

Meeting Report

Regional Core Group Meeting for the Validation of the Elimination of Parents-to-Child Transmission of HIV and Syphilis in Asia and the Pacific



10 November 2014
Bangkok, Thailand



(WP)HSI/2014/DCD

English only

Report Series Number: RS/2014/GE/65(THA)

**REGIONAL CORE GROUP MEETING FOR THE VALIDATION
OF THE ELIMINATION OF PARENTS-TO-CHILD TRANSMISSION
OF HIV AND SYPHILIS IN ASIA AND THE PACIFIC**

**10 November 2014
Bangkok, Thailand**

Convened by:

World Health Organization
Regional Office for the Western Pacific

United Nations Children's Fund
East Asia and Pacific

Not for sale

Printed and distributed by

World Health Organization
Regional Office for the Western Pacific
Manila, Philippines

16 February 2015

NOTE

The views expressed in this report are those of the participants who attended the Regional Core Group Meeting for the Validation of the Elimination of Parents-to-Child Transmission of HIV and Syphilis in Asia and the Pacific and do not necessarily reflect the policies of the World Health Organization and the United Nations Children's Fund – East Asia and the Pacific Regional Office.

This report was prepared by the World Health Organization regional offices for the Western Pacific and the United Nations Children's Fund – East Asia and the Pacific Regional Office for governments of Member States in the Region and for those who participated in the Regional Core Group Meeting for the Validation of the Elimination of Parents-to-Child Transmission of HIV and Syphilis in Asia and the Pacific on 10 November 2014 in Bangkok, Thailand.

ACRONYMS

ANC	antenatal care
ART	antiretroviral therapy
CS	congenital syphilis
EID	early infant diagnosis
EPTCT	elimination of parents-to-child transmission
HIV	human immunodeficiency virus
GVC	global validation committee
GVS	global validation secretariat
MDG	millennium development goals
MNCH	maternal, newborn and child health
MTCT	mother-to-child transmission
NVC	national validation committee
NVT	national validation team
PAHO	Pan American Health Organization
PCR	polymerase chain reaction
PPTCT	prevention of parents-to-child transmission
RVC	regional validation committee
RVS	regional validation secretariat
RVT	regional validation team
STI	sexually transmitted infection
TOR	terms of reference
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNICEF EAPRO	East Asia and the Pacific Regional Office of UNICEF
UNICEF ROSA	South Asia Regional Office of UNICEF
WHO	World Health Organization

EXECUTIVE SUMMARY

As Member States progress towards elimination of parents-to-child transmission (EPTCT) of HIV and syphilis, a validation mechanism for elimination is needed. The World Health Organization (WHO) in collaboration with the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) has developed *Global Guidance on Criteria and Processes for Validation for elimination of mother-to-child transmission (EMTCT) of HIV and syphilis*, which outlines minimum processes and criteria for validation in a country; provides a description of global EPTCT validation targets and indicators; explains the operation of validation committees and secretariats; and reviews the validation procedure.

The Asia-Pacific regional core group meeting for the validation of EPTCT of HIV and syphilis was convened to establish a regional mechanism for validation and to discuss next steps to support regional and country activities in the Asia-Pacific. An additional objective of the meeting was to learn from the experiences of pilot validation exercises in the Asia-Pacific and the Latin America and the Caribbean. The process for the validation, operational tools, and the experiences from the regions were introduced to the meeting participants.

Some of the issues and challenges that were highlighted for the region include:

- Low burden of disease among women in the region with limited resource for HIV testing at antenatal care (ANC) and during labour
- Women receiving antiretrovirals (ARVs) in late pregnancy or at delivery
- Limited access to care at ANC among marginalised populations
- Limited and decreasing funding for EPTCT
- Lack of quality control for laboratories
- Weak monitoring and evaluation (M&E) systems
- Lack of data from the private sector on ANC, delivery, and prevention of parents-to-child transmission (PPTCT)

The meeting discussed the proposed regional mechanism for validation. It was suggested the mechanism should be built on the existing platform of the Asia Pacific PPTCT Task Force, in which the Regional Validation Secretariat (RVS) will be provided by WHO Regional Office for South-East Asia and the Regional Office for Western Pacific Region in partnership with UNICEF East Asia and Pacific Regional Office and the South Asia Regional Office. The terms of reference (TOR) for the Regional Validation Committee and the selection criteria of its members were also discussed.

The next steps include the finalization of the TOR for RVC, nomination of candidates and the establishment of the RVC, and planning and implementation of pre-validation in selected candidate countries.

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1. INTRODUCTION

1.1 Background

Elimination of parents-to-child transmission (EPTCT)¹ of HIV and syphilis will contribute to improving the health of women and babies. In 2010 the regional goal of EPTCT was endorsed at the 8th Asia Pacific PPTCT task force meeting, November 2010, Vientiane, the Lao People's Democratic Republic. As Member States progress towards *EPTCT*, the need for a mechanism to validate EPTCT of HIV and syphilis became apparent. WHO in collaboration with UNICEF, UNFPA, and UNAIDS developed a *Global Guidance on Criteria and Processes for Validation for EMTCT of HIV and syphilis*.² This guidance outlines minimum processes and criteria for validation in a country; provides a description of global EPTCT validation targets and indicators; explains the operation of validation committees and secretariats; and reviews the validation procedure. Subsequently in September 2014, WHO headquarters hosted a global technical partners meeting on validation of elimination, to review global minimum standards and processes for EPTCT validation, review operational tools to support regional and country processes, and outline next steps for collaboration with global technical partners, including resource mobilization and advocacy. Meeting participants reviewed and discussed draft tools for data quality and impact assessments, laboratory assessment, human rights/gender/and community engagement, costing, and governance.

