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World Health Organization

Validation of EMTCT of HIV and/or syphilis

Tools and checklists for in-country evaluation of four required components

1		**Data assessment and verification**

Background

Assessment of EMTCT surveillance data and data quality are the cornerstones of EMTCT validation. Key to this process is review and evaluation of data quality in addition to data analyses from which the values for the process and outcome indicators are derived. In this tool, checklists for data collection processes and mechanisms are included to assist reviewers in evaluating country-level EMTCT data. At each level of data assessment, data quality dimensions should be considered as these contribute to the achievement and sustainability of EMTCT processes and indicators.

Methodology

The following activities are common in data verification[1,2]

1. **Description**: description of the connection between the health facilities and the completion of source documents to record the event.
2. **Documentation review**: review of the completeness, availability, and timeliness of all source documents in the reporting period.
3. **Trace and verification**: tracing and verifying reported numbers through a) recounting of the reported numbers from the various available source documents; b) comparing the verified numbers with the site reports.
4. **Cross-checks**: comparing verified report totals with other data sources (i.e. laboratory reports, registers, etc.)
5. **Spot-checks**: verify the actual delivery of services and/or commodities to the target population.

[1] Measure Evaluation. Data Quality Audit Tool. Measure Evaluation, USA, 2008. Available at: http://www.cpc.unc.edu/measure/tools/monitoring-evaluation-systems/data-quality-assurance-tools

[2] WHO Stop TB Department Geneva. Manual on use of routine data quality assessment (RDQA) tool for TB monitoring. WHO 2011

Some relevant documents and systems review for the data verification assessment include:

- Electronic surveillance systems
- Case definitions and reporting systems
- Routine surveillance reports
- EMTCT progress reports
- Surveillance/M&E manual(s), plans and policies
- Copies of legislation related to surveillance/M&E (i.e. notifiable diseases, etc.)
- Description of surveillance/M&E system(s), including organizational charts, staffing, etc.
- Operational definitions of the impact and coverage indicators
- Copies of data collection and reporting forms and tools
- Surveillance/M&E reports over the past 1–3 years
- Surveillance case definitions, including surveillance of infant births, deaths and stillbirths
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The data verification and impact assessment should include:

1. The national, sub-national and service delivery level:

    a. National level: the national epidemiology or M&E unit, with responsibility for national aggregation, analysis and compilation of data, and development of national reports.

    b. Sub-national level: units with responsibility for regional or sub-regional aggregation (and analysis) of data and onward reporting to the next level.

    c. Service delivery level: the sites generating the data. These include antenatal clinics, hospitals, HIV treatment centers, STI clinics, and sites providing post-delivery care for mothers and infants.

2. The private sector or other sectors[3] not included in the national data then data must be verified in these sectors)

    a. The data collection and reporting mechanisms and requirements.

    b. If and how the private or other sector data is collected and incorporated in the national data.

The following table summarizes the recommended scope of the data verification and impact assessment

Level	**Verification period**	**Estimated time needed**
Service delivery sites	3-6 months	2-4 hours per site
Sub-national units	12 or more months	2-3 hours per site
National level	24 months	4-8 hours

[3] Other sectors providing health care could include non-public hospitals and other health services, health insurance schemes, voluntary and private organizations in health, as well as the pharmaceutical industry and drug wholesale companies. In many developing countries, private not-for-profit health care providers constitute an important part of the health sector, sometimes owning up to half of a country's hospitals.

Data quality dimensions	
Attribute	**Definition**
Accuracy	Data considered accurate or valid if they measure what they were intended to measure and minimize errors
Reliability	Data generated based on consistent application of standardized protocols and procedures
Precision	Data collected with sufficient detail to accurately reflect group and subgroup characteristics
Completeness	Data that represent the complete domain of eligible persons or events
Sensitivity	The proportion of cases detected by the system
Timeliness	Data that are up to date, generated without much delay, and available when needed
Integrity	Data have integrity when the systems used to generate them are protected from deliberate bias or manipulation
Confidentiality	Confidentiality means that clients are assured that their personal information will not be disclosed inappropriately, and that data in hard copy and electronic form are treated with appropriate levels of security.

Source: Measure Evaluation. Data quality audit tool. Guidelines for implementation [webpage] (http://www.cpc.unc.edu/measure/resources/tools/monitoring-evaluation-systems/data-quality-assurance-tools/dqa-auditing-tool-implentation-guidelines.pdf, accessed 11 October 2015).

Review and evaluation of process and outcome indicators

Percentage of pregnant women attended by skilled health personnel during the prenatal period at least once (ANC1 coverage)

Validation target: ≥95%

Numerator: **Number of pregnant women visiting ANC clinic at least once**
Denominator: **Number of pregnant women**

Common or potential data issues

1. May not be able to distinguish between other visits (e.g. ANC2, 3, 4, etc.) and first ANC visit.
2. Numbers of expected pregnancies in a year may not be accurate.
3. Data may not be available from the private sector.

Triangulation Sources ANC1:

- Programme records aggregated from facilities
- Population-based surveys
- Estimated number of pregnant women:
    - national estimates
    - estimates derived from population-based surveys
    - UN Population Division estimate of live births.

Checklist:

- List, describe and review each data collection tool and methods to understand the data source. This includes a review of patient cards, registers, reporting forms, SOPs for aggregation; any estimation methods; any specific issues to note for the population-based survey of interest.
- Identify any potential issues or biases such as:
    - Completeness of reporting (from reporting completeness section above)
    - Double-counting or systematic errors from data aggregation for reporting
    - Over or under-estimation (e.g. UN Pop division estimates live births which we would expect to be less than the number of pregnancies)
- Assess inequities looking at data from underserved or hidden populations if available (e.g., migrants, immigrants, homeless, indigenous groups, etc.)
- Data *verification* results for routinely collected and reported programme data
    - Review data verification results if available from the preceding 24 months
    - Conduct data verification exercise if recent results not available
    - Minimum standard: within +/- 10%
- Data *validation* (i.e., accuracy and validity of data) through triangulation of data from different sources
- Final assessment

Testing coverage among pregnant women: Validation target ≥95%

For HIV

Numerator: **Number of pregnant women who have been tested (or know their positive status*)**
Denominator: **Estimated number of pregnant women**

*For example, pregnant women who already knew their HIV-positive status before pregnancy are included in the numerator.

