Methods for surveillance and monitoring of

Congenital syphilis elimination within existing systems

World Health Organization

Initiative for the Global Elimination of Congenital Syphilis

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Abbreviations

ECS	elimination of congenital syphilis
EIA	enzyme immunoassay
MDG	Millennium Development Goal
M&E	monitoring and evaluation
MNCH	maternal, newborn, and child health
PAHO	Pan American Health Organization
PMTCT	prevention of mother-to-child transmission
RPR	rapid plasma reagin
STI	sexually transmitted infection
TPHA	Treponema pallidum haemagglutination assay
TPPA	Treponema pallidum particle agglutination
UA	Universal Access (reporting system)
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
VDRL	venereal disease research laboratory
WHO	World Health Organization

Contents

Executive summary

The Initiative for the Global Elimination of Congenital Syphilis supports global efforts to achieve the Millennium Development Goals (MDGs) 4 (reduce child mortality), 5 (improve maternal health), and 6 (combat human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), malaria, and other diseases). Surveillance, monitoring, and evaluation are together considered one of the four critical pillars of efforts to eliminate congenital syphilis.

This surveillance, monitoring, and evaluation tool was developed for use at the global, regional, and national level by public health practitioners who are responsible for efforts to eliminate congenital syphilis. The purpose of this document is to provide guidance on the core indicators for elimination of congenital syphilis (ECS) efforts in regions and countries that are harmonized with and can be integrated into existing data collection systems, in order to strengthen the underlying information systems. The use of common global indicators and tools by regions and countries will facilitate comparability of the resulting data between countries, allow establishment of global and regional monitoring of ECS efforts, improve service delivery, and assist in attainment of the MDGs.

It is important to establish clearly delineated policy support for ECS in every country, since, in many countries, activities related to congenital syphilis span multiple programmes and it is often unclear which programme takes primary responsibility. Every country should monitor three core indicators that are necessary for basic ECS programme monitoring and management:

1. testing of antenatal care attendees for syphilis at first visit
2. positive syphilis serology in pregnant women
3. treatment of syphilis-seropositive pregnant women.

Additional ECS-specific and routine maternal, newborn, and child health (MNCH) indicators that are useful for monitoring and management of an ECS programme have been identified, and should be adopted if deemed relevant and feasible to the country context. Special study indicators can be of assistance in measuring the impact of programme efforts, but may be difficult to obtain routinely.

Once a country has established a monitoring policy, selected indicators, and established targets, routine analysis and data dissemination at all levels (local, national, regional, and global) is important. Although the specific analytic plan will vary depending upon the context, at a minimum the three core indicators should be monitored annually and should include assessment of trends over time in syphilis testing coverage, positivity, and treatment of syphilis-seropositive women attending antenatal care.

Introduction

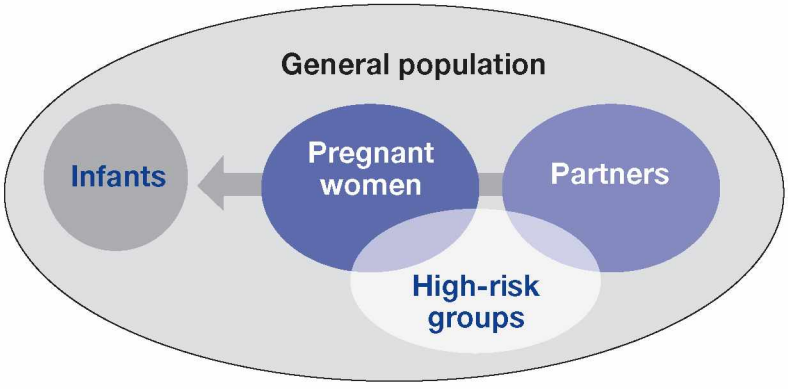
Globally, nearly 2 million pregnant women are infected with syphilis each year, most of whom are not tested; of those who are tested, most are either not treated promptly or not treated at all. Approximately 50% of women with untreated syphilis will transmit the infection to their unborn child, resulting in profound adverse outcomes (i.e. stillbirth, neonatal death, prematurity, low birth weight, or congenitally infected infant), including an estimated 440 000 perinatal deaths each year (*1*).

Thus, for many years, universal syphilis screening for pregnant women has been part of the basic antenatal care package recommended by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) (*2, 3*). Even in populations of pregnant women at low risk of syphilis infection, full coverage of testing and treatment of pregnant women is critical for avoiding transmission of syphilis to infants, otherwise known as congenital syphilis (*4*). Given the dynamics of syphilis transmission, the prevalence of syphilis among the general population and in high-risk populations both have important effects on the prevalence of syphilis among pregnant women (see Fig. 1).

Adverse pregnancy outcomes associated with syphilis can be prevented by screening pregnant women early in pregnancy and prompt treatment of those identified with positive tests (preferably prior to 24 weeks' gestational age). A single dose of long-acting penicillin cures syphilis and prevents its consequences in the unborn child, while syphilis in the woman can be effectively treated with either one (primary or secondary disease) or three (latent disease) penicillin doses, depending on the stage of disease. Syphilis screening and treatment can cost less than US$ 1 per syphilis test and US$ 0.50 per penicillin dose, and health economists estimate this is among the most cost-effective public health interventions in existence (*5*).

In order to prevent fetal and infant deaths caused by maternal syphilis, WHO launched the Initiative for the Global Elimination of Congenital Syphilis in 2007 (*5*). Elimination of congenital syphilis (ECS) is an important and attainable component of global efforts to achieve the Millennium Development Goals (MDGs) 4 (reduce child mortality), 5 (improve maternal health), and 6 (combat HIV/AIDS, malaria, and other diseases). Surveillance, monitoring, and evaluation are together considered one of the four critical pillars of ECS efforts, in addition to advocacy, access to maternal, newborn, and child health (MNCH) services, and screening and treatment of pregnant women (see Box 1). Furthermore, in order to support local and national MNCH monitoring systems and attainment of the MDGs, ECS surveillance, monitoring, and evaluation must be implemented within existing information systems for sexually transmitted infections (STIs), HIV, and MNCH.

Figure 1. Syphilis transmission dynamics: testing and treatment of pregnant women is critical for avoiding transmission of syphilis to infants



Box 1: Initiative for the Global Elimination of Congenital Syphilis

The overall goal of the Initiative for the Global Elimination of Congenital Syphilis is to eliminate congenital syphilis as a public health problem by 2015 (*5*). The specific goal of the elimination effort is to prevent maternal-to-child transmission of syphilis and resultant perinatal morbidity and mortality. This can be achieved by strengthening antenatal care and reproductive and sexual health programmes to ensure:

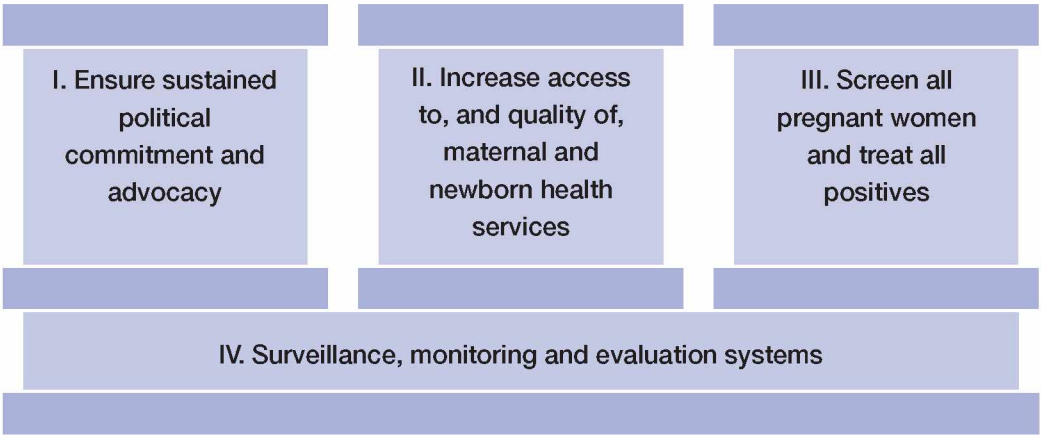
1. early antenatal care for all women, with universal syphilis screening and prompt treatment of those infected
2. treatment of all neonates born to syphilis-seropositive mothers
3. treatment of all sexual partners of infected women, promotion of condom use during pregnancy, and counselling of all women on how to prevent infection.

Because case definitions for congenital syphilis vary widely by country, the specific targets of the global initiative are that:

- at least 90% of pregnant women will be screened for syphilis by 2015
- at least 90% of syphilis-seropositive pregnant women be treated appropriately by 2015.

WHO adopted a strategy for the ECS initiative that consists of four critical pillars:

The four pillar strategy for elimination of congenital syphilis



Intended audience and use of this tool

This tool was developed primarily for use by country programme managers to strengthen monitoring and evaluation within existing national systems. In addition, it is intended for regional and global professionals to support strengthened monitoring and evaluation (M&E) of ECS efforts. This tool is a focused synthesis of existing WHO guidance on surveillance, monitoring, and evaluation.

Guiding principles for ECS monitoring and evaluation activities

According to the guiding principles of the ECS initiative, M&E activities should be country-driven, integrated, rights-based, and collaborative.

Country-driven

Data used to guide global ECS efforts originate from individual countries and must be of value to countries for them to be motivated to conduct high-quality surveillance on a routine basis. Sharing country data with regional and international organizations allows organizations to better assist in the development of policies and guidance that support and respond to country needs.

Integrated

Integration of ECS efforts ensures that such efforts strengthen existing STI, HIV, reproductive health, and MNCH services. ECS M&E is not intended to be a vertical activity, but rather to occur within the context of existing MNCH information systems. In addition, monitoring of syphilis in pregnancy is one of the critical STI surveillance tools included as a key component of second-generation surveillance for HIV in all HIV epidemic settings (i.e. low-level, concentrated, and generalized) (*6*).

In most countries, an integrated approach is important because data for different programmes may come from a common source, and staff are often responsible for more than one programme. The guidance in this document is intended to harmonize data collection for ECS with existing monitoring guidance provided for related programmes (see Box 2). Harmonization with WHO guidance should be done in the context of existing national and regional guidance, and all guidance documents may not be relevant for all settings.

Rights-based

A rights-based approach to ECS efforts ensures that all individuals have the knowledge and supportive conditions to participate in decision-making about their health, and access to high-quality care. A rights-based approach to ECS M&E is one that supports collection of data of the highest possible quality on all affected populations, and that always uses data in a manner that consistently respects individual confidentiality and reduces stigma, discrimination, and any form of human rights violation.

Collaborative

A collaborative approach to ECS efforts encourages government bodies, donors, the private sector, and communities, including those affected by, being at risk of, or vulnerable to STIs, to work together to optimize use of resources.

Policy support for ECS monitoring and evaluation

It is recognized that STI surveillance can be difficult, and is insufficient in many countries. For example, a 2006 review of existing national antenatal syphilis screening policies of 14 low-, medium-, and high-burden countries found that important M&E components, including antenatal syphilis prevalence among pregnant women, were lacking in most countries. While 10 countries reported active surveillance for ECS, national statistics on congenital syphilis cases were available from only six countries, and sentinel surveillance for only four. In addition, the case definition of congenital syphilis varied between countries

Box 2: Surveillance, monitoring, and evaluation for elimination of congenital syphilis: related WHO guidance documents

Reproductive health

- National-level monitoring of the achievement of universal access to reproductive health: conceptual and practical considerations and related indicators (*8*)
- Reproductive health indicators: guidelines for their generation, interpretation and analysis for global monitoring (*9*)
- Monitoring and reporting on the health sector's response towards universal access to HIV/AIDS treatment, prevention, care, and support 2009-2010. WHO framework for global monitoring and reporting (*10*)

HIV/AIDS

- Guidelines for second generation HIV surveillance: an update (*6*)
- Monitoring the Declaration of Commitment on HIV/AIDS: guidelines on construction of core indicators. 2010 reporting (*11*)
- Monitoring and evaluating prevention of mother-to-child transmission of HIV: a guide for national programmes (*12*)
- Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT (including malaria prevention during pregnancy) and TB/HIV: standardized minimum data set and illustrative tools (*13*)

STI

- Global strategy for the prevention and control of sexually transmitted infections: 2006–2015: breaking the chain of transmission (*4*)
- Strategies and Laboratory Methods for Strengthening Surveillance of Sexually Transmitted Infections (*14*)

Regional

- Regional initiative for the elimination of vertical transmission of HIV and congenital syphilis in Latin America and the Caribbean: regional monitoring strategy (*15*)
- Elimination of new paediatric HIV infections and congenital syphilis in Asia-Pacific, 2011–2015: conceptual framework, monitoring and evaluation guide (*16*)

(*7*). Such data highlight the need for improving the quality of surveillance, monitoring, and evaluation for ECS.

In order to do so, it is important to establish clearly delineated policy support for ECS M&E in every country. In many countries, activities for congenital syphilis have suffered because responsibilities span multiple programme (e.g. STI, HIV, MNCH), and it is unclear which programme is responsible for policy-setting, programme implementation, and monitoring. Clearly delineated programme responsibilities for congenital syphilis can be an effective means of promoting effective and positive linkages between programmes, while avoiding a scattered ECS programme, which is negative and occurs when responsibilities are unclear.

In some countries, a single programme (i.e. MNCH, STI, or prevention of mother-to-child transmission [PMTCT]) is accountable for all three aspects of policy-setting, programme implementation, and M&E of ECS activities. Harmonization with HIV programmes must also take place, since in many countries programmes for ECS and PMTCT of HIV share similar monitoring systems, both HIV and syphilis in pregnancy may affect similar subpopulations, and an incident STI such as a new syphilis infection can be a sign of increased risk of HIV acquisition or transmission. It is important that the lead

programme communicates routinely with other programmes and establishes a coordinating body for ECS efforts to promote strong linkages, since prevention of syphilis in pregnant women ultimately depends on effective control of syphilis in the general population and a strong antenatal care platform.

A useful means of clearly delineating accountability for ECS activities is elaboration of a national ECS strategy, policy, workplan, guideline, and/or protocol. Although a national ECS strategy can solely address congenital syphilis, a more integrative approach is to develop a national strategy that addresses vertical transmission of both HIV and syphilis through strengthening of the underlying MNCH system.