To initiate and plan the validation mechanism in the Asia Pacific region, a regional core group meeting for the validation of EPTCT of HIV and syphilis was jointly convened by WHO Regional Office for Western Pacific and UNICEF Regional Office for East Asia-Pacific.

1.2 Meeting objectives

The objectives of the meeting were:

- 1) to introduce WHO global guidance on criteria and processes for validation;
- 2) to learn from experiences of pilot validation exercises in Asia-Pacific and Latin America and the Caribbean;
- 3) to discuss the mechanism and methods of validation in the Region; and
- 4) to plan next steps for validation of EPTCT in the Region.

1.3 Expected outcomes

The expected outcomes of the meeting were:

- 1) a draft of criteria for nomination of the Regional Validation Committee (RVC);
- 2) a draft terms of reference (TOR) for the RVC;
- 3) identification of candidate countries for validation; and
- 4) identification of the next steps.

2. PROCEEDINGS

2.1 Opening remarks

Daniel Toole, Regional Director of UNICEF EAPRO

Despite the global reductions in new infections and mortality from HIV, progress falls short of the 90% target to achieve elimination of parents-to-child transmission. The HIV epidemic in the Asia-Pacific region is most prevalent among key populations. There is a need to prioritize programmes, as there are long-standing issues with treatment in terms of delayed initiation, large drop-out and loss to follow-up. Prevention of HIV transmission to infants has been successful but now the attention needs to turn to elimination. EPTCT requires a change in strategy with a strong focus on validation. It is important to define elimination and how to validate this in the Asia Pacific region and be prepared to establish new milestones. Thailand is the only country in the region that has shown readiness to embark on a validation process. Challenges include poor data collection systems that impact the ability to provide evidence for EPTCT.

During this meeting there is a need to determine the formation of the Regional Validation Committee (RVC) and agree on the process required for validation of EPTCT of HIV and congenital syphilis (CS). UNICEF is committed to EPTCT in the Region in partnership with WHO.

2.2 Introduction to global guidance on criteria and process for validation

Lori Newman, WHO Headquarter

HIV infection among pregnant women is decreasing and antiretroviral therapy (ART) coverage is improving, but the decline in numbers of newly HIV infected children is far from target. Syphilis is devastating for fetuses and babies and the disease impacts 1% or more of antenatal attendees in one in three countries. Even in low prevalence settings, treatment of maternal syphilis and exposed infants is cost-effective. Nevertheless there are still many countries where testing coverage for syphilis among antenatal attendees is <50% even in high burden settings. Regional dual elimination goals for parents-to-child transmission of HIV and syphilis are gaining momentum. Latin America and the Caribbean region have made the most progress so far. The African and European regions are planning regional meetings in 2015. Credible, standardized processes are required to monitor progress towards elimination.

A technical consultation on process for validation of EPTCT of HIV and syphilis was held in June 2012 as a joint initiative of WHO, UNICEF, UNFPA, and UNAIDS. Pilot exercises from eight countries helped to inform the meeting.

Decision points included:

- Although preferable to aim for DUAL elimination of HIV and syphilis, countries could aim to eliminate either
- Added case rate for HIV (e.g. 0.5 new child HIV infections per 1,000 live births) to provide an absolute target for high & low burden countries
- Consensus on congenital syphilis case definition is required
- WHO recommended to serve as Secretariat in collaboration with the other partners (UNICEF, UNAIDS, UNFPA)

As an outcome of the meeting, WHO in collaboration with UNICEF, UNFPA, and UNAIDS developed a *Global Guidance on Criteria and Processes for Validation for Elimination*

of *Mother-to-Child Transmission of HIV and Syphilis*.² This guidance outlines minimum processes and criteria for validation in a country; provides a description of global EPTCT validation targets and indicators; explains the operation of validation committees and secretariats; and reviews the validation procedure.

Qualifying requirements for validations include:

1. National-level EMTCT validation indicators
 - **Impact** indicator targets for **1 year; and**
 - **Process** indicator targets for **2 years**
2. Review of equity considerations, e.g.
 - Low performance district or high burden area
 - Key populations and other vulnerable groups
3. Robust national monitoring and surveillance system
4. Basic human rights considerations must be met

Indicators for validation of EPTCT:

HIV impact indicators
<ul style="list-style-type: none"> • MTCT HIV case rate of ≤ 50 new paediatric HIV infections per 100 000 live births • Mother-to-child transmission of HIV of $<5\%$ in breastfeeding populations
OR
<ul style="list-style-type: none"> • Mother-to-child transmission of HIV of $<2\%$ in non-breastfeeding populations
Syphilis impact indicator
<ul style="list-style-type: none"> • Incidence of congenital syphilis < 50 cases per 100 000 live births
Process indicators
<ul style="list-style-type: none"> • Antenatal care (ANC) coverage (1 visit) of $\geq 95\%$ • Coverage of HIV/syphilis testing of pregnant women at first ANC visit of $\geq 95\%$ • Anti-retroviral (ARV) coverage of HIV-positive pregnant women of $\geq 90\%$ • Treatment of syphilis-seropositive pregnant women $>95\%$

Countries can apply for validation when they determine that they have met these targets and that EPTCT has been achieved in at least one of the lowest-performing sub-national administrative units.