For syphilis

Numerator: **Number of pregnant women who have been tested for syphilis in ANC**
Denominator: **Number of pregnant women in ANC**

WHO screening and treatment guidelines for maternal syphilis can be found at:
www.who.int/reproductivehealth/publications/rtis/syphilis-ANC-screenandtreat-guidelines/en/

Common or potential data issues

1. Re-tests or repeat tests may result in overestimation of the numerator, if repeat tests are not distinguished from first tests when aggregating data for reporting.
2. Denominator (estimated number of pregnant women) may not be accurate.
3. May not be representative of actual service delivery practices if conducted under special study or sentinel surveillance conditions.
4. May be unclear if appropriate test type is not used.
5. Additional information on whether test results were received may help understand whether most women know their status (where relevant) and provide insight into the expected treatment coverage and final impact measure.
6. Data may not be available from the private sector.

Triangulation sources

Reported number of HIV and syphilis tests among pregnant women:

  - programme records of ANC
  - retrospective reviews of maternity hospital records (often include data on testing, and sometimes dates of testing, during ANC)
- Lab testing, including lab data from private providers
  - related case reporting or surveillance data
- Estimated number of pregnant women:
  - national estimates
  - estimates derived from population-based surveys
  - UN Population Division estimate of live births
  - ANC1

Checklist:

- List, describe and review each data collection tool and methods to understand the data source. This includes a review of patient cards, clinic-attendance registers, reporting forms, SOPs for aggregation; laboratory testing records, any estimation methods; any specific issues to note for the population-based survey of interest.
- Identify any potential issues or biases such as:
    - Completeness of reporting (from reporting completeness section above)
    - Double-counting or systematic errors from data aggregation for reporting
    - Over or under-estimation (e.g. UN Pop division estimates live births which we would expect to be less than the number of pregnancies)
- Data *verification* results for routinely collected programme data
    - Review data verification results if available from the preceding 24 months
    - Conduct data verification exercise if recent results not available
    - Minimum standard: within +/- 10% or +/- 1 standard deviation
- Data *validation* through triangulation of data from different sources
- Final assessment

Treatment coverage among pregnant women validation target: ≥95%

For HIV

Numerator: **Number of HIV+ pregnant women who received ART**
Denominator: **Number of HIV+ pregnant women who delivered in the same time interval**

For syphilis:

Numerator: **Number of syphilis-positive pregnant women who have been treated with at least one dose of benzathine penicillin 2.4 mU at least 30 days prior to delivery**
Denominator: **Number of syphilis-positive pregnant women**

Common or potential data issues:

- Overestimation due to double-counting women who silently transfers to a different facility (without telling original facility they have transferred out) as another women receiving treatment
- If women receive treatment from a different site, the number of women receiving treatment may not be accurately recorded and aggregated without a standard SOP to accommodate this scenario
- Treatment data may not be recorded, particularly for stillborn infants

- Timing of treatment may be difficult to obtain (**CS case definition includes treatment requirement > 30 days prior to delivery**)
- Treatment coverage does not assess quality of treatment important to achieve impact targets: appropriate regimen, retention, adherence
- Data may be difficult to obtain or may not be available from the private or other health sectors (if public sector data accounts for less than 90% of all pregnant women in country, other sectors must be assessed for validation purposes)

Triangulation sources

- Number of pregnant women who received ART:
  - programme records
  - also collate and review data on regimen and retention to contextualize treatment coverage estimate
  - pharmacy records.
- Number of pregnant women who received syphilis treatment:
  - programme records
  - pharmacy records.
- Estimated number of HIV-positive pregnant women needing ART:
  - country estimates.
- Other modelled estimates (e.g. Spectrum if country estimates are different):
  - programme records of identified HIV-positive pregnant women.
- Estimated # syphilis-positive pregnancies:
  - modelled estimate
  - programme records of identified syphilis-positive pregnant women.
- Coverage:
  - country estimate of treatment coverage
  - coverage from a representative survey
  - coverage among pregnant women identified as HIV positive or syphilis positive, to review facility performance and use for triangulation purposes.

Checklist:

- List, describe and review each data collection tool and methods to understand the data source for the numerator and denominator. This includes a review of patients' cards, registers, reporting forms, delivery facilities, infant birth and death (e.g., stillborn, neonatal death) registries, SOPs for aggregation; any estimation methods such as Spectrum; any specific issues to note for the population-based survey of interest.
- Identify any potential issues or biases such as:
  - Completeness of reporting (from reporting completeness section above)
  - Double-counting or systematic errors from data aggregation for reporting
  - Over or under-estimation (e.g. if identified HIV or syphilis+ pregnant women are case-reported but not all positive cases are identified, this would be an underestimate of the total number of HIV or syphilis + pregnant women;
- Data *verification* results for routinely collected programme data
  - Review data verification results if available from the preceding 24 months
  - Conduct data verification exercise if recent results not available
  - Minimum standard: within +/- 10%
- Data *validation* through triangulation of data from different sources

- Final assessment

Impact indicators for EMTCT validation

For HIV:≤50 new paediatric HIV infections due to MTCT per 100 000 live births

Numerator: **number of reported children who were diagnosed as positive born to mothers living with HIV within a given calendar year**

Denominator: **Estimated number of live births within the same calendar year**

MTCT rate of either <5% in breastfeeding populations or <2% in non-breastfeeding populations

Numerator: **number of reported infants born to HIV-positive mothers, who were diagnosed as HIV positive in a given calendar year**

Denominator: **Reported number of infants born to HIV-positive mothers within the same calendar year with definitive diagnosis (HIV positives + HIV negatives)**