Why data on ECS are important

Data on ECS are necessary at the global, regional, and national levels to:

- advocate for resources and prioritization of ECS and strengthening antenatal care
- establish a baseline for the ECS initiative and identify feasible targets
- monitor progress towards elimination of preventable MNCH morbidity and mortality caused by untreated syphilis infection
- identify gaps that need addressing, such as:
  - additional guidelines and tools
  - areas for operational research
  - technical assistance and resources.

Indicators for ECS monitoring and evaluation

In order to support global monitoring and translatability of findings between regions and countries, WHO supports the use of three commonly defined *core ECS indicators* by all regions and countries, *additional ECS-specific* and *routine MCH indicators* as selected by regions and countries, and *special study indicators* to be obtained periodically (see Box 3). Regions and countries should select additional ECS-specific and routine MCH indicators from the list provided in Box 3, or identify important country-specific indicators, according to contextual factors such as the health-system structure, existing monitoring systems, the burden and distribution of

Box 3: Summary of indicators for monitoring and evaluation of efforts to eliminate congenital syphilis

Core ECS indicators

1. Testing of antenatal care attendees for syphilis at first visit
2. Positive syphilis serology in pregnant women
3. Treatment of syphilis-seropositive pregnant women

Additional ECS-specific indicators

4. The rate of congenital syphilis
5. Treatment of infants born to syphilis-seropositive women
6. Treatment of sexual partners of syphilis-seropositive pregnant women
7. The existence of a national congenital syphilis policy
8. Antenatal care clinics routinely testing for syphilis
9. Stock-out of syphilis testing materials
10. Stock-out of long-acting intramuscular penicillin

Routine MNCH indicators that are useful for ECS

11. Antenatal care coverage
12. Early antenatal care
13. Stillbirth rate

Special study indicators

14. Estimated proportion of all syphilis-infected pregnant women who receive treatment by 24 weeks' gestation
15. Proportion of stillbirths attributable to maternal syphilis

disease, country-specific sociodemographic aspects, and availability of resources for M&E. The recommended definitions of core, additional ECS-specific, routine MCH, and special study indicators, as well as other characteristics, are described in Appendix A: Indicator definitions and descriptions.

Core ECS indicators

Core ECS indicators are those indicators that every country is strongly encouraged to adopt, as these provide fundamental information for basic ECS programme monitoring and management.

Core ECS indicators provide data about:

1. testing of antenatal care attendees for syphilis at first visit
2. positive syphilis serology in pregnant women
3. treatment of syphilis-seropositive pregnant women.

Additional indicators

Additional indicators are those that have been identified as providing information that is useful for ECS programme monitoring and management. While some of the indicators are specific for ECS efforts, others are collected routinely for MNCH programme purposes and can also contribute towards the interpretation of ECS efforts. Countries are encouraged to review the list of additional indicators and implement collection of any additional indicators deemed relevant and feasible to their country context.

Additional ECS-specific indicators provide data about:

4. the rate of congenital syphilis
5. treatment of infants born to syphilis-seropositive women
6. treatment of sexual partners of syphilis-seropositive pregnant women
7. the existence of a national congenital syphilis policy
8. antenatal care clinics routinely testing for syphilis
9. stock-out of syphilis testing materials
10. stock-out of long-acting intramuscular penicillin.

Routine MNCH indicators that are useful for ECS

Routine MNCH indicators that are useful for ECS provide data about:

11. antenatal care coverage
12. early antenatal care
13. stillbirth rate.

Special study indicators

These are indicators that are critical to assessing national programme impact in all countries, but are acknowledged as being difficult to obtain through routine surveillance, monitoring, and evaluation efforts. In many countries, these may require special studies that are carried out on a routine basis.

Special study indicators **include:**

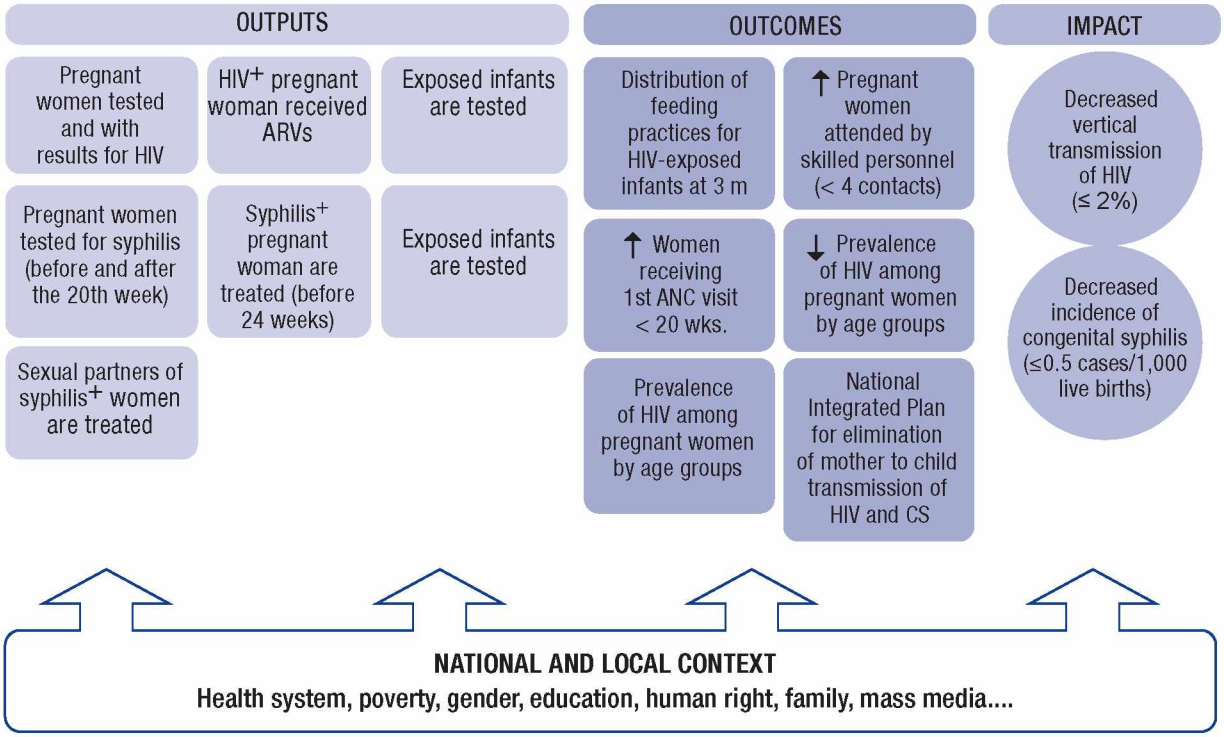
14. the estimated proportion of all syphilis-infected pregnant women who receive treatment by 24 weeks' gestation
15. the proportion of stillbirths that are attributable to maternal syphilis.

It is generally most useful to select a combination of process indicators (e.g. testing at first visit, and treatment of seropositive pregnant women), intermediate outcome measures (e.g. positive syphilis serology in pregnant women), and long-term outcome indicators (e.g. rates of congenital syphilis and syphilitic stillbirth).

Setting ECS targets

Although global targets exist for some indicators (see Appendix 1), regions and countries are encouraged to identify targets that are appropriate for the indicators they have selected, the context of their epidemic, and the planned scale of public health interventions. The WHO Western Pacific Region and South-East Asia Region, and the Pan American Health Organization (PAHO),

Figure 2. Map of selected M&E indicators for the Regional Initiative for the Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis in Latin America and the Caribbean



for example, have identified regional targets for several ECS indicators that can be adopted or adapted for use by countries (see Fig. 2) (*15–18*).