There are three levels of structure required for the validation process:

- 1) National Validation Committee (NVC) + National Validation Team (NVT)
- 2) Regional Validation Committee (RVC) + Regional Validation Team (RVT)
- 3) Global Validation Committee (GVC)

It is envisaged that most of data collection and analysis will occur at NVT and RVT level. Details of the validation process are yet to be finalised, but the process begins at the national level when the Minister of Health of a particular country makes a request to the Regional Secretariat. A pre-validation process will be requested, but if the application is strong, it may go straight into the validation phase, which will be conducted in country by the RVT, which prepares and submits a report to RVC. If criteria are met, this is then submitted to the GVC.

Even after initial validation, ongoing programme evaluation is required to maintain validation. Data will be collected and reviewed annually by the RVS.

The next steps for validation at the global level include:

- Nominate global validation committee
- Support establishment of regional processes and committees
- Finalize tools to facilitate validation
 - Data quality assessment checklist
 - Laboratory quality assessment checklist
 - Human rights and community engagement checklist
 - Costing tool, governance guide, template letters
- Identify funding for validation
- Initiate country validation exercises

2.3 Progress on EPTCT in the Asia Pacific Region

Wing-Sie Cheng, UNICEF Regional Office for East Asia-Pacific

In 2013, new paediatric HIV infections in the Asia Pacific region made up 9% of the global total.³ Globally there has been a 43% reduction in new HIV infections in children, although in Asia the reduction has only been around 16% from 2009-2013.³ PPTCT coverage has increased 30% in South-East Asia and 62% in Western Pacific and this is inadequate to reach 2015 targets.⁴ Option B/B+ has been adopted in 12 Asia Pacific countries. Apart from Thailand and Cambodia the incidence of new infections has not declined significantly among HIV exposed, and data for China are consistently unavailable.⁵ In 2013 Thailand was the only country approaching the targeted rate for EPTCT with a reported PPTCT rate of 2.6%.⁶ Eight countries have committed to a dual goal of EPTCT HIV and syphilis, Myanmar to eliminating HIV alone and China and Fiji have committed to the triple goal of eliminating HIV, syphilis and hepatitis B.⁷

Global EPTCT validation criteria require very high levels of HIV testing among pregnant women. In Asia the epidemic is generally low and concentrated, and universal access to HIV testing is a challenge. Apart from Cambodia, Malaysia and Thailand HIV testing coverage among pregnant women is mostly geographically focused on high HIV prevalence areas, with most countries not providing data. Early infant diagnosis (EID) coverage remained low, at 25% and 4 % in East-Asia Pacific and South-Asia regions, respectively.⁸ Paediatric ARV coverage was 38% for East-Asia Pacific and 30% for South-Asia regions.³ Country data on the EPTCT cascade demonstrate data gaps, which also reveal progressive drop-out at critical phases of interventions, and EID data are not systematically collected in many instances.

It is estimated that the Asia Pacific region has a high burden of congenital syphilis.⁹ Coverage of syphilis testing varies in the Region, with Sri Lanka, Malaysia, Fiji and Mongolia reporting syphilis screening rates above 95%.¹⁰ Untreated syphilis during pregnancy, especially early syphilis, can lead to stillbirth, perinatal death, or other adverse outcomes. Asia has the highest number of adverse outcomes associated with syphilis in pregnancy. In fostering an integrated agenda, the HIV sector should build strong linkages with the maternal, newborn and child health (MNCH) sector, which is spearheading the “Every Woman, Every Child” initiative globally. Efforts should also be made to better detect syphilis as a contributing cause of stillbirth, neonatal death and clinical diseases by improving verbal autopsy, case management and reporting.

Despite a decline in new HIV infections in children, the region has not shown a commensurate decline in AIDS-related death among children.¹¹ Nevertheless, improving the

response to HIV and syphilis in pregnant women and their infants will contribute to improving maternal and newborn health outcomes, in particular, in reducing maternal mortality ratio, stillbirth rate and neonatal mortality rate at the impact level. It is also a position that could gain buy-in and support from the MNCH sector on the dual elimination of HIV and syphilis in newborn.

2.4 EPTCT in Latin America and the Caribbean

Sonia Caffè and Massimo Ghidinelli, WHO Regional Office for Americas/Pan-American Health Organization (PAHO)

In 2010, WHO Region of the Americas adopted the WHO regional strategy for EPTCT. All countries in PAHO provide replacement feeding for EPTCT of HIV and therefore subscribe to targeted PPTCT rates of $\leq 2\%$. Coverage targets for ANC attendance, HIV testing and ARV treatment of pregnant women, were all set at $\geq 95\%$. Regional implementation of this programme has been conducted in collaboration with UNICEF, UNAIDS, UNFPA, CDC and other partners. Tools were developed for the region including a concept document, a regional monitoring tool, regional monitoring strategy, a costing tool, a field guide, and a guiding document on syphilis testing. There is a regional reporting mechanism and *2014 Update for EPTCT of HIV and Syphilis in the Americas* was shared with meeting participants.