For syphilis

≤50 cases of congenital syphilis per 100 000 live births (No MTCT rate)

Numerator: **number of reported cases of congenital syphilis within a given calendar year**

Denominator: **Estimated number of live births within the same calendar year**

The global surveillance case definition for congenital syphilis includes:

1. a live birth or fetal death at >20 weeks of gestation or >500 g (including stillbirth) born to a woman with positive syphilis serology and without adequate syphilis treatment*

Adequate maternal treatment is defined as at least one injection of 2.4 million units of intramuscular benzathine benzylpenicillin at least 30 days prior to delivery.[4,5]

OR

2. a live birth, stillbirth or child aged <2 years born to a woman with positive syphilis

[4] In pregnant women with late syphilis or unknown stage of syphilis, WHO recommends benzathine penicillin 2.4 million units intramuscularly once weekly for three consecutive weeks *(4)*.

[5] A woman with a past history of syphilis diagnosis and for whom previous syphilis treatment can be confirmed should be evaluated for risk of re-infection. Those without physical (e.g., ulcer, unexplained rash) or laboratory evidence of syphilis (increasing non-treponemal titre) need not be classified as having current syphilis. However, women living in high prevalence settings or who have personal or partner behavioural risk or whose partners were not treated for syphilis may warrant evaluation for re-infection later in pregnancy. An infant born to a woman with a documented history of prior adequate treatment for syphilis prior to the current pregnancy, in whom no physical or laboratory evidence of re-infection (e.g., increasing maternal non-treponemal titre) can be excluded from the country counts of congenital syphilis cases.

serology or with unknown serostatus, and with laboratory and/or radiographic and/or clinical evidence of syphilis infection (regardless of the timing or adequacy of maternal treatment).

Laboratory and radiographic evidence consistent with a diagnosis of congenital syphilis includes any of the following:

a. demonstration by dark field microscopy or fluorescent antibody detection of *Treponema pallidum* in the umbilical cord, placenta, nasal discharge or skin lesion material or autopsy material of a neonate or stillborn infant;

b. reactive cerebrospinal fluid (CSF) analysis for Venereal Disease Research Laboratory (VDRL) test, or elevated CSF cell count or protein;

c. long bone radiographs suggestive of congenital syphilis (e.g. osteochondritis, diaphyseal osteomyelitis, periostitis);

d. infant with a reactive non-treponemal serology titre fourfold or greater than that of the mother;

e. infant with a reactive non-treponemal serology titre less than fourfold greater than that of the mother but that remains reactive ≥6 months after delivery;

f. infant with a reactive non-treponemal serology test of any titre AND any of the clinical signs listed below born to a mother with positive or unknown serology, independent of treatment.[6]

g. In settings where a non-treponemal titre is not available, infant born to a mother with positive or unknown serology, independent of treatment, and whose 6 month examination demonstrates any of the early clinical signs listed below.

Clinical signs associated with congenital syphilis

Early clinical signs that may be present in an infant with congenital syphilis include non-immune hydrops, hepatosplenomegaly, rhinitis (snuffles), skin rash, pseudoparalysis of an extremity or failure to thrive or achieve developmental milestones. An older infant or child may develop additional signs or symptoms such as frontal bossing, notched and pegged teeth (Hutchinson teeth), clouding of the cornea, blindness, bone pain, decreased hearing or deafness, joint swelling, sabre shins, and scarring of the skin around the mouth, genitals and anus.

[6] All neonates with **reactive** non-treponemal tests should have careful follow-up examinations and repeat non-treponemal tests every 2–3 months until the test becomes non-reactive. Infants with a **non-reactive** non-treponemal test at birth and whose mothers were reactive at birth should be retested at 3 months to rule out incubating syphilis. In an infant who was NOT treated because congenital syphilis was considered unlikely, non-treponemal antibody titres should decline by age 3 months and be non-reactive at 6 months. Any infant ≥6 months of age with a reactive non-treponemal serology titre should be considered a case of congenital syphilis. Syphilis-exposed infants should receive treatment according to WHO syphilis treatment guidelines *(4).*

Common or potential data issues

- National pediatric HIV due to MTCT definition may not be standardized for reporting surveillance purposes (e.g. Ukraine, 2 year old diagnosed with HIV is not counted as MTCT infant HIV case, same for syphilis).
- National congenital syphilis case definition may not be harmonized with global case definition (e.g., inclusion of stillbirths or not, definition of stillbirths, definition of appropriate treatment, diagnostic test or clinical criteria). **Please note that countries may be using a clinical case definition and not a surveillance case definition**. For validation purposes the national case definition will be assessed against the internationally recommended standards.
- Surveys may not be representative of population of interest (HIV and syphilis positive pregnant women and outcomes of their exposed infants)
- Timeliness and accuracy of data: There may be high numbers of HIV exposed children without definitive diagnosis
- Case reported data may be incomplete or unrepresentative
- Outcome data may be missing, including stillbirths and possibly early neonatal deaths
- Ideally, syphilis testing should include non-treponemal and treponemal testing
- The use of treponemal tests only may overestimate pregnant women with new syphilis (pregnant women with previously treated syphilis will have positive test)
- The use of non-treponemal testing only may overestimate positivity rates in women with biologic false positive results
- Data may be difficult to obtain or may not be available from the private or other health sectors (if public sector data accounts for less than 90% of all pregnant women in country, other sectors must be assessed for validation purposes)

Triangulation sources:

- Live births
  - Total number of live births – country estimates
  - Total number of live births – UN Pop estimates
- HIV
  - MTCT rate and new child HIV infections due to MTCT
  - Final outcome data on known HIV-exposed children from programme records
  - Case reporting data on new child HIV infections
  - Lab data on child HIV testing
  - Data from surveys, e.g. health facility surveys for PMTCT effectiveness
  - Data from mother-infant follow up cohort
  - Modelled estimates, for example from Spectrum
- Syphilis
  - National case report data
  - Sentinel case report data ANC
  - Data from mother-infant follow up cohort
  - Maternal syphilis treatment records
  - Lab data on child testing
  - Modelled estimates, for example based on process indicators (methods not currently validated)

- **General:**
  - total number of live births – country estimates or UN Population Division estimates
  - total number of HIV positive mothers giving birth
- **HIV: MTCT rate and new child HIV infections due to MTCT:**
  - final outcome data on known HIV-exposed children from programme records
  - case-reporting data on new child HIV infections
  - programme data on child HIV testing and other indicators for triangulation
  - laboratory data on child HIV testing
  - data from surveys, e.g. health facility surveys for effectiveness of prevention of mother-to-child transmission (PMTCT)
  - data from mother–infant follow-up cohort
  - modelled estimates, for example, from Spectrum.