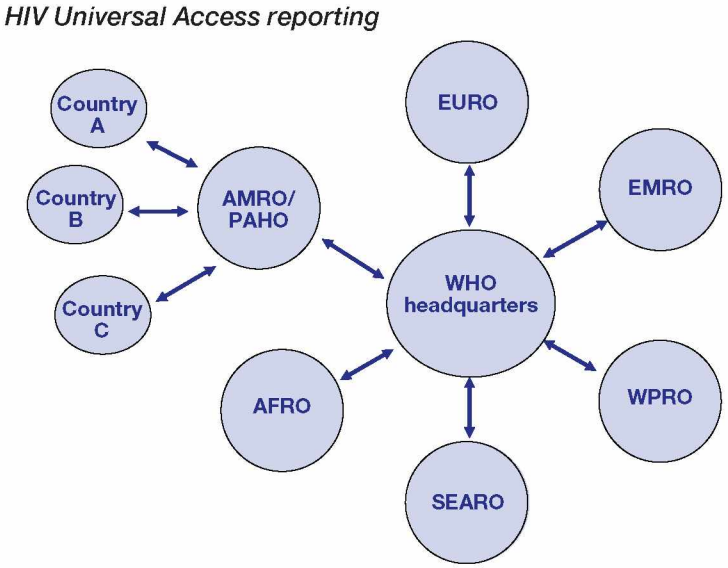
Data collection for ECS monitoring and evaluation

Core ECS indicators can be obtained in some countries from routine MNCH national programme records. Core indicators can also be obtained through sentinel surveillance, or special studies. For routine programme data collection, WHO recommends that countries adopt the standardized minimum data set and illustrative tools outlined in the *Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT (including malaria prevention during pregnancy), and TB/HIV* (*13*). In addition, regional guidance may be available. For example, WHO and UNICEF regional offices have provided guidance for countries in the Americas and the Asia Pacific on M&E for vertical transmission of HIV and syphilis (*15, 16*).

In order to guide national ECS efforts, all countries are strongly encouraged to collect and analyse data on ECS core indicators annually, to support improvement of basic antenatal service. In addition, countries are encouraged to submit data to the regional and global level for the ECS core indicators, through existing mechanisms such as the HIV Universal Access (UA) reporting system (*10, 19*). Core data should be collected annually in each country, validated at the country level, and sent via the regional office to WHO or UNAIDS headquarters (see Fig. 3).

Countries with the resources and capacity to collect *additional ECS-specific indicators* are encouraged do so on a routine basis (i.e. annually where feasible, or at least every 2–3 years). Additional indicators may be obtained from routine national programme records, sentinel surveillance, or special studies (e.g. national health-facility surveys, population-based surveys). Countries are encouraged to collect the *special study indicators* at baseline and every 2–3 years, to assess the programmatic and public health

Figure 3. Example of flow of ECS data on core indicators



AMRO, WHO Regional Office for the Americas; EMRO, WHO Regional Office for the Eastern Mediterranean; EURO, WHO Regional Office for Europe; PAHO, Pan American Health Organization; SEARO, WHO Regional Office for South-East Asia; WPRO, WHO Regional Office for the Western Pacific.

impact of ECS efforts. The format and mechanism of transmission of these data may vary by region (e.g. PAHO transmits a supplemental page of regional initiative data integrated into their HIV UA reporting Excel file). Links to regional guidance and methodology are available on WHO regional websites as well as on the WHO *Eliminating congenital syphilis* site (*20*).

Data analysis

Data analysis should occur at all levels: local, national, regional, and global. Although the specific analytic plan will vary depending upon the context, at a minimum the three core indicators should be monitored annually, and include assessment of trends over time in syphilis testing coverage, positivity, and treatment of women attending antenatal care.

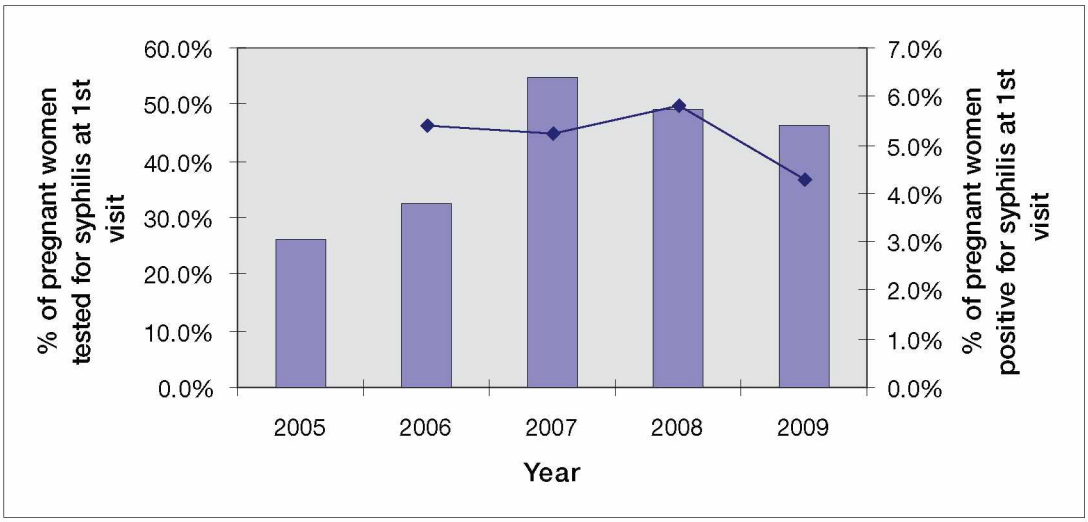
There are a variety of useful formats, including tables, trend lines, bar charts, or combinations of these visual display options. Tabular display of data is useful if the data are to be disseminated to programme managers, for example, who need to know specific values (see Table 1). However, visual display of data may be more useful if the data must be interpreted rapidly in the context of a national report, for example (see Fig. 4). Even simpler display of data may be of value at the regional level, where it is important to synthesize data from several countries (see Fig. 5). Blank Excel versions of these figures that can be downloaded for individual country use from the web are available at: (http://www.who.int/reproductivehealth/topics/rtis/syphilis/en/index.html).