In the Region, EPTCT has been recognized as a marker of quality maternal and child health services. Overall coverage of HIV testing of pregnant women in PAHO region was 74% in 2013, and ARV coverage was 93%. New HIV infections in children have decreased by 50% and 30% in the Caribbean and Latin America respectively. Overall PTCT rates have dropped from 18% to 5% (2010-2013). HIV and syphilis test kits are procured by governments from the national budget in more than 70% of countries in the Region. Nine countries in the PAHO region may have met elimination of HIV goals and a further eight countries have transmission rates between 2-5%. For syphilis, data available for 20 countries showed syphilis testing rates of approximately 80% and treatment rates around 70%, although some countries report treatment rates of $>80\%$. In 2013, 15 countries demonstrated data compatible with EPTCT of congenital syphilis and seven countries have data compatible with dual elimination with a further eight being close to dual elimination of HIV and syphilis. However, data from many countries are still inadequate.

In May 2014, WHO Region of the Americas established a regional validation committee (RVC), convened by the PAHO director, including 11 independent experts, UN partners and regional technical organizations. The main role is to provide regional oversight of the validation process, coordinate country evaluation exercises, and determine whether a candidate country can be recommended for validation. PAHO serves as the secretariat and maintains a roster for the validation teams as well as development or updating of regional validation documents or tools in collaboration with headquarters. Requests for validation of EPTCT HIV and syphilis have already come from Cuba and Jamaica.

Regional tools have been developed for data quality and impact as well as programme assessment; global tools are in development for the other components of the RV process.

Special considerations in the PAHO Region:

- Small populations (e.g. the Caribbean Islands) believe that they have achieved elimination. However, the transmission rate is unstable because even one case can make the transmission rate appear large. In order to address this, case information is required and if the case was deemed not preventable, it may not be counted toward the validation of elimination.

- A substantial proportion of care occurs in the private sector and gaps in data exist. The Region is in discussion regarding how to deal with this issue, including conducting special studies or sufficient private sector representation in assessment samples.
- Country data systems vary, some are electronic but others are paper based.
- Despite universal testing strategies, some women do not access antenatal care.

The programme is presented in a manner that supports health strengthening and there is a perception that dual elimination is a marker of progress for maternal child health programmes, which makes implementation of the programme more compelling.

2.5 EPTCT of HIV and syphilis in Thailand

EPTCT of Syphilis in Thailand

Kittipoom Chinhiran, STI Cluster, Bangkok Hospital

In Thailand, antenatal care coverage has been >95% since 2012 and coverage of HIV and syphilis testing among pregnant women has been $\geq 95\%$ in 2013 and 2014. Treatment of syphilis sero-positive women is $\geq 95\%$ in 2013 and 94% in 2014. New pediatric HIV infections were less than 50 per 100 000 in 2009.

The rate of syphilis infections was 0.01/1000 live births. There are no recent data for the congenital syphilis infection rate. Treatment of infants born to syphilis sero-positive mothers increased from 38% to 59% between 2013 and 2014.

Challenges for preventing congenital syphilis include:

- The syphilis infection rate indicator may have been under-reported.
- There has been a lack of adequate case definition for congenital syphilis.
- There is under-reporting of stillbirths.
- The perinatal HIV implementation monitoring systems (PHIMS) has been used, which is derived mainly from public hospital system in Thailand (more than 60% patients attend public hospitals).
- A limited number of private hospitals report to the PHIMS, but the Department of Health is conducting a survey to obtain information from private hospitals.
- Including information on non-Thai residents has been a challenge, however, approximately 30,000 – 40,000 cases included in the data are actually from non-Thai people (migrants).

Countdown To Zero, Elimination of PTCT of HIV in Thailand

Sarawat Boonsuk, Bureau of Health Promotion, Department of Health, Ministry of Public Health Thailand

In 2013 prevalence of HIV in Thailand was 0.6%. Thailand's national policy includes opt out HIV counseling and testing for all pregnant women. Women are routinely tested for complete blood count, blood group, hepatitis B, syphilis, and HIV. If HIV positive, CD4 cell count was provided at 14 weeks and every six months thereafter. Lopinavir/ritonavir based therapy is provided for women and AZT for exposed infants; or triple ARVs for high-risk infants. Transmission of HIV has been decreasing; the unadjusted rate in 2013 was 1.7% but the adjusted rate was 2.1%.

Early infant diagnosis is conducted at 1-2 and 4-6 months. More than 80% of women attending ANC receive ART, however among women who do not attend ANC, 43% do not receive ART, and only 20% receive appropriate ART.

Some of the ongoing challenges for EPTCT of HIV in Thailand include:

- HIV Infected women have a lower ANC attendance rate than the general population (10% vs. 2%).
- About 25% attend their initial ANC visit later than 28 weeks gestation
- 15% do not receive optimum ART.
- About half are starting ART at a CD4 <350.
- Of the exposed children 20-25% did not receive EID

To address these challenges, Thailand's programme for EPTCT and pediatric HIV cure aims to provide ANC to everyone at any point where they access services. PPTCT guidelines have been revised. However, option B+ is not included in these updates although this has been recommended to Department of Health. An active case management programme to help women obtain ART more easily, diagnose their exposed infants earlier and track HIV positive children is underway. Likewise there is an action plan to prevent HIV transmission to babies, which includes prevention of unintended pregnancies. A special programme to diagnose high-risk exposed infants at birth is also in place, which will include PCR testing at birth.