Checklist:

Programme data – outcome of HIV-exposed infants, MTCT where cohort-pair data are linked

- Estimate what % of estimated HIV-exposed infants the available data represent, and what type of children may be missing asymptomatic, dead, etc.).
- Estimate possible outcomes of HIV-exposed infants with missing data, including sensitivity analyses.

Laboratory data

- Check if data can be sorted by unique patient ID and patient age at the time of testing (helps interpret data derived from laboratory).
- Estimate what % of estimated HIV-exposed infants the available data represent and what type of children may be missing (asymptomatic, dead, etc.).
- Estimate possible outcomes of HIV-exposed infants with missing data, including sensitivity analyses.

HIV Case reporting

- Estimate what % of estimated HIV-exposed children the available data represent and what type of children may be missing (asymptomatic, dead, etc.).
- Estimate possible outcomes of HIV-exposed infants with missing data, including sensitivity analyses.
- Consider review of fetal death and infant and paediatric death records, death certificates, cause of death.
- Estimate outcomes of HIV-exposed infants where mothers are untreated, lost to follow up, or have died.

F**acility-based surveys for PMTCT effectiveness**

- Assess representativeness and generalizability of survey.
- Estimate possible outcomes of HIV-exposed infants with missing data, including sensitivity analyses.

Cohort-pair data

- Estimate what % of estimated HIV-positive mothers and HIV-exposed children the available data represent and what type of children may be missing (e.g. asymptomatic, dead, unreported death; relocated, refugee, migrant, orphaned, abandoned etc.), and assess representativeness and generalizability.

Triangulation sources for syphilis

- sentinel case report ANC data
- maternal syphilis treatment records
- modelled estimates, for example, based on process indicators (see modeling estimate tool)

National case-reporting data

- Assess how discrepancies between national and global case definitions may affect the CS rate.
- Assess how consistently CS is diagnosed within the country and examine criteria for diagnosis. Are mothers of stillborn children tested for syphilis?
- Identify any potential concerns about the representativeness of reported CS cases.
- Conduct a retrospective record review of stillbirths from a sentinel site(s) to assess what proportion of stillbirths may have been associated with syphilis, and if any of these potential syphilitic stillbirths were not reported as CS cases.
- Consider the impact that laboratory testing methods may have on CS case reporting.
- Consider the impact that clinical diagnostic methods may have on CS case reporting.
- Estimate what proportion of CS cases may have been missed (through comparison with the number of pregnant women with syphilis who did not receive treatment).
- Evaluate what efforts are made to determine the etiology of stillbirth.

Sentinel case-reporting data

This should be as for national case reporting. In addition, identify how generalizable sentinel case reporting data are and whether key subpopulations or geographical areas have been missedOverall Checklist:

- List, describe and review each data source and methods to understand the data source for the numerator and denominator. This includes a review of patients' cards, registers, reporting forms, SOPs for aggregation; any estimation methods such as Spectrum; any specific protocols for surveys or special studies.
- Identify any potential issues or biases such as:
    - Completeness of reporting (from reporting completeness section above)
    - Double-counting or systematic errors from data aggregation for reporting
    - Representativeness and generalizability, and quality of data from case reporting or surveys
    - Over or under-estimation
- Data *verification* results for routinely collected programme data
    - Review data verification results if available from the preceding 24 months
    - Conduct data verification exercise if recent results not available
    - Minimum standard: within +/- 10%
- Data *validation* through triangulation of data from different sources
- Final assessment

Confidentiality

The validation team might need to access patient cards and other sources containing personal and medical information. All members of the team will be required to sign a confidentiality statement prior to their participation. Under no circumstance will members of the team record personal information, make photocopies, or remove source documents from the service delivery sites or the aggregation sites.

Duplication or removal is only allowed for aggregated reports that do not contain any personal identifiers or information.

DATA ANALYSIS AND SYNTHESIS

The main synthesis questions are:

1. **Are the data generated by the country reliable to assess achievement of the EMTCT targets?**
    - Is there coherence in the data collection methods on national, sub-national and local level?
    - Does the national data incorporate and adequately reflect the national situation?
    - Are the mechanisms for identification and correction of data errors?

    Standards:

    - Country EMTCT strategic information system appears to comply with international standards and minimum data quality dimensions: accuracy, reliability, and completeness.
    - Completeness of reporting complies with the minimum standard of **90%**

2. **Has the country achieved the EMTCT targets?**
    - Does the verified (and corrected) data on the EMTCT impact targets comply with global minimum requirements?
    - Is there sub-national equity in the achievement of the EMTCT impact and coverage targets?

    Standards:

    - EMTCT impact targets
    - EMTCT coverage targets

Upon completion of the data verification and impact assessment, the validation team will make an expert determination regarding above synthesis questions.

Based on the joint analysis, the validation team can arrive at any of the following conclusions:

1. Unqualified endorsement of the EMTCT achievement of targets
2. Endorsement of the EMTCT achievement of targets with clear recommendations for strengthening of components that might pose a current or future threat
3. Determination of insufficiencies that preclude EMTCT validation

The conclusions outlined in the presentation should also be summarized in a report that clearly outlines the key findings from the mission, the principal conclusions and the recommended next steps. A template for this report will be provided.