Table 1. Example of tabular display of data: percentage of pregnant women tested, positive, and treated for syphilis during the first antenatal care visit, Paraguay, 2005–2009

Indicator	2005	2006	2007	2008	2009
1. % of pregnant women tested for syphilis at first visit	26.1	32.5	54.7	49.2	46.2
Number of pregnant women tested for syphilis at first antenatal visit	37 030	54 511	55 467	55 266	58 857
Number of pregnant women attended in antenatal care	141 662	167 484	101 380	112 318	127 322
2. % of pregnant women who are seropositive for syphilis	N/A	5.4	5.2	5.8	4.3
Number of syphilis-seropositive pregnant women in antenatal care	N/A	2933	2890	3215	2523
Number of pregnant women tested for syphilis in antenatal care	N/A	54 511	55 467	55 266	58 657
3. % of syphilis-seropositive pregnant women treated	N/A	85.6	60.0	57.0	61.8
Number of syphilis-seropositive pregnant women treated	N/A	2511	1734	1832	1558
Number of syphilis-seropositive pregnant women identified	N/A	2933	2890	3215	2523

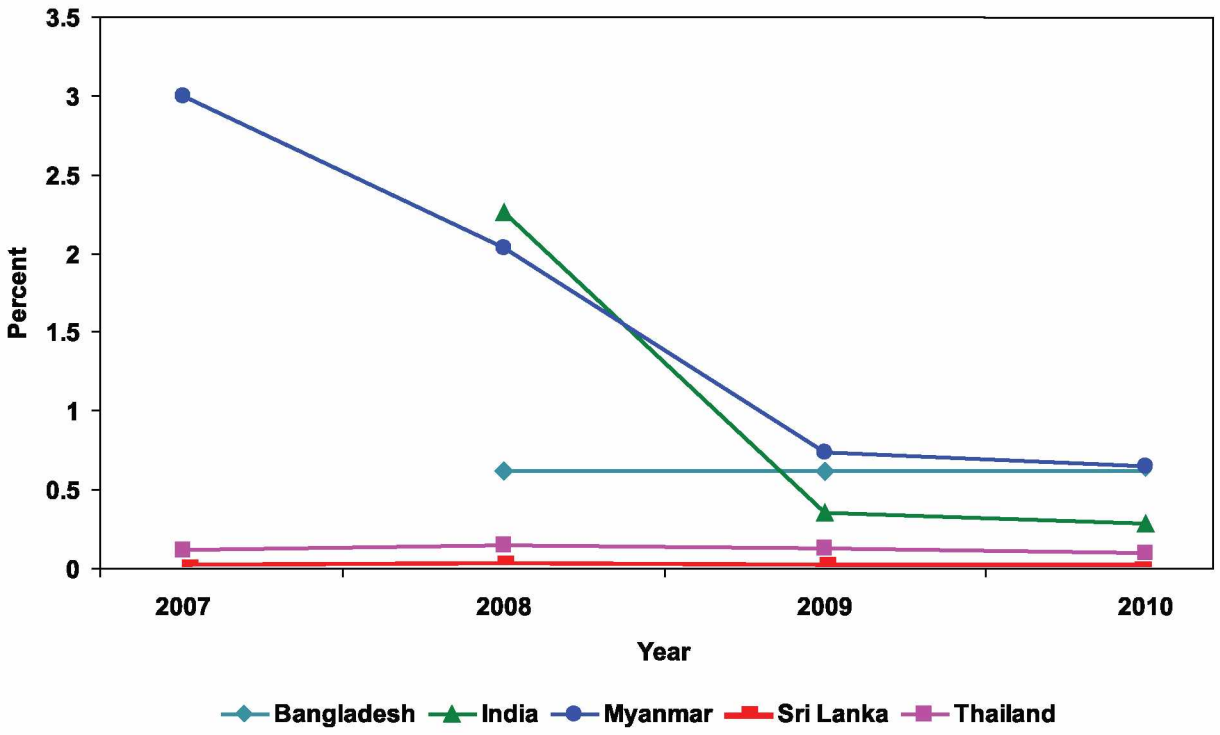
Source: unpublished data, National AIDS Program, Ministry of Health, Paraguay, 2011.

Fig. 4. Example of visual display of data: percentage of pregnant women tested for syphilis at their first antenatal visit and positive for syphilis in Paraguay, 2005–2009



Source: unpublished data, National AIDS Program, Ministry of Health, Paraguay, 2011.

Fig. 5. Prevalence of syphilis serology among pregnant women attending ANC services – 2007-2010



Source: WHO Regional Office for South-East Asia, routine programme data.

ECS data dissemination

Core ECS indicators should be presented and analysed in a national report, summarizing ECS efforts on an annual basis, through either stand-alone or integrated programme reports. Efforts should be made to coordinate MNCH, STI, and HIV programme perspectives. National programmes should ensure that the reporting sites receive feedback on the data they report and are an integral part of analysis and dissemination, and that ownership of data is ensured for reporting sites. Dissemination should be done in a manner that emphasizes the use of ECS data to guide policy and programme interventions.

Dissemination should also be conducted routinely at a regional level on an annual basis. ECS regional data should be used annually to identify successful efforts that can serve as model programmes for other countries and regions, as well as to identify countries in need of additional or intensified support. Regional dissemination should include assessment of regional progress in elimination efforts, annually or every 2–3 years.

Data collection, reporting, analysis, report writing, and dissemination of the global data on core indicators will also be conducted by WHO headquarters, and reviewed with the regional offices on an annual basis. A summary of core indicators will be presented in the HIV UA report annually. A more detailed analysis of core indicators, along with any available additional indicator or special study data provided from regional or country offices, will be included in a global ECS report that will be produced annually, or every 2–3 years.

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Appendix A: Indicator definitions and descriptions

Core ECS indicators

Indicator 1 – Core	Testing of antenatal care attendees for syphilis at first visit
What it measures	The percentage of antenatal care attendees tested for syphilis at the first antenatal care visit
Rationale	Syphilis testing and treatment can effectively prevent adverse pregnancy outcomes caused by maternal syphilis exposure, and is the core intervention in control of congenital syphilis. Congenital syphilis can be prevented if all pregnant women are tested and treated sufficiently early in pregnancy, before poor outcomes in the fetus occur. Syphilis testing is part of the recommended basic antenatal services package; thus, testing of antenatal care attendees for syphilis is also a marker of the quality of provision of essential antenatal care services.
Numerator	Number of antenatal care attendees in a year tested for syphilis at first visit
Denominator	Number of first-visit antenatal care attendees in a year
Reference	Indicator also described in WHO global STI strategy (*4*), WHO ECS strategy (*5*), and WHO HIV UA guidance documentation (*10*)
Data source	Ideally data should be obtained from routine national MNCH programme records. If this is not feasible, sentinel surveillance, seroprevalence surveys, or other special studies may be used if the data are felt to be representative of national program services.
Frequency	Annually
Disaggregation	By age group and trimester of pregnancy
Comments	Analysis of only first antenatal care visits is helpful in understanding the quality of syphilis-testing programmes in antenatal care, since syphilis treatment must occur sufficiently early to avoid early fetal loss and stillbirth. Countries that are unable to distinguish the first visit from subsequent visits can still report data on this indicator, but should clearly indicate this difference when reporting the data. Disaggregation by age allows identification of differences in testing coverage for different subpopulations. Although difficult to do on a routine basis, disaggregation by trimester of pregnancy allows determination of what proportion of women are getting tested early enough in pregnancy to prevent poor pregnancy outcomes.
Data utilization	*Global*: examine trends over time to assess progress towards target levels of testing coverage. Knowledge of testing policies and practices should be used to assist with interpretation of trends in coverage. *Local*: data can be used to identify clinics that are not fully implementing national policy.
Proposed target	Global: >90% (*4*, *5*); PAHO: ≥95% (*15*); Asia Pacific: ≥90% (*16*)

