to penicillin. In case of allergy, care providers, if trained, should desensitize and then treat positive women, or refer the patient to a higher-level facility.
- Treat all sexual partners of seropositive women.
- Ensure that women are not reinfected through education, counselling, use of condoms and treatment of partners.
- Screen all patients attending STI clinics for syphilis and treat those found to be positive.
- Test all women with a history of an adverse pregnancy outcome for syphilis (abortion, stillbirth, infants with congenital syphilis, etc.).
- Screen all seropositive women for other STI including HIV, and provide counselling and treatment as appropriate.
- Make plans for the care of the baby at birth.
- Carefully examine the infants of seropositive women for congenital syphilis.
- Treat all asymptomatic infants born to seropositive women with a single dose of penicillin and follow up every three months during the first year of life.

- In symptomatic babies, confirm the diagnosis by testing the mother with a rapid test.
- Treat infants with congenital syphilis with parenteral penicillin for 10 days (*see Annex for details*).

Each country should develop its own screening strategies for maternal syphilis, depending on the prevalence of the disease and level of health care available.

Strategy 4

Establishing surveillance, and monitoring and evaluation systems

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

The main interventions are as follows:

- Carry out a rapid assessment to establish baseline data on maternal and congenital syphilis in order to plan interventions, and monitor and evaluate the ECS programme.
- Establish a surveillance system for maternal and congenital syphilis and integrate it into the MCH services. A simple recording and reporting system should be put in place, starting with selected sentinel sites and extending it gradually to the rest of the country. It must, however, be noted that the prevalence of maternal syphilis does not necessarily reflect the effects of the ECS programme. Rather, the prevalence of maternal syphilis reflects the prevalence of syphilis in the community. Accurate surveillance for maternal syphilis is difficult to achieve owing to the possibility of false-positive test results. A combination of treponemal and non-treponemal tests, which may not be available in all ANC facilities, will be required to improve the accuracy of the test results. A practical option to deal with this situation would be to carry out periodic serosurveillance among a representative sample of pregnant

women in the country using both types of tests.

- Develop or strengthen a system for monitoring progress using routinely collected programme indicators. These indicators should be integrated into the monitoring of ANC services and should be practical, useful and not too many. The data should be routinely reported to higher levels where they should be regularly compiled, analysed and reported back to the lower levels.
- Develop and strengthen a system for evaluating the outcomes and determining the effectiveness of the programme using a set of predetermined targets. These targets could include local programme success, rate of congenital syphilis and measurement of one or more of the most important adverse outcomes of pregnancy associated with maternal syphilis.
- Develop indicators for community awareness, ANC attendance, coverage of screening and treatment, and quality of care in order to measure the effectiveness of the interventions.

As a diagnostic test for congenital syphilis is not yet available, indirect indicators will have to be used at present. When such a test becomes available, an indicator may be developed to measure the incidence of congenital syphilis. Until then, the case definition of congenital syphilis may be used for developing indicators.

6.1 At the Regional level

The Regional strategy for ECS will consist of enhancing political commitment and advocacy, mobilizing resources, developing guidelines and training materials, and capacity building.

The strategy at the Regional level will emphasize on the following:

- Development and implementation of a Regional initiative for ECS with the involvement and collaboration of the health sector, other concerned sectors, NGOs, and bilateral and multilateral agencies and donors;
- Collection of strategic information including surveillance, monitoring and evaluation data;

- Development of guidelines and training materials;
- Building the capacity of national programmes for developing and implementing national programmes;
- Mobilization of resources.

6.2 At the country level

The national strategy for ECS should be based on the four strategies and four guiding principles stated earlier. The national programme should build on the existing ANC services and utilize existing health-care providers including those at the field level. Wherever possible, the programme should be integrated with the PMTCT of HIV, STI prevention and control, and other reproductive health services.

Adequate attention should be paid to the development of national guidelines and operational tools, capacity building, mobilization of resources, logistics, surveillance, monitoring and evaluation.