Data verification and impact assessments at the national level

Country: _____ Date: _____

Description

Name of the site/unit:	Address:
Types and quantity of staff:	

Name of Person Interviewed	**Position**	**Email**	**Contact number (mobile)**

Documents Reviewed	**Comments**

Checklist (national level)

Data collection mechanisms and processes	Yes	No	Not able to assess	Comments
There are written national guidelines on what needs to be reported by and to whom, how and when				
There are case definitions for congenital syphilis				
The national case definitions for congenital syphilis comply with international standards, including still births				
There is a surveillance system in place for congenital syphilis				
Congenital syphilis is a reportable condition				
Perinatal HIV is a reportable condition				
National data includes data from all health sectors: public, private, social security, military, etc.				
There are mechanisms in place for review of the quality of reports received (accuracy, completeness, timeliness)				
The data review and collation procedures minimize the risks for double counting and other errors				
There written procedures to address late, incomplete, inaccurate, or missing reports				

There are mechanisms for systematic feedback to the reporting levels on the quality and analysis of their reports				
There are quality controls in place for when data is transferred from one source to another (i.e. from paper to electronic)				
The different subsystems are integrated into one national information systems				
There are issues with the integration of the information system. How can it be improved?				
Health system strengthening *(triangulate with program assessment)*	**Yes**	**No**	**Not able to assess**	**Comments**
Leadership: There is a visible leadership in the monitoring and evaluation of the elimination initiative, as needed to ensure integration of all data into one functional system.				
Human resources: There appears to be sufficient staff designated for review, collation and analysis of reports				
Human resources: Staff has been trained in data management processes and tools				
Financing: The information system is fully funded with national sources. Are there other issues with financing the information system? Please explain.				
Financing: There are issues with financing the information system. Please explain.				
Sustainability: The information system is sustainable in its current operating mode.				

Data verification action at the national level

Please name and define country specific "subnational level" (e.g. province, district or health facility)

	Action	Complete
1	Describe and review the central-level aggregation process (paper, electronic)	
2	• Compare the number of reports received with the expected number of reports over a specified period of time (month, quarter, year).	
3	• Review the completeness and timeliness of reports received. • Identify missing data in reports received.	
4	• Re-aggregate reported numbers from all intermediate aggregation sites and compare the total to the numbers in the central-level reports. • Include estimated missing data and recalculate national impact and national and sub-national coverage indicators.	
5.	• How are new cases of HIV in children detected? • Does the surveillance and monitoring system adequately capture new cases?	

Data quality	**%**	**Not able to assess**	**Comments**
What percentage of monthly/quarterly reports are received at the national or subnational level as of the last quarter? (standard ≥90%)			
What percentage of cases reported at the local level appears at the intermediate or central level?			
Are recalculated values similar to the reported values?	( ) Yes ( )No		
What can be done to help improve routine M&E? *(Suggestions/comments from interviewed staff)*	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____		

Assessment of report on ANC coverage and data completeness – national level

COVERAGE of pregnant women attended by skilled health personnel during prenatal period at least once [ANC1 COVERAGE] and completeness [National level]

ANC1 Coverage	Year 1	Year 2	Other year?
Number of pregnant women seen in antenatal care services at least once (1)			
Source:			
Official estimate for number of pregnant women (2)			
Source:			
ANC estimate from other source [ex.Survey data] (3)			
Source:			
United Nations Population Division estimate of live births (4)			
[A] % coverage of ANC1 (1)/(2) [country estimate]			
[B] % coverage of ANC1 from other source (1)/(3) [ex. Survey data]			
[C] % coverage of ANC1 (1)/(4) [UN Pop]			
Comments:			

Assessment of report ANC1 visit coverage and completeness

Assessment of report ANC1 visit coverage and completeness		Comments
Number of sub-national units reporting number of pregnant seen in antenatal care services		
% coverage of sub-national units reporting number of pregnant seen in antenatal care services		
% of monthly/quarterly sub-national units reports received		
% of monthly/quarterly reports received by the lowest performing unit		
% all private and other health sectors reports included		
Characteristics of private or other health sectors:		

Final assessment of ANC1 coverage [National level]

Data verification TESTING coverage [National level]

HIV Testing Coverage	Year 1	Year 2	Other year?
Number of pregnant women tested for HIV (1)			
Source:			
Number of pregnant women (2)			
Source:			
[A] % coverage of HIV testing among pregnant women (1)/(2) [country data]			
[B] % coverage of HIV testing among pregnant women from other source [ex. Survey data]			
Source for survey data:			
[C] % coverage of HIV testing among pregnant women [use UN Pop]			
Syphilis Testing Coverage	**Year 1**	**Year 2**	**Other year?**
Number of pregnant women tested for syphilis (3)			
Source:			
Number of pregnant women attending antenatal care services (4)			
Source			
[A] % coverage of syphilis testing among pregnant women (3)/(4) [country data]			
[B] % coverage of syphilis testing among pregnant women from other source [ex. Survey data]			

Source for survey data::
Comments:

Assessment of report TESTING coverage and completeness

Final assessment of report TESTING coverage and completeness	HIV	Syphilis
Number of sub-national units performing testing among pregnant women		
Number of sub-national units that report test results among pregnant women		
% coverage of sub-national units reporting test results among pregnant women		
% of monthly/quarterly sub-national units reports received		
% of private and other health sectors reports included		
Characteristics of private or other health sectors:		

Final assessment of report TESTING coverage at national level

Data verification TREATMENT coverage [National level]