2.6 Pilot validation exercise in Malaysia and Sri Lanka Dongbao Yu, WHO Regional Office for the South East Asia

Malaysia

PPTCT of HIV was piloted in 1997 and implemented nationwide in 1998. Opt-out HIV screening was offered for ANC attendees with testing in labour ward if not previously done. Malaysia reportedly has high levels of ANC coverage.

Syphilis testing coverage and treatment of seropositive women is nearly 100%, and HIV screening of pregnant women is at 98-100% in public health facilities and more than 50% at private health facilities. In 2011, more than 90% of all antenatal mothers were screened for HIV and the prevalence rate was 0.07%.

A pilot study was conducted in May – June 2012. A validation tool and impact measures were piloted. After piloting, the proposed definition for EPTCT was that new HIV infections in children should be <10% of the 2009 value, and vertical transmission rates of HIV should be <2%. Programme target indicators were developed with ARV coverage of women set at ≥95%. Validation tools were developed, a data validation scoring system and quality assessment tool were developed and process measures for programme implementation were investigated.

Lessons learnt include:

- The validation process is facilitated by having a good surveillance system in place
- Online data monitoring accelerates validation process
- Integrated services are key for elimination
- Good referral systems ensure better and prompt patient care
- Verification and validation should be conducted at all levels

Sri Lanka

Sri Lanka has a very low HIV prevalence and sexually transmitted infections (STI) surveillance that includes HIV. EPTCT of HIV and syphilis are in the strategic plan. A team has been established and a piloting process for validation of CS has also been conducted. Available data on impact and programme measures were collected, and discussion of the data with assessment of data sufficiency, challenges and issues were documented. A summary of lessons learnt with some recommendations for global guidance were presented in a brief report.

This process included defining elimination of CS, developing impact and process indicators, as well as assessing quality and steps needed for maintenance of elimination. The pilot demonstrated that it is reasonable to assume that CS has been eliminated in Sri Lanka, however it could take some time to amend the current data system to provide the information required for validation of EMTCT of syphilis.

2.7 Overview of operational validation tools

Lori Newman, WHO Headquarters

Validation requires assessments of data quality, impact, laboratory, human rights, gender equality and community engagement. Countries must have strong surveillance systems and criteria for validation must be met at the lowest performing subunit to avoid disparities. This should be consistent with human rights considerations. Standardized tools are needed to ensure criteria are assessed uniformly across countries.

Data quality assessment tool

For data quality assessment, overall reporting completeness should be $\geq 90\%$ and quality of each process indicator should be ensured.

Impact assessment tool

Impact assessment may be qualitative. This will depend on the case definition, representativeness of the data and the role of the private sector. Countries have different components, but they should try to provide real data not only that which has been modelled. Areas of weakness in the data need to be determined, although perfection is not the aim. Underlying data collection and reporting systems can collect the process and impact targets for EPTCT validation, with clear and aligned definitions and mechanisms for data collection and analysis.

Laboratory assessment tool

This tool will assess the quality of regional, national, local and even private sector laboratories. The process will consist of facility assessments and national and subnational checklists to ensure minimum available equipment. The process is similar to Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) in attempting to improve the quality of public health laboratory system. Laboratories should have a proficiency-testing programme with 99% accuracy for HIV, for syphilis, non-treponemal and treponemal tests should have $\geq 95\%$ accuracy.

Human rights, gender and community engagement assessment tool

Validation criteria must be met in a manner consistent with basic human rights and gender equality. This requires a desk review and government and civil society input. This may take the form of questionnaires for civil society representatives.

Countries cannot be eligible for validation if some non-negotiable criteria are apparent. Examples of these include if the country:

- criminalizes HIV or syphilis exposure & transmission, including but not limited to vertical transmission
- has mandatory testing or treatment of HIV/syphilis for any population
- does not have a law, policy or regulation to protect patient confidentiality around HIV status
- has no informed consent policies
- is reported to be coercive or forces abortion or sterilization
- has no policy on accountability and remedies for violations of human rights

- has no policy addressing gender-based violence
- has any policy or regulatory restrictions/practices that limit access to family planning or sexual reproductive health for any population
- has no policy that requires community engagement

Key outstanding issues

- Data quality and impact assessment tool
 - If there is no policy for universal HIV testing of pregnant women, how can we demonstrate that the national strategy identifies most infected pregnant women?
 - Challenges with impact assessment
 - What are the best sources of data?
 - How to verify that this is the true figure?
 - How best to estimate unknown outcomes?
- Laboratory assessment tool
 - Does this meet reasonable minimum proficiency standards?
- Human rights, gender equality, community engagement
 - What is the timing and support for this process?
 - How should civil society questionnaire be implemented?
 - How to determine the “bright lines”/non-negotiable?

2.7 Regional mechanism for validation

Naoko Ishikawa, WHO Regional Office for the Western Pacific

A draft regional mechanism for validation was presented. The global guidance recommends that Member States initiate the validation process. The Minister of Health, with the NVC, and/or NVT, will initiate the process for validation from National level. A validation report will be developed and sent to the RVS which will establish, convene, and coordinate the RVC, provide oversight to the validation processes and activities and monitor maintenance of validation. The RVC will review national validation reports, conduct country reviews and prepare regional validation report. Subsequently this report will be sent to the GVS, which will then provide official notification of validation, review the regional validation report and prepare a global validation report. The regional validation mechanisms should be built on the existing platform of the Asia Pacific PPTCT Task Force (Figure 1).