6.3 Requirements

The requirements for ECS at the country level include the following:

- A national policy with sustained commitment at all levels of the health services, and guidelines on the prevention, management and care of maternal and congenital syphilis;
- Strategic information on the epidemiological situation of maternal and congenital syphilis, and interventions being carried out to prevent and control syphilis;
- Effective programme management with advocacy at all levels, financial sustainability and transparency, and clear-cut assignment of roles and responsibilities;
- Access by all women to care during pregnancy, childbirth and the postpartum period;
- Competent health-care providers trained in syphilis prevention, screening during pregnancy, treatment of positive women and their partners, diagnosis of congenital syphilis, prophylactic and curative

treatment of newborn infants, and counselling on the prevention of syphilis and reinfection, including promotion and use of condoms;

- On-site screening in ANC clinics and maternity wards;
- Availability of supplies including diagnostic reagents and penicillin in antenatal clinics, maternity wards and postnatal clinics;
- Quality assurance of laboratory tests;
- A referral system for desensitization of women allergic to penicillin and for the treatment of symptomatic congenital syphilis;
- Health education activities to raise awareness in the community of the primary prevention of syphilis and other STI, adverse outcomes of syphilis during pregnancy, and importance of seeking ANC early in pregnancy for syphilis prevention and treatment. Education should also be provided on the need for treatment of seropositive women, their partners and newborn infants, follow up of seropositive women and infants during the postnatal period, and reduction of stigma and discrimination associated with a positive diagnosis of syphilis;
- An effective surveillance, monitoring and evaluation system.

7.1 Targets

7.1.1 Targets at the Regional level

Tools are available for the diagnosis of syphilis and an effective drug for treatment, thus making ECS feasible. SEARO will work with Member States to eliminate congenital syphilis from the Region by 2020. Elimination will be considered to have been achieved when the incidence of congenital syphilis falls below 0.5 per 1000 live births. As it may not be feasible to start the ECS programme in all countries at the same time, a phase-wise approach will be adopted, beginning with a few countries and scaling up gradually until all the countries are covered.

The following targets have been set for launching the ECS programme in the Region:

TARGETS FOR LAUNCHING THE ECS PROGRAMME

2009 India, Indonesia, Sri Lanka and Thailand

2010 Bangladesh, Maldives, Myanmar, Nepal

2011 Bhutan, DPR Korea, Timor-Leste

The following targets have been set for eliminating congenital syphilis in the Region:

TARGETS FOR ELIMINATING CONGENITAL SYPHILIS

2015 Sri Lanka and Thailand

2020 Bangladesh, Bhutan, DPR Korea, India, Indonesia, Maldives, Myanmar, Nepal and Timor-Leste

7.1.2 Targets at the country level

Each country will set its own targets for ECS. The following national targets are suggested for 2015 for Sri Lanka and Thailand, and for 2020 for the remaining countries of the Region:

- Screening of pregnant women for syphilis at least once: >90%;
- Prevalence of maternal syphilis to be reduced to <1% or half of the existing rate, whichever is lower;
- Proportion of positive pregnant women treated: >90%;
- Proportion of partners of positive pregnant women treated: >80%;
- Proportion of newborn babies of positive women treated: >80% (90% for those who deliver at health facilities).

7.2 Indicators

7.2.1 Regional indicators

The indicators for measuring the achievement of the above targets would be:

- a) Number of countries that have launched the programme by 2009, 2010 and 2011
- b) Number of countries that have achieved elimination by 2015
- c) Number of countries that have achieved elimination by 2020

7.2.2 National indicators

The indicators for measuring the achievement of the above targets will be as follows:

- Key/core indicators
 - Proportion of pregnant women screened for syphilis at least once during pregnancy
 - Proportion of positive pregnant women treated
- Additional indicators
 - Proportion of partners of positive pregnant women tested and treated
 - Proportion of newborn babies of positive women treated
 - Proportion of pregnant women seeking ANC at least once during pregnancy
 - Proportion of pregnant women seeking ANC four or more times during pregnancy.

Additional indicators in the form of input, output and outcome indicators will be developed in detail at the country level. Examples of these indicators are given below.