HIV Treatment Coverage	Year 1	Year 2	Other year?
Number of pregnant women who received ART (1)			
Source:			
Number of HIV-positive pregnant women (2)			
Source:			
[A] % coverage of ART among HIV positive pregnant women (1)/(2) [country data]			
[B] % coverage of ART among HIV positive pregnant women from other source [ex. Survey data]			
Source for survey data:			
[C] % coverage of ART among HIV positive pregnant women [Spectrum if available]			
Syphilis Treatment Coverage	**Year 1**	**Year 2**	**Other year?**
Number of pregnant women appropriately treated for syphilis (3)			
Source:			
Number of syphilis-positive pregnant women (4)			
Source:			
[A] % coverage of syphilis treatment among syphilis positive pregnant women (3)/(4) [country est.]			
[B] % coverage of syphilis treatment among syphilis positive pregnant women from other source [ex. Survey data]			

Source for survey data:
Comments:

Assessment of report TREATMENT coverage and completeness

Final assessment of report TREATMENT coverage and completeness	HIV	Syphilis
Number of sub-national units providing treatment for pregnant women		
Number of sub-national units that report treatment for pregnant women		
% coverage of sub-national units reporting treatment for pregnant women		
% of monthly/quarterly sub-national units reports received		
% of private and other health sectors reports included		
Characteristics of private or other health sectors:		

Final assessment of report TREATMENT coverage at National level

Distribution of outcomes of exposed infants [National level]

HIV[#]	[2014 birth cohort] Number	[2015 birth cohort] Number	Data source:
Total number of infants, born to HIV positive mothers ("HIV-exposed infants")			
Total number of infants, born to HIV positive mothers that are diagnosed as POSITIVE for HIV			
Total number of infants, born to HIV positive mothers that are diagnosed as NEGATIVE for HIV			
Total number of infants, born to HIV positive mothers, classified as INDETERMINATE*			
Comments:			

Syphilis	Year	Year	Data source:
Total number of infants born to syphilis positive mothers			
Total number of stillbirths born to syphilis positive mothers			
Total number of infants + stillbirths born to syphilis infected mothers that were either NOT treated > 30 days prior to delivery OR had unknown treatment status			

Total number of reported congenital syphilis cases (live births)**			
Total number of reported congenital syphilis cases (stillbirths)**			
% of stillbirths investigated for microbiological evidence of syphilis***			
Comments:			

Consider indeterminate those without a final HIV assessment status; all lost to follow up, death before definitive diagnosis, indeterminate lab results.

* Case definition for **congenital syphilis**: A stillbirth, live birth, or fetal loss at >20 weeks of gestation or >500 grams to a syphilis-seropositive mother without adequate syphilis treatment **OR** A stillbirth, live birth, or child ages < 2 years with microbiological evidence of syphilis infection.

** Microbiological evidence of congenital syphilis includes any one of the following: demonstration by dark field microscopy or fluorescent antibody detection of *T. pallidum* in the umbilical cord, the placenta, a nasal discharge, or skin lesion material; detection of *T. pallidum*-specific IgM; or infant with a positive non-treponemal serology titre greater than fourfold that of the mother.

Assessment of report infant outcomes and completeness [National Level]

Final assessment of report infant outcomes and completeness	HIV	Syphilis
Number of sub-national units providing testing of infants		
Number of sub-national units that report testing of infants		
% coverage of sub-national units reporting testing of infants		
% of monthly/quarterly sub-national units reports received		
% of private and other health sectors reports included		
Characteristics of private or other health sectors:		

Final assessment of INFANT OUTCOMES at National level

Revised version date 29 March 2018

Summary of validation targets [National level]

Impact indicators:	Target	Year			Year		
		%	Numerator	Denominator	%	Numerator	Denominator
MTCT rate of HIV	≤2%						
Annual rate of new pediatric HIV infections per 100,000 live births	≤50						
Annual rate of congenital syphilis per 100,000 live births	≤50						
Key monitoring indicators:							
Antenatal care coverage	≥95%						
HIV testing coverage of pregnant women	≥95%						
Syphilis testing coverage of pregnant women	≥95%						
ART coverage of HIV-positive pregnant women	≥95%						
Treatment coverage of syphilis-positive pregnant women	≥95%						

Final Assessment of Impact Targets:

MTCT of HIV rate:

Child HIV Infections due to MTCT per 100,000 live births:

MTCT of syphilis rate:

Congenital syphilis cases per 100,000 live births (including stillbirths):

DATA VERIFICATION AND IMPACT ASSESSMENT - SUB-NATIONAL LEVEL TOOL

Date: _____ Interviewer:_____

Description

Name of the site/unit:	Address:
Was this considered a low-performance unit? ( ) YES ( ) NO *Comments*:	
Types and quantity of staff:	

Persons Interviewed			
Name	**Position**	**E-mail**	**Contact number (mobile)**

Documents Reviewed	

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Checklist [Sub-national level]

Data collection mechanisms and processes	Yes	No	Not able to assess	Comments
There is an understanding of the national guidelines on what needs to be reported on perinatal HIV and CS to whom, how and when				
Sub-national level understands case definitions for congenital syphilis				
There are mechanisms in place for review of the quality of reports received (accuracy, completeness, timeliness)				
The data review and aggregation procedures minimize the risks for double counting and other errors (within and between levels of reporting)				
There are written procedures to address late, incomplete, inaccurate, or missing reports (inclusion/exclusion, correction, follow-up, etc.)				
There are mechanisms for systematic feedback to the reporting levels on the quality and analysis of reports?				
There are quality controls in place for when data is transferred from one source to another (i.e. from paper to electronic)				
There appear to be sufficient designated staff responsible for review, collation and analysis of data				
Staff has been trained in data management processes and tools				

Sub-national data includes data from all health sectors [relevant if public sector data accounts for <90% of reports]				

Data Quality	**%**		**Not able to assess**	**Comments**
Which percentage of monthly/quarterly reports is received at sub-national level? (Standard ≥ 90%)				
Which percentage of cases reported at local level appears at intermediate level?				
Recalculated values are similar to the reported values	( ) Yes	( ) No		
What can be done to help improve routine M&E?	*(Suggestions/comments from interviewed staff)*			

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Data verification TESTING coverage [Sub-national level]