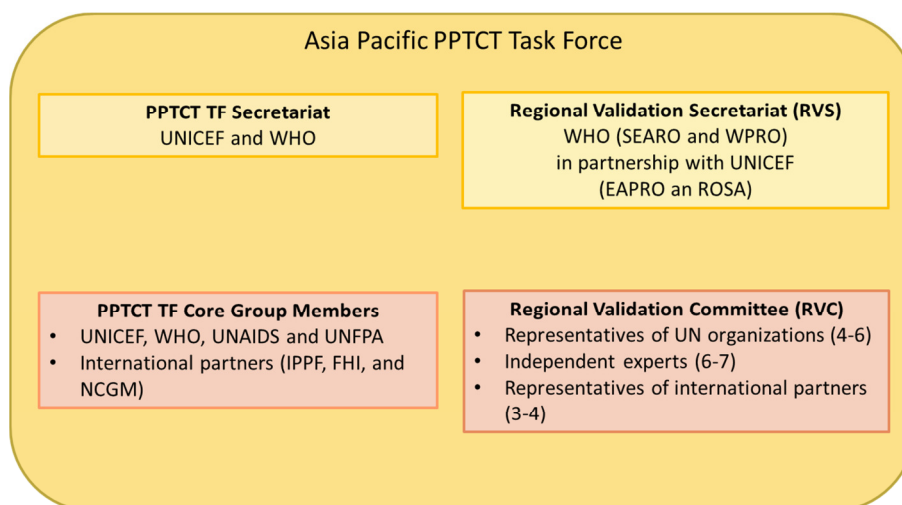
- Asia-Pacific Regional Validation Secretariat

The regional validation secretariat (RVS) takes overall responsibility for the regional validation process. The RVS will be provided by WHO Regional Office for South-East Asia and the Regional Office for Western Pacific Region in partnership with UNICEF East Asia and Pacific Regional Office and the South Asia Regional Office. The RVS will establish and convene the regional validation committee (RVC). WHO and UNICEF will provide joint support to the RVC.

- Asia-Pacific Regional Validation Committee

The main task of the regional validation committee (RVC) is to review and determine whether candidate countries' achievements in EPTCT of HIV and syphilis can be recommended for the global validation.

Figure 1. Proposed regional mechanism for validation



The functions of the RVC include:

- To review country status reports on elimination initiatives;
- To work with country to assess readiness for validation;
- To establish and supervise regional validation team (RVT) if necessary to assist with country validations;
- To review national validation reports to determine national compliance with regional and global criteria for validation of EPTCT of HIV and/or syphilis;
- To assist countries with efforts to initiate/complete validation or prepare for future validation activities; and
- To prepare a regional validation report that will inform national and global partners whether the country meets regional and global minimum criteria for validation.

The two WHO regional directors will appoint the RVC members including:

- two co-chairs who are independent of UN affiliation
- 13-15 members, six to seven independent experts, and three to four representatives from international partners, and four to six representatives of UN organizations.
- Optimum diversification in terms of professional background, gender, geographical representation, international standing and affiliations will be considered.
- Replacement of RVC members will take place on a rolling schedule
- 50% of members will be replaced after two years the rest after three years
- The co-chairs will be rotated every three years.

Frequency and cost of activities:

- The frequency of activities will depend on country progress and the number and timing of validation requests.
- Travel expenses of representatives of international partners will be covered by their respective agencies. WHO, UNICEF and other partners will mobilize resources to support additional costs, including travel of independent RVC members.
- In addition to the validation exercises, the RVC will meet as needed (annually or less frequently) for periodic stocktaking.

3. DISCUSSION

3.1 Issues and recommendations for validation in the Asia Pacific region:

- 1) The validation of EPTCT is a means to support and motivate countries to improve efforts towards elimination of PTCT of HIV and CS. This is not a goal in itself. The validation process should be participatory and the countries should be engaged actively.
- 2) Validation-related activities should build on the systems and tools available in the Region.
- 3) The burden of HIV is small in women in the Asia Pacific region. Many are tested too late. The challenge is how to identify women earlier in settings where universal HIV testing is not offered to pregnant women.
- 4) Case management programmes may assist with earlier identification of HIV positive pregnant women and improve the retention of women and children through the cascade of care. Thailand has recently launched an active case management programme, and lessons from this programme could be shared with other countries in the Region.
- 5) In many countries high-risk women (e.g. migrants or spouses of people who inject drugs or men who have sex with men) are marginalized and may not access health care services. This was found in the pilot study conducted in Malaysia and there was uncertainty where these high-risk populations of women access care. Thailand has addressed this problem by passing legislation recently that all women, including migrants, can access antenatal care at any facility at any time.
- 6) Data from the private sector are missing. WHO headquarters recommends that efforts should be made to research the private sector data if the proportion of women accessing private sector antenatal services is above 10%. Thailand plans to gain access to this data; the Department of Health is conducting a survey to obtain information from private hospitals.
- 7) Validation at national and provincial levels may differ. Some Asian countries have a low prevalence of HIV although some areas within countries have a higher disease burden. In some countries, there is no clear policy on universal HIV testing of pregnant women although these countries are considering targeting high burden areas or provinces, for example India and Indonesia. There was discussion about whether countries be allowed to validate where universal testing is not being performed. In this situation, it may be better to focus on validation of EPTCT at the provincial level first, targeting the high burden provinces. While a flexible approach to validation is required, strong data/epidemiological evidence that more than 95% of cases are captured is required. Validation will not be afforded to countries where areas are excluded from the validation because vulnerable populations are not being identified. This would keep the goal of targeting elimination in a manner consistent with basic human rights considerations.
- 8) Laboratories need to undergo quality control processes. Where these are already in place, these systems may be incorporated.