Input indicators

- Existence of a national policy, guidelines and plans on ECS
- Proportion of health-care facilities with ANC facilities where on-site screening for syphilis is available
- Proportion of antenatal clinics with an adequate supply of penicillin for the treatment of syphilis
- Proportion of antenatal clinics with skilled staff to perform on-site screening and provide treatment.

Output indicators

- Proportion of positive women treated appropriately
- Proportion of pregnant women attending antenatal clinics screened for syphilis

- Proportion of partners of positive women treated
- Proportion of newborn babies of positive women given prophylactic treatment
- Proportion of babies with symptoms of congenital syphilis appropriately treated.

Outcome indicators

- Incidence of congenital syphilis
- Perinatal and neonatal morbidity and mortality due to congenital syphilis
- Stillbirth rate
- Prevalence of maternal syphilis.

8.1. Role of WHO

8.1.1 Role of WHO at the Regional level

At the Regional level, WHO will strengthen links within the Organization and coordinate with other UN agencies, donors, NGOs and other partners. WHO will take a leading role in providing technical support to Member countries.

WHO will:

- Advocate for high-level commitment and allocation of priority to ECS, and adequate resources by raising awareness about and highlighting the cost-effectiveness of ECS;
- Develop guidelines, protocols and tools for implementing, monitoring and evaluating the programme;
- Build the capacity of countries to launch the ECS programme;
- Provide technical support to countries to implement, monitor and evaluate the programme;
- Promote integration of the ECS programme with PMTCT of HIV, and STI prevention and control programmes;
- Mobilize resources;
- Form a Technical Working Group to review technical issues, provide updates, and recommend certification of elimination.

8.1.2 Role of WHO at the country level

At the country level, WHO will provide support to countries:

- To raise awareness about the problem of congenital syphilis and promote early seeking of ANC by pregnant women;
- To conduct an assessment of the situation, determine the burden of maternal and congenital syphilis, and identify needs and gaps;
- To identify populations and areas that need greater attention;
- To prepare plans and strategies for ECS;
- To implement programmes for ECS;
- To provide training to health workers in implementing the ECS programme;
- To develop an effective management system including human resources, logistics and financial management;
- To ensure integration of the ECS programme into the MCH services, PMTCT of HIV infection, and STI prevention and control programmes;
- To develop and implement a system for surveillance, supervision, monitoring and evaluation of the programme;
- To encourage collaboration among various partners;
- To mobilize resources.

8.2 Role of countries

It is the responsibility of countries to plan, implement, monitor and evaluate the programme for ECS. In this context, countries will:

- Formulate a policy on a priority basis for ECS and allocate adequate resources;
- Include the ECS programme in the national health plan;
- Secure sustained commitment at all levels to ensure that the required resources are allocated for ECS;
- Raise awareness in the community about congenital syphilis and encourage all pregnant women to seek early ANC;
- Integrate ECS into the MCH services, PMTCT of HIV infection, and STI

- prevention and control programmes;
- Conduct an assessment of the situation to obtain baseline epidemiological data and identify needs and gaps in order to prepare plans and monitor and evaluate the programme;
 - Manage the programme effectively by addressing issues related to advocacy at all levels, availability of human resources, an efficient logistics system and financial sustainability;
 - Through training, provision of guidelines and supervision, build the capacity of health workers to diagnose maternal and congenital syphilis, treat positive women, their partners and newborn infants, treat babies with congenital syphilis, and provide education and counselling;
 - Mobilize communities including health volunteers and traditional birth attendants (wherever they exist) to refer pregnant women to antenatal clinics for care and syphilis screening;
 - Develop a surveillance system including recording and reporting of cases;
 - Incorporate monitoring and evaluation as an integral part of the programme.