HIV Testing Coverage	year	year	Other year?
Number of pregnant women tested for HIV (1)			
Source:			
Number of pregnant women (2)			
Source:			
[A] % coverage of HIV testing among pregnant women (1)/(2) [country data]			
[B] % coverage of HIV testing among pregnant women from other source [ex. Survey data]			
Source:			
Syphilis Testing Coverage	**year**	**year**	**Other year?**
Number of pregnant women tested for syphilis (3)			
Source:			
Number of pregnant women attending antenatal care services (4)			
Source:			
[A] % coverage of syphilis testing among pregnant women (3)/(4) [country data]			
[B] % coverage of syphilis testing among pregnant women from other source [ex. Survey data]			
Source:			
Comments:			

Assessment of report TESTING coverage and completeness

Final assessment of report TESTING coverage and completeness	HIV	Syphilis
Number of facilities performing testing among pregnant women		
Number of facilities that report test results among pregnant women		
% coverage of facilities reporting test results among pregnant women		
% of monthly/quarterly facility reports received		
% of private or other health sectors reports included		
Characteristics of private or other health sectors:		

Final assessment of report TESTING coverage [Sub-national level]

Data verification action at sub-national level

	Action
1	• Describe and review the regional aggregation process (paper, electronic)
2	• Compare the number of reports received with the expected number of reports over a specified period of time (month, quarter, year)
3	• Review completeness and timeliness of reports received: ○ Compare the estimated, recorded and reported numbers of pregnant women tested for HIV and syphilis, number of seropositive women treated and exposed infants diagnosed ○ Identify missing data related to the impact and coverage indicators in reports received ○ Updating of reports when final laboratory data are identified ○ Tickler systems in place to ensure no women testing positive go untreated, or receive delayed treatment [i.e. a system for reminding of critical deadlines and appointments]
4	• Re-aggregate reported numbers from all service delivery sites and compare the total to the numbers in the regional reports • Include estimated missing data and (re)calculate impact and coverage indicators for selected administrative units and compare with reported numbers to identify discrepancies

Data verification TREATMENT coverage [Sub-national level]

HIV Treatment Coverage	year	year	Other year?
Number of pregnant women who received ART (1)			
Source:			
Number of HIV-positive pregnant women (2)			
Source:			
[A] % coverage of ART among HIV positive pregnant women (1)/(2) [country data]			
[B] % coverage of ART among HIV positive pregnant women from other source [ex. survey data]			
Source:			
Syphilis Treatment Coverage	**year**	**year**	**Other year?**
Number of pregnant women appropriately treated for syphilis (3)			
Source:			
Number of syphilis-positive pregnant women (4)			
Source:			

[A] % coverage of syphilis treatment among syphilis-positive pregnant women (3)/(4) [country data]			
[B] % coverage of syphilis treatment among syphilis-positive pregnant women from other source [ex. survey data]			
Source:			
Comments:			

Assessment of report TREATMENT coverage and completeness [Sub-national level]

Final assessment of report TREATMENT coverage and completeness	HIV	Syphilis
Number of facilities providing treatment for pregnant women		
Number of facilities that report treatment for pregnant women		
% coverage of facilities reporting treatment for pregnant women		
% of monthly/quarterly facilities reports received		
% of private or other health sectors reports included		
Characteristics of private or other health sectors:		

Final assessment of report TREATMENT coverage [Sub-national level]

Distribution of outcomes of exposed infants [Sub-national level]

HIV#	[Year birth cohort] Number	[Year birth cohort] Number	Data source:
Total number of infants born to HIV positive mothers ("HIV-exposed infants")			
Total number of infants born to HIV positive mothers that are diagnosed as POSITIVE for HIV			
Total number of infants born to HIV positive mothers that are diagnosed as NEGATIVE for HIV			
Total number of infants born to HIV positive mothers, classified as INDETERMINATE			
Comments:			
Syphilis	**Year**	**Year**	**Data source:**
Total number of infants born to syphilis positive mothers			
Total number of stillbirths born to syphilis positive mothers			
Total number of reported congenital syphilis cases (live births)*			

Total number of reported congenital syphilis cases (stillbirths)*			
% of stillbirths investigated for microbiological evidence of syphilis**			
Comments:			

Consider indeterminate those without a final HIV assessment status; all lost to follow up, death before definitive diagnosis, indeterminate lab results.

* Case definition for **congenital syphilis**: A stillbirth, live birth, or fetal loss at >20 weeks of gestation or >500 grams to a syphilis-seropositive mother without adequate syphilis treatment **OR** A stillbirth, live birth, or child ages < 2 years with microbiological evidence of syphilis infection.

** Microbiological evidence of congenital syphilis includes any one of the following: demonstration by dark field microscopy or fluorescent antibody detection of *T. pallidum* in the umbilical cord, the placenta, a nasal discharge, or skin lesion material; detection of *T. pallidum*-specific IgM; or infant with a positive non-treponemal serology titre greater than fourfold that of the mother.

Assessment of report infant outcomes and completeness [Sub-national level]

Final assessment of report infant outcomes and completeness	HIV	Syphilis
Number of units providing testing of infants		
Number of units that report testing of infants		
% coverage of units reporting testing of infants		
% of monthly/quarterly units reports received		
% of private and other health sectors reports included		
Characteristics of private or other health sectors:		

Final assessment of INFANT OUTCOMES [Sub-national level]

DATA VERIFICATION AND IMPACT ASSESSMENT – SERVICE DELIVERY LEVEL TOOL

Description

Name of site: Location:	Date: ____/____/____ Interviewer:
Type	
❑ Primary care clinic ❑ Hospital ❑ Other: _____	❑ Public ❑ Private ❑ Other:_____
Services provided by the site (check all that apply):	
❑ Antenatal care ❑ HIV testing (ANC/general) ❑ Syphilis treatment (ANC/general)	❑ Delivery care ❑ Syphilis testing (ANC/general) ❑Antiretroviral therapy