Indicator 2 – Core	Positive syphilis serology in pregnant women
What it measures	The percentage of pregnant women aged 15 to 24 years attending antenatal clinics, with a positive syphilis serology
Rationale	Syphilis infection in antenatal care attendees is a marker of syphilis prevalence in the community, and thus a measure of the effectiveness of the STI-prevention programme (not the effectiveness of the congenital-syphilis-prevention programme). This indicator is useful in measuring overall burden of disease and may provide early warning of potential changes in HIV transmission in the general population.
Numerator	Number of antenatal care attendees each year aged 15 to 24 with a positive syphilis serology
Denominator	Total number of antenatal care attendees each year aged 15 to 24 who received syphilis serology testing
Reference	Indicator also described in WHO global STI strategy (*4*), WHO ECS strategy (*5*), WHO reproductive health indicator guidance (*8*), and WHO HIV UA guidance documentation (*10*)
Data source	Data are recommended to be collected in coordination with HIV antenatal prevalence data, either from routine national MNCH programme records, periodic sentinel surveillance, seroprevalence surveys, or other special studies.
Frequency	Annually
Disaggregation	If data sources allow, analysis should also estimate the prevalence of syphilis seropositivity in all pregnant women (regardless of age). If data sources allow, analysis should estimate the prevalence of high-titre syphilis seropositivity using a non-treponemal test titre threshold of ≥1:8.
Comments	Since most countries will have data from a variety of test types, subanalysis is restricted to 15- to 24-year-old women, to increase the likelihood that test positivity reflects recent infection. Syphilis positivity is ideally measured using a combination of non-treponemal tests (e.g. rapid plasma regain [RPR] or venereal disease research laboratory [VDRL]) and treponemal tests (e.g. *Treponema pallidum* haemagglutination assay [TPHA], *Treponema pallidum* particle agglutination [TPPA], enzyme immunoassay [EIA], or a variety of available rapid tests). In many clinical settings, only one test will be used. For example, rapid treponemal tests alone may be performed in antenatal care settings without basic laboratory capacity. Use of these point-of-care tests has allowed syphilis testing to occur in settings without laboratory capacity, greatly increasing the number of women who can be tested and treated for syphilis in pregnancy. A reactive non-treponemal test, particularly if the titre is ≥1:8, is suggestive of active infection. Positivity with a treponemal test indicates any previous infection (even if treated successfully) and cannot distinguish between older and more recent infections. If both treponemal and non-treponemal test results on an individual patient are available, then syphilis positivity should be defined as having positive results on both tests.

Comments (continued)	Because most in-country data systems do not maintain unique identifiers and women may be tested more than once in a pregnancy, these data may reflect syphilis positivity rather than true prevalence. However, for most countries, positivity is not thought to differ greatly from true prevalence in the antenatal care setting. Whenever possible, only the result of the first syphilis test run on an antenatal care attendee should be reported.
Data utilization	*Global*: estimate the burden of MNCH mortality and morbidity caused by syphilis that could be averted with effective programmes. *Regional*: identify countries with the greatest burden of congenital syphilis and greatest need of comprehensive congenital syphilis prevention within existing antenatal care systems. *Local*: identify settings of greatest need for comprehensive congenital syphilis prevention within existing antenatal care. *All levels*: compare data on trends of syphilis and HIV, to look for early warning of increased risk of HIV transmission. Knowledge of testing practices (e.g. proportion of treponemal versus non-treponemal testing used) should be used to assist with interpretation of disease trends.
Proposed target	Global target: <2% (*4*). Regions and countries may want to set more aggressive targets. For example, the WHO Regional Office for South-East Asia recommends that the prevalence of maternal syphilis be reduced to <1% or half of the existing rate, whichever is lower (*18*).

Indicator 3 – Core	Treatment of syphilis-seropositive pregnant women
What it measures	The percentage of antenatal care attendees each year with a positive syphilis serology who are adequately treated to prevent congenital syphilis
Rationale	Treatment of antenatal care attendees who test positive for syphilis is a necessary component for elimination of congenital syphilis. Treatment is also a marker of the quality of provision of essential antenatal care services, and a proxy measure of the effectiveness of congenital syphilis prevention efforts.
Numerator	Number of antenatal care attendees with a positive syphilis serology who received at least one dose of long-acting intramuscular penicillin
Denominator	Number of antenatal care attendees with a positive syphilis serology
Reference	Indicator also described in WHO global STI strategy (*4*), WHO ECS strategy (*5*), and HIV UA guidance (*10*)
Data source	Ideally data should be obtained from routine national MNCH programme records. If this is not feasible, sentinel surveillance, seroprevalence surveys, or other special studies may be used if the data are felt to be representative of national program services.

Frequency	Annually
Disaggregation	Transmission of syphilis from mother to child can occur at any time during gestation, with most adverse outcomes occurring after 20 weeks' gestation (2nd trimester). To avert profoundly adverse outcomes such as stillbirth, neonatal death, and prematurity/low birth weight, infected mothers should be treated as early as possible and ideally before 24 weeks. Given this, analysis is most informative if restricted to treatment administered before 24 weeks.
Comments	Documentation of a single dose of long-acting intramuscular penicillin is sufficient for this indicator, as this treatment (if done sufficiently early) prevents congenital syphilis in the infant. A single dose of penicillin is also effective in treating a mother with primary or secondary syphilis. However, most pregnant women will have latent syphilis, requiring three injections of benzathine benzylpenicillin spaced at weekly intervals, to prevent tertiary syphilis in the mother.
Data utilization	*Global/regional/local*: estimate programme effectiveness in reducing syphilis-associated MNCH morbidity and mortality. *Local*: identify areas in need of assistance with programme implementation or additional resources. Knowledge of treatment policies and practices should be used to assist with interpretation of trends in treatment.
Proposed target	Global: >90% by 2015 (*4*, *5*). PAHO: ≥95% (*15*); Asia Pacific: ≥90% (*16*)

Additional ECS-specific indicators

Indicator 4 – Additional	The rate of congenital syphilis
What it measures	The incidence of congenital syphilis per 1000 live births
Rationale	The rate of congenital syphilis is a measure of the adverse consequences of syphilis infection in pregnancy, and trends in this rate can be important for advocacy and monitoring purposes. Regions and countries that have established a case definition for the rate of congenital syphilis may consider its inclusion as a fourth core indicator, but should take care in developing the case definition (see below).
Numerator	Number of reported cases of congenital syphilis during a specified period per national case definition
Denominator	Estimated number of live births per United Nations Development Programme (UNDP) regional, or national source during a specified period
Reference	Indicator not yet defined globally
Data source	Routine health-service data
Frequency	Annually

Disaggregation	None
Comments	Surveillance of congenital syphilis is challenging, since diagnosis of congenital syphilis relies on clinical history and examination, and is most reliable when using specific diagnostic tests that are seldom available in developed countries. As a result, the optimal case definition for congenital syphilis is controversial, definitions vary widely by country, and a globally accepted case definition does not yet exist. For public health purposes, experts suggest using simple, sensitive (rather than specific) definitions, as missing a true case has profound implications for the pregnancy. For example, some countries use a case definition based primarily on syphilis seropositivity in the mother, even though it is understood that such definitions overestimate true congenital syphilis rates. Consistent use of a well-defined case definition allows trends in disease in a country to be monitored over time. The case definition proposed by PAHO and related considerations are available (*15*, *21*). Three options for case definitions proposed by SEARO are available (*18*). Given the difficulties in diagnosing congenital syphilis, and depending on the case definition used, either underreporting or overreporting can be a common problem. The likely magnitude of such reporting errors should always be considered when looking at rates of congenital syphilis.
Data utilization	Look at changes in rates over time to assess trends in disease.
Proposed target	Region- or country-specific (PAHO (*15*) and Asia Pacific (*16*): ≤0.5 cases per 1000 live births; WHO Regional Office for the Western Pacific (*17*): no reported new cases of congenital syphilis)