8.3 Role of the community

Communities have an important role to play in the successful implementation of the ECS programme. Without their participation, elimination will be difficult to achieve. Efforts should be made

- To raise awareness and understanding of maternal syphilis and its adverse outcomes in the community;
- To encourage pregnant women to seek early ANC;
- To ensure treatment of positive women, their partners and newborn infants;
- To reduce the stigma and discrimination associated with syphilis;
- To promote primary prevention of syphilis and other STI among adults;
- To address issues related to the beliefs and practices of women and

the community about MCH, particularly maternal syphilis, the stigma associated with STI, role of men as motivators or barriers to seeking health care, and the dynamics of household decision-making and preferences for ANC;

- To build on already existing community participation efforts such as those for HIV/AIDS and expand the focus to include ECS.

Participation of the community is important for compliance with the recommended behavioural changes and acceptance of health programmes.

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Treponema pallidum, the bacterium that causes syphilis, can be transmitted from the blood of a pregnant woman to the fetus. Fetal infection usually occurs through placental transfer or at delivery. The more recent the infection, the more likely that the infant will be affected.¹ The transmission rate is higher in the early stages of syphilis (known as early syphilis) than in the late stages (known as late syphilis), and can reach up to 80% in early syphilis. Most infants born to mothers with late syphilis are uninfected.¹ Transmission usually takes place between the 16th and 28th weeks of pregnancy, although it can take place during other periods too, as *Treponema pallidum* can cross the placenta at any time during pregnancy.

Adverse outcomes of untreated maternal syphilis can occur in up to 80% of cases. These include stillbirth, spontaneous abortion, perinatal death, low birth weight and neonatal infection with syphilis. Based on various models, the global annual number of cases with congenital syphilis has been estimated to range from 713 600 to 1 575 000.²

Following infection with syphilis, blood tests can take 10–45 days to become positive, depending on the test that is used. Therefore, if the first test is negative, it does not guarantee the absence of infection and should ideally be repeated later during pregnancy or at the time of delivery, particularly in countries with a high prevalence of syphilis or if the mother is considered to be at high risk for STI. Testing at the time of delivery will

also be required to detect reinfection, particularly in women whose partners were not treated or if no test was done in the past.

Signs and symptoms

Congenital syphilis may be asymptomatic, especially in the first weeks of life, in about 50% of cases. Usually, symptoms appear in the first 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%), blistering skin rash (40%), fever (16%), low birth weight (10–40%), bleeding (10%), swelling of the joints, abnormal facies, oedema, abdominal distension, pallor, respiratory distress and pseudoparalysis.^{3–5} Case fatality rates for symptomatic congenital syphilis have been reported to vary between 15% and 38% in sub-Saharan Africa.^{5,6}

Case definition of congenital syphilis

Congenital syphilis is not easy to diagnose in all cases. The commonly available serological tests that are based on the detection of immunoglobulin G (IgG) are not useful because of the passive transfer of maternal antibodies. Signs and symptoms of congenital syphilis may not appear in the first weeks of life in about 50% of cases. Facilities for the clinical diagnosis of congenital syphilis may not be adequate at the primary health-care level. A case definition of congenital syphilis does not exist in many countries. Where it exists, it may vary from country to country. While countries can choose their own case definition, the following are suggested for consideration in making a decision.

Case definition 1

Congenital syphilis is defined as a liveborn infant with clinical evidence of syphilis (one major and two minor criteria) born to a mother with syphilis (clinical or seropositive) who has not been treated or was inadequately treated.

MAJOR CRITERIA	MINOR CRITERIA
Swelling of the joints	Hepatosplenomegaly
Bullous skin lesions	Jaundice
Snuffles	Anaemia
	Radiological changes in the long bones

Case definition 2

Congenital syphilis is defined as an asymptomatic, liveborn baby, born to a woman positive for syphilis, whose serological titre of the non-treponemal test is at least fourfold higher than that of the mother or who remains seroreactive beyond four months after birth or is positive for IgM antibodies.

Case definition 3

Congenital syphilis is defined as a liveborn infant, stillbirth or fetal loss born to a mother:

- with clinical evidence of syphilis and/or
- who has a positive immunochromatographic strip (ICS) test or a reactive non-treponemal test confirmed by a treponemal test carried out in the prenatal period or during delivery, and
- who has not been treated or was inadequately treated (not completed treatment according to the stage of syphilis or treated with non-penicillin regimens or treated less than four weeks before delivery)
- in whom treatment was not documented.