- 9) Regions may incorporate additional indicators if deemed important to the local situation.
- 10) Monitoring and evaluation (M&E) systems are weak in many countries including data from the private sectors. The process of validation of EPTCT is intended to strengthen M&E systems for countries.
- 11) Guidance is required for how to target EPTCT with limited funding.
- 12) Countries should begin the national validation process possibly through the pre-validation assessment. RVC and RVT should provide technical guidance and support.
- 13) The importance of real data was emphasized. Perfect data is not necessarily required but reporting on the quality of each process indicator is necessary to understand areas of weakness.
- 14) A good precedent is needed for data collection and reporting that is not burdensome.

3.2 Regional validation mechanism

3.2.1 Suggestions for the RVC

Roles of the RVS

- 1) Develop regional operational tools by adapting tools that are already available elsewhere
- 2) Inviting countries, where systems are in place, to share experiences and support other countries where these are not yet in place
- 3) Mobilizing resources
- 4) Assisting with updating regional data and developing progress reports

Membership of the RVC

- 1) Representation on the committee from UN organizations (e.g. WHO, UNICEF, UNAIDS, and UNFPA) is to be discussed among partners.
- 2) Experts from the region should be sought and invited to become members of the RVC. They will be chosen for their particular skill set rather than as a representative of the particular country from which they come. Required skills should include:
 - Epidemiologists and/or statisticians who can strengthen data systems, and who may assist with pre-assessment before starting validation process.
 - National managers and programme officers for HIV/AIDS and/or STI
 - National managers and programme officers for maternal and child health
 - Laboratory scientists
 - Representative of civil society and nongovernmental organizations including and women and men living with HIV/AIDS, and community members.
 - Experts on HIV and other STIs
- 3) One representative from the National Validation Committee should be a part of the validation process at the regional level.

- 4) Meet regularly (could tag RVC meetings onto other regional events such as the PPTCT task force meeting)
- 5) Review the validation mechanisms of the polio eradication, neonatal tetanus and measles elimination to guide processes for validation of EMTCT of HIV and syphilis.
- 6) Produce annual updates such as the one developed by PAHO.

3.3 Next steps

- 1) Finalize the TOR of RVC based on the meeting discussion and submit for the approval of the regional directors of WHO Regional Office for South-East Asia and the Western Pacific (revised draft included in Annex III).
- 2) Finalize selection criteria, nominate and appoint candidates to establish the RVC.
- 3) Develop validation tools for the region by adapting global tools and other available tools.
- 4) Plan and implement pre-validation of EPTCT in selected candidate countries
 - i. Thailand is nominated as a candidate for country pre-validation of EPTCT of HIV/syphilis. Epidemiologist/statisticians will be needed to conduct an impact assessment on Thailand's data. A proposal was made that Thailand undergo a pre-validation process; this could apply to Malaysia as well. Pre-validation for Thailand and Malaysia could be conducted by 2015 after the consultation with countries. Assessment of tools could be also conducted during the pre-validation.
 - ii. A targeted approach may be applied to Cambodia. This may provide a model for the process of validation in low prevalence settings where there are high burden pockets. Cambodia is finalizing a strategic plan and is setting a target of EPTCT of HIV for 2020. Cambodia is committed to EPTCT and pre-validation of Cambodia could be planned in due course.
 - iii. The regional secretariat will communicate the intentions for the validation process directly with Thailand, Malaysia and Cambodia and coordinate with the global validation secretariat (GVS).
- 5) Costing of validation activities in the Asia Pacific region is needed from 2015 to 2018.

Timeline		
2014	December	Finalization of selection criteria and TOR of RVC
2015	Q1	Nomination of RVC members Establish (appointment) RVC Start in-country consultation to assess status/progress on EPTCT
	Q2	RVC meeting and pre-validation in candidate country
	September	10 th Asia Pacific PPTCT task force meeting

4. FOOTNOTES AND REFERENCES

¹ The term “prevention of parents-to-child transmission” is used in the Asia Pacific region to emphasize the importance of primary prevention of HIV for women and the involvement of partners.

² WHO. Global guidance on criteria and processes for validation: elimination of mother-to-child transmission (EMTCT) of HIV and syphilis, 2014
<http://www.who.int/reproductivehealth/publications/rtis/9789241505888/en/>

³ UNAIDS. HIV and AIDS estimates 2013, August 2014

⁴ WHO. Global update on the health sector response to HIV, 2014

⁵ UNAIDS. AIDSInfo online data, www.aidsinfoonline.org, UNAIDS Spectrum estimates, 2013

⁶ UNICEF Statistical Update 2014 – Providing pediatric HIV care and treatment in low- and middle-income countries

⁷ Conclusions and Recommendations, the 9th Asia-Pacific PPTCT Task Force meeting, November 2010, Vientiane, Lao PDR

⁸ UNAIDS, UNICEF and WHO. 2005–2013 Global AIDS Response Progress Reporting (GARPR), and UNAIDS 2005–2013 HIV and AIDS estimates, August 2014

⁹ Newman L, Kamb M, Hawkes S, Gomez G, et al. Global Estimates of Syphilis in Pregnancy and Associated Adverse Outcomes: Analysis of Multinational Antenatal Surveillance Data. *PLoS Med* 10(2): e1001396. doi:10.1371/journal.pmed.1001396, 2013

¹⁰ WHO. Baseline report on global sexually transmitted infection surveillance 2012, WHO, Geneva, 2013 and GARPR 2013.