Indicator 5 – Additional	Treatment of infants born to syphilis-seropositive women
What it measures	Of infants born to syphilis-seropositive women, the proportion who are treated with penicillin
Rationale	Treatment of infants at risk for syphilis is a marker of both the quality of or access to antenatal services, and the quality of provision of essential newborn services. In addition, it is a measure of the effectiveness of congenital syphilis prevention efforts.
Numerator	Number of infants treated with at least one dose of long-acting penicillin who were born to syphilis-seropositive women
Denominator	Total number of live births to syphilis-seropositive women
Reference	Indicator described in WHO ECS strategy (*5*)
Data source	Data may be obtained from routine national programme records, sentinel surveillance, seroprevalence surveys, or other special studies.
Frequency	Annually
Disaggregation	None

Comments	All asymptomatic infants born to syphilis-seropositive women should receive, at birth, a prophylactic single dose of benzathine benzylpenicillin. Newborn infants showing any clinical sign of congenital syphilis should be treated with penicillin crystalline or procaine penicillin for 10 days (*5*). Infants should be treated based on weight. WHO guidelines should be used if national guidelines are not available.
Data utilization	Look at trends over time to assess trends in the effectiveness of STI-prevention programmes. Knowledge of treatment policies and practices should be used to assist with interpretation of trends in treatment.
Proposed target	Global: >90% (*5*); WHO Regional Office for South-East Asia: proportion of newborn babies of syphilis-seropositive women treated: >80% (90% for those who deliver at health facilities) (*18*); Asia Pacific: ≥90% *(16)*

Indicator 6 – Additional	Treatment of sexual partners of syphilis-seropositive pregnant women.
What it measures	The proportion of syphilis-seropositive pregnant women whose partners are appropriately treated.
Rationale	This indicator measures the effectiveness of STI partner notification and referral services. Treatment of sexual partners is necessary to prevent repeat infection.
Numerator	Number of syphilis-seropositive pregnant women for whom at least one partner was treated with at least one dose of long-acting intramuscular penicillin
Denominator	Number of syphilis-seropositive pregnant women.
Reference	Indicator also described in WHO ECS strategy (*5*).
Data source	Data may be obtained from routine national programme records, sentinel surveillance, seroprevalence surveys, or other special studies.
Frequency	Annually
Disaggregation	None
Comments	None
Data utilization	Look at changes in rates over time to assess trends.
Proposed target	Region or country-specific. WHO Regional Office for South-East Asia: proportion of partners of syphilis-seropositive pregnant women treated: >80% (*18*)

Indicator 7 – Additional	Existence of a national congenital syphilis policy
What it measures	The existence of a written national policy, strategy, workplan, guidance, or protocol addressing congenital syphilis

Rationale	Clear policy and programme guidance are necessary for the success of ECS efforts. The existence of such documents demonstrates commitment of national government to ECS.
Numerator	"Yes", "Under development", or "No"
Denominator	None
Reference	Indicator also described in WHO ECS strategy (*5*)
Data source	National government documentation
Frequency	Annually
Disaggregation	None
Comments	Recording the existence of such documentation does not provide insight into its effectiveness. Countries are encouraged to provide reference or linkage to policy and guidance documents in the comments section, or to provide to WHO. An effective ECS policy or strategy can be a stand-alone document or integrated with elimination of vertical transmission of HIV, or other MNCH or policy documents. Ideally, an effective ECS policy or strategy document addresses all four pillars described in (*5*). In addition to having a policy, countries should also have a designated individual who is accountable for implementation of the policy.
Data utilization	Data can be used to identify countries in need of ECS policy.
Proposed target	All countries should have such a document in place.

Indicator 8 – Additional	Antenatal care clinics routinely testing for syphilis
What it measures	The proportion of antenatal care clinics routinely testing for syphilis
Rationale	High coverage of syphilis screening is needed for the elimination of congenital syphilis. Knowledge of the testing capacity of an antenatal care clinic is an important measure of potential access to care, as well as being important for programme planning (training, procurement, etc.).
Numerator	Number of health facilities providing antenatal care that conduct routine syphilis testing for pregnant women (i.e. are able to provide syphilis tests for most women attending services)
Denominator	Total number of health facilities providing antenatal care

Reference	None
Data source	Routine MNCH health-service data
Frequency	Annually
Disaggregation	By clinic subtype (e.g. antenatal care, primary care)
Comments	In some countries, many antenatal care clinics do not offer routine syphilis testing services. These clinics should be targeted for introduction of rapid point-of-care syphilis (treponemal) tests.
Data utilization	*Global*: understand national and regional programme coverage. *Local*: understand local programme needs and target services. Estimate national programme coverage in order to estimate the impact of ECS on reducing MNCH morbidity and mortality. Look at trends over time to assess trends in coverage.
Proposed target	Regional or country-specific

Indicator 9 – Additional	Stock-out of syphilis testing materials.
What it measures	The proportion of antenatal care clinics that have experienced a stock-out of syphilis testing materials in the last 6 months.
Rationale	This indicator is a measure of the quality of procurement services, and can identify gaps in access to syphilis testing. To successfully achieve ECS, syphilis testing must be continuously available in all antenatal care facilities.
Numerator	Number of antenatal care clinics that have experienced at least one stock-out of syphilis testing materials in the last 6 months.
Denominator	Total number of clinics providing antenatal care services.
Reference	Indicator briefly mentioned in WHO ECS strategy (5)
Data source	Routine health-service data or surveys.
Frequency	Every 6 months for countries, annually for WHO.
Disaggregation	By type of testing material (if possible).
Comments	The specific definition of “syphilis testing materials” will vary by country, but should include any of the critical items necessary to conduct syphilis testing. For example, key materials include RPR cards or rapid-test kits and reagents; other important materials may include pipettes, gloves, test tubes, and rotators.
Data utilization	Data can be used to identify problems with laboratory supply chain management.
Proposed target	Country-specific

Indicator 10 – Additional	Stock-out of long-acting intramuscular penicillin in the last 6 months
What it measures	The proportion of antenatal care clinics that have experienced a stock-out of long-acting intramuscular penicillin or other key syphilis treatment materials in the last 6 months
Rationale	This indicator measures the quality of procurement services, and can identify gaps in access to syphilis treatment. In addition to long-acting intramuscular penicillin, other important syphilis treatment materials include syringes, needles, gloves, and safe-disposal boxes. These must be available in all antenatal care facilities to effectively achieve ECS and effectively provide services.
Numerator	Number of antenatal care clinics that have experienced at least one stock-out of long-acting intramuscular penicillin, syringes, or needles during the last 6 months
Denominator	Total number of clinics providing antenatal care services
Reference	Indicator briefly mentioned in WHO ECS strategy (*5*)
Data source	Routine health-service data or surveys
Frequency	Every 6 months for countries, annually to WHO
Disaggregation	By type of treatment material (if possible)
Comments	None
Data utilization	Data can be used to identify problems with pharmaceutical supply chain management.
Proposed target	Country-specific