Management

Diagnosis of maternal syphilis

A number of serological tests are available for the diagnosis of syphilis. Traditionally, the tests are done in two steps. First, a non-treponemal screening test is done to detect reaginic antigen. Examples are the Venereal Diseases Research Laboratory (VDRL) test and rapid plasma reagin (RPR) test. If the first test is positive, a second or confirmatory treponemal test, using an antigen of *T. pallidum*, is carried out. Examples are the *T. pallidum* haemagglutination assay (TPHA) and *T. pallidum* particle agglutination assay (TPPA). A combination of the two types of tests is recommended.

The advantages of the non-treponemal tests are that they are inexpensive and sensitive, especially in early infection. They can differentiate between recent and old, treated infections. However, non-treponemal tests are non-specific and can give false-positive results. Up to 28% of positive RPR results in pregnant women have been found to be false positive.⁷ Therefore, where feasible, a positive non-treponemal test should be confirmed by a treponemal test.

The treponemal tests are specific for *T. pallidum* but they can also give false-positive results. They cannot differentiate between active (untreated) infection and old, treated infection. The traditional treponemal tests, TPHA and TPPA, require a laboratory equipped with expensive equipment and technical expertise, which is not usually available in primary health-care facilities.

Rapid, simple treponemal tests using ICS use whole blood, do not need equipment or special storage conditions and require minimal training. These are now available and can be used on-site including in peripheral areas. They have sensitivities of 85–98% and specificities of 92–98%. Their sensitivity is higher than that of RPR while the specificity is comparable.

It must, however, be noted that the sensitivities of the ICS tests are low in low-titre syphilis (e.g. RPR titre <1:8). They cost US\$ 0.93–1.44 per woman screened. Although these tests are more expensive than the earlier standard tests, the new tests are in fact more cost-effective because more women can be tested and treated in a timely manner, thus preventing more cases of congenital syphilis. However, they cannot differentiate between active infection and past treated infections, as the treponemal antibodies persist for years, and are also not useful for monitoring the effectiveness of treatment.

Newer diagnostic tests, such as enzyme immunoassays (EIAs), immunoblots and polymerase chain reaction (PCR) are now available but they are expensive and require a well-equipped laboratory and hence may be off-limits for developing countries.

All women found to be positive for syphilis should be encouraged to undergo testing for HIV as well, because the risk factors for HIV and syphilis are the same.

Diagnosis of congenital syphilis

Diagnosis of congenital syphilis in infants is not easy owing to the clinical similarity with other congenital diseases and the limitations of diagnostic tests. All infants born to seropositive mothers should be examined for clinical evidence of congenital syphilis; in particular, infants born to seropositive untreated, inadequately treated or lately treated mothers. Seropositivity of the mother and the presence of signs, even nonspecific ones such as fever, low birth weight or skin lesions, may point to a diagnosis of congenital syphilis.

Because of the passive transfer of maternal antibodies to the fetus, qualitative serological tests based on IgG are not recommended for the diagnosis of syphilis in an infant born to an infected mother. Where feasible, quantitative non-treponemal tests (RPR or VDRL) should be

performed, although they have their own limitations, particularly in developing countries. An RPR/VDRL titre which is four times greater in an infant than that in the mother suggests congenital syphilis. Serum from the neonate is the preferred specimen, since cord blood may give false-positive results.

Maternal IgM does not cross the placental barrier. IgM in the infant can be detected by the fluorescent treponemal antibody absorption test (FTA-ABS) or IgM enzyme-linked immunosorbent assay (ELISA) tests and its presence is indicative of syphilis infection. IgM can be detected in more than 80% of symptomatic infants. However, false-positive results may occur and the test remains positive for some time even after successful treatment. The test is expensive and is not available in most developing countries.