❑Post-delivery care for infants (general)	❑ Post-delivery care for HIV-exposed infants
❑ Post-delivery care for syphilis-exposed infants	❑Antiretroviral therapy
❑Post-delivery care for women	

Persons Interviewed			
Name	Position	E-mail	Telephone number (mobile)

Documents Reviewed	

Checklist at service delivery level

Data collection mechanisms and processes	Yes	No	Not able to assess	Comments
There is an understanding of the national guidelines on what needs to be reported on perinatal HIV and CS to whom, how and when				
There are clear instructions on how to complete the data collection and reporting tools				
The data collection and reporting tools appear to be used consistently at the site				
The data collection and reporting tools include the core data elements to monitor the EMTCT targets				
The data collection and reporting tools minimize the risks for double counting and other errors				
There are quality controls in place for when data is transferred from one source to another (i.e. from paper to electronic)				
Patient records are maintained according to national and international				

confidentiality guidelines				
There appear to be sufficient staff designated for data entry and reporting				
Staff has been trained in data management processes and tools				
There is a tickler systems in place to ensure no women testing positive go untreated, or receive delayed treatment [i.e. a system for reminding of critical deadlines and appointments]				
Reports are updated when final laboratory results are released				
Data Quality	**Yes**	**No**	**Not able to assess**	**Comments**
Congenital syphilis case definitions are accurately and consistently applied				
Maternal syphilis case definitions are accurately and consistently applied				
Maternal HIV case definitions are accurately and consistently applied				

Stillbirths attributable to syphilis are recorded and reported				
Data Quality	**%**		**Not able to assess**	**Comments**
What % of reviewed ANC patient cards or registers indicates syphilis testing? (Standard ≥95%)				
What % of reviewed ANC patient cards or records indicates HIV testing? (Standard ≥95%)				
What % of reviewed cards or records from syphilis-seropositive pregnant women indicates syphilis treatment? (Standard ≥95%)				
What % of reviewed cards or records from HIV-positive pregnant women indicates HIV treatment? (Standard ≥95%)				
In what % of cases there was consistency between recorded and reported CS cases? (Standard ≥95%)				
What % of syphilis-exposed infants has been diagnosed? (Standard ≥95%)				

In your opinion, what are major challenges with EMTCT M&E?			
What can be done to improve routine EMTCT M&E?			

REVIEW OF RECORDS			
Type of records reviewed	**Method used to select the records**	**Number of records reviewed**	**Results and comments**

Data Verification Action at Service Delivery Level

	Action
1	Verify syphilis testing of pregnant women on sample of patient records
2	Verify that locally used CS case definition is in line with national definition
3	Review the existence and completeness of case investigation or other documents to assess consistency of process for final diagnosis of CS cases
4	Verify if stillbirths are included in the reported number and how stillbirth cases are diagnosed (syphilis status of mother, autopsy, etc.)
5	Compare recorded cases with reported cases to determine consistency
6	Compare reported number of pregnant women tested for HIV with total number of pregnant women seen at the site
7	Verify patient records to determine timing of initiation of ANC and number of ANC visits
8	Compare registered number of HIV-exposed infants with registered number of HIV-positive pregnant women
9	Compare registered number of HIV-exposed infants with registered number of infants with final diagnosis
10	Compare recorded number of HIV-positive infants with reported number

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Data verification TESTING coverage [Service delivery level]

HIV Testing Coverage	**year**	**year**
Number of pregnant women tested for HIV (1)		
Source:		
Number of pregnant women seen in antenatal care services (2)		
Source:		
% coverage of HIV testing among pregnant women (1)/(2)		
Syphilis Testing Coverage	**year**	**year**
Number of pregnant women tested for syphilis (3)		
Source:		
% coverage of syphilis testing among pregnant women (3)/(2)		
Comments:		

Data verification TREATMENT coverage [Service delivery level]

HIV Treatment Coverage	**year**	**year**
Number of pregnant women who received ART (1)		
Source:		
Number of HIV-positive pregnant women (2)		
Source:		
% coverage of ART among HIV-positive pregnant women (1)/(2)		
Syphilis Treatment Coverage	**year**	**year**
Number of pregnant women appropriately treated for syphilis (3)		
Source:		
Number of syphilis-positive pregnant women (4)		
Source:		
% coverage of syphilis treatment among syphilis-positive pregnant women (3)/(4)		
Comments:		

Distribution of outcomes of exposed infants [Service delivery level]

HIV[#]	[year birth cohort] Number	[Year birth cohort] Number	Data source:
Total number of infants born to HIV positive mothers ("HIV-exposed infants")			
Total number of infants born to HIV positive mothers that are diagnosed as POSITIVE for HIV			
Total number of infants born to HIV positive mothers that are diagnosed as NEGATIVE for HIV			
Total number of infants born to HIV positive mothers, classified as INDETERMINATE[##]			
Comments:			

Syphilis	**year**	**year**	**Data source:**
Total number of infants born to syphilis positive mothers			
Total number of stillbirths born to syphilis positive mothers			
Total number of reported congenital syphilis cases (live births)*			
Total number of reported congenital syphilis cases (stillbirths)*			
% of stillbirths investigated for microbiological evidence of syphilis**			
Comments:			

Consider indeterminate those without a final HIV assessment status; all lost to follow up, death before definitive diagnosis, indeterminate lab results.

* Case definition for **congenital syphilis**: A stillbirth, live birth, or fetal loss at >20 weeks of gestation or >500 grams to a syphilis-seropositive mother without adequate syphilis treatment **OR** A stillbirth, live birth, or child ages < 2 years with microbiological evidence of syphilis infection.

** Microbiological evidence of congenital syphilis includes any one of the following: demonstration by dark field microscopy or fluorescent antibody detection of *T. pallidum* in the umbilical cord, the placenta, a nasal discharge, or skin lesion material; detection of *T. pallidum*-specific IgM; or infant with a positive non-treponemal serology titre greater than fourfold that of the mother.