Additional MNCH indicators that are useful for ECS

Indicator 11 – Additional	Antenatal care coverage
What it measures	The proportion of pregnant women attended, at least once during their pregnancy, by skilled health personnel for reasons relating to pregnancy
Rationale	Antenatal care coverage provides information on the proportion of women who receive antenatal care services by skilled health personnel. Understanding antenatal care coverage is important for interpreting Core indicator 1 “Testing of antenatal care attendees for syphilis on their first visit”, since women who do not receive antenatal care will generally not be screened and treated for syphilis in pregnancy.
Numerator	Number of pregnant women attended, at least once in their pregnancy, by skilled personnel for reasons related to pregnancy, during a fixed period

Denominator	Total number of live births during the same period per UNDP, regional, or national source.
Reference	Indicator also described in WHO reproductive health indicator guidance (*9*)
Data source	Routine health-service data (e.g. vital registration) or population-based (e.g. household survey) data
Frequency	Annually if routine health-service data, every 3–5 years if done by survey
Disaggregation	None
Comments	A "skilled health attendant" is defined as an accredited health professional (such as a midwife, doctor or nurse) who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth, and the immediate postnatal period (*9*). Although in theory all births should be included, in practice only live births are used, because of difficulty in obtaining information about non-live births. The exclusion of non-live births underestimates the need for antenatal care in the population. In practice, however, this potential for underestimation is reduced because in most surveys only women giving birth to live offspring are included in the numerator. Routine health-service data may be of poor quality. Data from household surveys are generally of good quality, but may be expensive and not routinely available. Data from vital registration may underestimate the denominator, and may not be available for the numerator.
Data utilization	Look at trends over time to assess trends in coverage. Knowledge of antenatal care policies and practices should be used to assist with interpretation of trends. Low antenatal care coverage will result in an overestimate of Core indicator 1 "Testing of antenatal care attendees for syphilis on their first visit".
Proposed target	Regional or country-specific

Indicator 12 – Additional	Early antenatal care
What it measures	The proportion of women with a first antenatal visit prior to the 6th month of pregnancy
Rationale	Treatment of syphilis in a pregnant woman is most likely to prevent adverse outcomes such as stillbirth, neonatal death, low birth weight, and preterm delivery, if provided before 24 weeks of pregnancy. It is important to measure early antenatal care if women are seeking care early enough for syphilis treatment to be able to avert adverse outcomes.
Numerator	Number of pregnant women with a first antenatal visit before 24 weeks of pregnancy, during a fixed period

Denominator	Total number of live births during the same period per UNDP, regional, or national source.
Reference	None
Data source	Routine MNCH health-service data, household-survey data, or vital-registration data
Frequency	Annually if routine health-service data, every 3–5 years if done by survey
Disaggregation	None
Comments	Although in theory all births should be included, in practice only live births are used because of difficulty in obtaining information about non-live births. The exclusion of non-live births underestimates the need for antenatal care in the population. In practice, however, this potential for underestimation is reduced because in most surveys only women giving birth to live offspring are included in the numerator. Routine health-service data may be of poor quality. Data from household surveys are generally of good quality, but may be expensive and not routinely available. This indicator is currently a routine indicator in demographic and health surveys. Data from vital registration may underestimate the denominator, and may not be available for the numerator.
Data utilization	Look at trends over time to assess trends in coverage. Knowledge of antenatal care policies and practices should be used to assist with interpretation of trends. Data on early antenatal care should be interpreted jointly with data on testing and treatment, to understand better how likely it is that syphilis testing and treatment are being offered early enough to avert adverse outcomes.
Proposed target	Country-specific

Indicator 13 – Additional	Stillbirth rate
What it measures	The incidence of stillbirth
Rationale	Stillbirth is one of the adverse consequences of syphilis infection in pregnancy. Approximately 25% of pregnancies affected by active syphilis result in early fetal loss and stillbirth.
Numerator	Number of reported stillbirths
Denominator	Estimated number of live births
Reference	Indicator also described in WHO ECS strategy (*5*)
Data source	Routine MNCH health-service data, vital statistics, or demographic health surveys
Frequency	Annually

Disaggregation	None
Comments	Mothers of stillborn infants should be routinely evaluated for preventable causes of stillbirth (e.g. obtain maternal syphilis test, screen for malaria, review for obstructed labour). A better understanding of stillbirth can improve maternal and child health services and reduce MNCH mortality in the future.
Data utilization	Look at changes in rates over time to assess trends. Since stillbirths can be attributable to a wide range of causes, data should be interpreted jointly with data on the etiology of stillbirth and Special study indicator 15 "Proportion of stillbirths attributable to syphilis in the mother".
Proposed target	Country-specific

Special study indicators

Indicator 14 – Special study	Estimated proportion of all syphilis-infected pregnant women who receive treatment by 24 weeks' gestation
What it measures	This summary process measure is a proxy for overall programme effectiveness and the impact of ECS efforts.
Rationale	This indicator measures programme progress in all pregnant women, not just those attending antenatal care. It allows comparison of programme progress among countries and regions.
Numerator	Number of pregnant women, whether or not antenatal care was obtained, who are infected with syphilis and who were treated with at least one dose of long-acting intramuscular penicillin by 24 weeks' gestation
Denominator	Estimated number of all pregnant women infected with syphilis, including women who attended antenatal care, women not attending antenatal care, and women who attended antenatal care but were not screened for syphilis.
Reference	Indicator also described in WHO ECS strategy (*5*)
Data source	*Numerator*: will require special study to determine number of seropositive pregnant women treated by 24 weeks. *Denominator*: can either be calculated directly through a special study, or estimated by multiplying the estimated number of pregnant women by the most representative source of data on syphilis positivity available for the country.
Frequency	Every 2–3 years
Disaggregation	None
Comments	None
Data utilization	Data can be used to provide information on proxy measure or progress on key programme indicators. Look at changes in rates over time to assess trends.
Proposed target	Proposed global target: ≥80%[†]

Indicator 15 – Special study	Proportion of stillbirths attributable to maternal syphilis
What it measures	The impact of ECS on reducing major syphilis-associated mortality
Rationale	Maternal syphilis infection leads to stillbirth in approximately 25% of untreated or inadequately treated cases. In some developing countries, syphilis accounts for 25% of all stillbirths. By measuring this important outcome of maternal syphilis infection, the global and local programmes can estimate the impact of the programme in reducing overall mortality.
Numerator	Number of reported stillbirths born to syphilis-seropositive mothers
Denominator	Total number of reported stillbirths
Reference	Indicator also described in WHO ECS strategy (*5*)
Data source	Routine MNCH health-service data, vital statistics, MNCH death reviews, sentinel surveillance, or other special studies
Frequency	Every 2–3 years
Disaggregation	None
Comments	Every stillbirth should lead to an evaluation of the cause (e.g. obtain maternal syphilis test, screen for malaria, review for obstructed labour).
Data utilization	Evaluate impact of global and local programmes. Look at changes in rates over time to assess trends.
Proposed target	Proposed global target: <2% †

† *Identification of indicators in the monitoring and evaluation of the global elimination of congenital syphilis initiative*. Geneva, World Health Organization, 2009 (teleconference meeting notes, 13 May).

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