Treatment of maternal syphilis

All women who test positive for syphilis should be treated to avoid missing any case of congenital syphilis, although it may result in some overtreatment because of false-positive results. If a quantitative test is done, a titre that is equal to or higher than 1:8 is a definite indication for treatment. Treatment of syphilis in adults is simple and effective. Treatment depends on the stage of the infection. In the early stages, a single intramuscular injection of 2.4 million IU benzathine benzylpenicillin is sufficient. Allergy to penicillin should be excluded before giving the full dose. In case of allergy, patients should be referred to an appropriate centre for desensitization. In the later stages, three weekly doses may be required. Whatever the stage of infection, even a single dose of penicillin will prevent infection in the fetus. Adequate treatment with penicillin will end infectivity within 24–48 hours. The RPR/VDRL titre decreases fourfold six months after treatment. The rate of seroreversion depends on the pretreatment titre and stage of disease.^{3,8}

Treatment should be provided early in pregnancy, preferably during the first trimester but definitely before the third trimester. A simple rule is to

treat as soon as the test for syphilis is found to be positive. The earlier the result of the test is available and treatment started, the better it is. Hence, new rapid tests that can be performed on-site and provide the results immediately are more effective than earlier tests whose results can be made available on subsequent visits only. Thus, the rapid tests will prevent the loss of patients to follow up. Presumptive treatment should be provided to all women who test positive with the rapid tests so that no case of maternal infection is missed. The risk of overtreatment, i.e. treatment of women with false-positive results, does exist but is outweighed by the benefits of expanded screening coverage. Pregnant women should be retested during the third trimester where indicated and closer to delivery in order to detect reinfection. Partners of seropositive women should also be treated in order to prevent reinfection.

A flowchart for the management of maternal syphilis is given in [Figure 7](#).

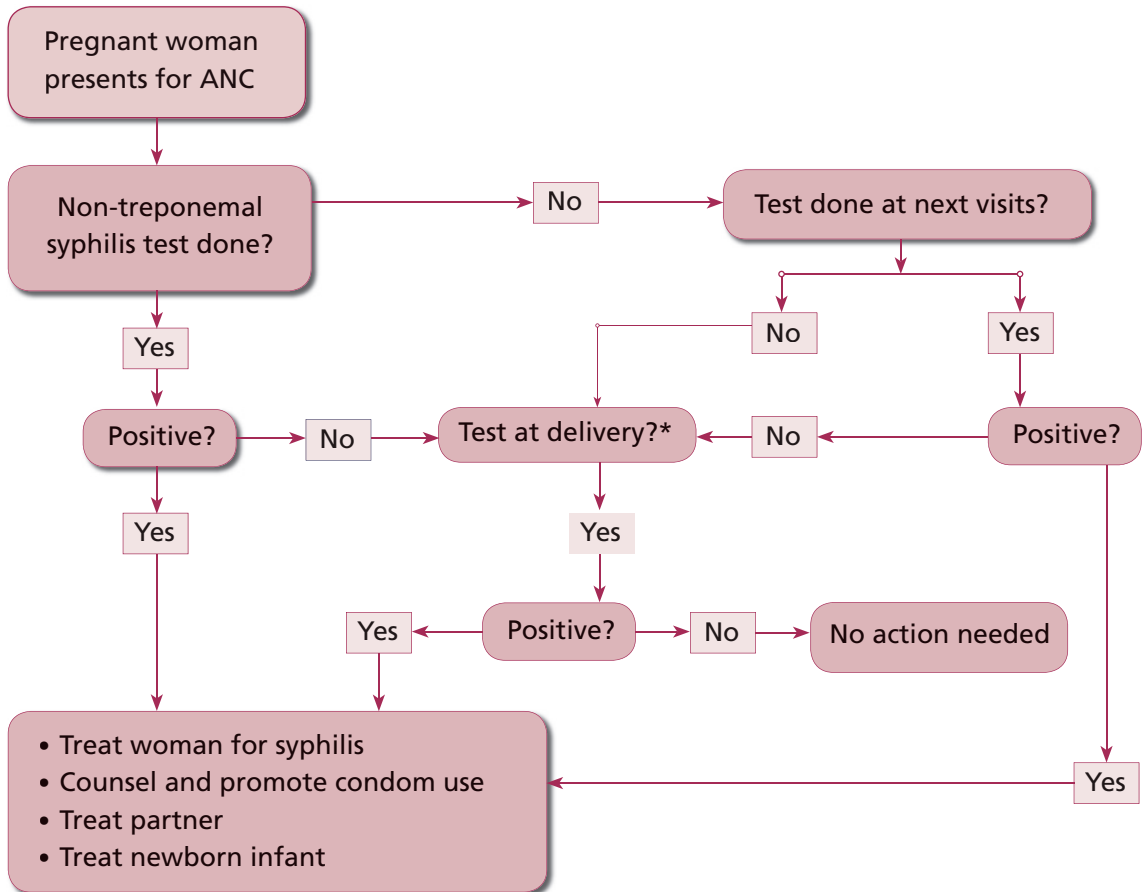
Modification of risk behaviour is also important for preventing reinfection. Seropositive women should be educated and counselled on how to prevent transmission and reinfection, including the use of condoms and the need to get their partners and newborn babies treated. Partners should also be educated and counselled.

Treatment of infants

All asymptomatic infants born to seropositive women who have been treated according to the stage of syphilis and more than four weeks before delivery should be treated with a single prophylactic dose of benzathine penicillin G 50 000 units/kg body weight given intramuscularly.

Treatment of infants with symptoms and signs of congenital syphilis is more difficult. Mothers of symptomatic infants should be tested with a rapid test to confirm the diagnosis. The standard treatment of symptomatic congenital syphilis is administration of aqueous crystalline penicillin G 100 000–150 000 units/kg body weight given as 50 000 units/kg/dose

Figure 7. Flowchart for the management of maternal syphilis



* where indicated

intravenously (IV) every 12 hours for the first 7 days and every 8 hours thereafter for a total of 10 days, or benzathine penicillin G or procaine penicillin 50 000 units/kg body weight intramuscularly daily for 10 days. If more than one day of treatment is missed, the entire course of treatment should be restarted. Hospitalization of the infant should be considered in order to ensure the full course of treatment. It is obvious that prevention of congenital syphilis by screening women in the early stages of pregnancy and treating seropositive women is far better than treating congenital syphilis.

Infants with suspected congenital syphilis and those born to mothers treated less than four weeks prior to delivery, or those treated with non-penicillin regimens, or those who were not treated or inadequately treated, or who have no records of having been treated should be treated for congenital syphilis with the IV regimen.

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, and serological markers such as RPR and IgM disappear within six months. Therefore, infants should be followed up for at least six months.

In high-prevalence areas, a single dose of benzathine penicillin G 50 000 units/kg body weight given intramuscularly may be offered to all neonates whose mothers were never tested or inadequately treated.

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Worldwide, syphilis accounts for an estimated 12 million cases, 2 million of them among pregnant women. Syphilis in pregnant women can result in adverse outcomes of pregnancy in up to 80% of cases, such as stillbirth and spontaneous abortion, perinatal death, and serious neonatal infections and low-birth-weight babies. The annual global number of cases of congenital syphilis is estimated to be between 713 600 and 1 575 000. More newborn infants are affected by congenital syphilis than any other infection including human immunodeficiency virus (HIV) and tetanus. The morbidity and mortality due to congenital syphilis is much higher than that due to mother-to-child transmission (MTCT) of HIV, yet syphilis has not received the same attention as HIV. This is mainly due to inadequate political commitment and insufficient national and international awareness of the burden of congenital syphilis.

This Regional strategy for the elimination of congenital syphilis (ECS) is aimed at various stakeholders concerned with ECS including national policy-makers, programme officials, nongovernmental organizations, international nongovernmental organizations, community-based organizations, multilateral and bilateral donor agencies, and United Nations agencies.

ISBN 978-92-9022-346-7



**World Health
Organization**

Regional Office for South-East Asia