¹¹ UNICEF. Towards an AIDS-Free Generation – Children and AIDS: Sixth Stocktaking Report, 2013, UNICEF, New York, 2013

MEETING AGENDA

10 November 2014

Time	Contents	Presenters
8:00– 8:30	Registration	
8:30– 8:35	Opening remarks	Daniel Toole Regional director (UNICEF EAPRO)
8:35– 8:40	Introduction - Introduction of participants - Objectives and outcomes	Naoko Ishikawa (WHO WPRO)
8:40– 9:00	Introduction to global guidance on criteria and processes for validation	Lori Newman (WHO HQ)
9:00– 9:30	EPTCT in Latin America and the Caribbean	Massimo Ghidinelli / Sonja Caffè (PAHO)
9:30– 9:50	Progress on EPTCT in Asia-Pacific	Wing-Sie Chen (UNICEF EAPRO)
9:50–10:30	EPTCT of HIV and syphilis in Thailand	HIV – Dr. Sarawut Boonsuk (MOPH) Syphilis – Dr.Kittibhum (STI Cluster, Bangrak Hospital)
10:30–10:45	Break	
10:45–11:15	Pilot validation exercise in countries (Sri Lanka and Malaysia)	Dongbao Yu (WHO SEARO)
11:15–12:30	Regional mechanism for validation - Criteria for nomination of the Regional Validation Committee (RVC) - Terms of reference (TOR) of the RVC	Naoko Ishikawa (WHO WPRO) Discussion (Chair: Ying-Ru Lo & Wing-Sie Chen)
12:30–13:30	Lunch break	
13:30–14:45	Overview of operational tools - Key indicators - Impact assessment tool - Pre-validation in country	Lori Newman (WHO HQ) Discussion (Chair: Lori Newman & Naoko Ishikawa)
14:45–15:00	Break	
15:00–16:00	Next steps - Potential candidate countries - Action plan (timeline of activities and cost) - EMTCT update report	Discussion (Chair: Wing-Sie Chen & Naoko Ishikawa)
16:00	Closing remarks	Ying-Ru Lo (WHO WPRO)
16:00–17:00	(PPTCT TF core group meeting)	

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ASIA PACIFIC REGIONAL VALIDATION MECHANISM
FOR ELIMINATION OF PARENTS-TO-CHILD TRANSMISSION
OF HIV AND SYPHILIS

Revised draft
(as of 2 March 2015)

1. Background

Elimination of parents-to-child transmission (EPTCT) of HIV and syphilis contributes to better maternal and child health and the attainment of Millennium Development Goals (MDGs) 4, 5, and 6. It is estimated that there are approximately 74 000 pregnant women living with HIV in the Region in 2013, of those 30% received antiretroviral drugs (ARVs) to prevent parents-to-child transmission of HIV.¹

The Asia Pacific United Nations Prevention of Parents-to-Child Transmission (PPTCT) Task Force was established in 1998. The members of the task force include WHO, UNICEF, UNFPA, UNAIDS, the Member States, and technical partners. In 2010, the task force developed the conceptual framework for EPTCT of HIV and syphilis in the Asia Pacific by 2015.² The regional goal of EPTCT of HIV and syphilis was endorsed at the 8th PPTCT task force meeting held in November 2010 at Vientiane, Lao PDR.

There is a commitment for the elimination of mother-to-child transmission (EPTCT) of HIV and syphilis, globally and regionally. An Initiative for the Global Elimination of Congenital Syphilis which was launched in 2007 by WHO³ and *the Global Plan towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive* was launched by UNAIDS and PEPFAR (The *President's Emergency Plan for AIDS Relief*) in June 2011⁴.

As Member States progress towards EMTCT, there is a need to establish a mechanism to validate elimination. WHO in collaboration with UNICEF, UNFPA, and UNAIDS developed a *Global Guidance on Criteria and Processes for Validation for EMTCT of HIV and syphilis*.⁵ This

¹ UNAIDS 2014 Gap Report and WHO 2014 Global update on the health sector response to HIV

² Elimination of paediatric HIV infections and congenital syphilis in Asia-Pacific, 2011-2015: conceptual framework & monitoring and evaluation guide
http://www.unicef.org/eapro/PPTCT_CF_and_ME_guide_17Aug11.pdf

³ WHO 2007. Global elimination of congenital syphilis: rationale and strategy for action.

⁴ UNAIDS 2011. Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive.

⁵ WHO 2014. *Global Guidance on Criteria and Processes for Validation: Elimination of Mother-to-Child Transmission of HIV and Syphilis* <http://www.who.int/reproductivehealth/publications/rtis/9789241505888/en/>

Annex 3

guidance outlines minimum processes and criteria for validation in a country; provides a description of global EPTCT validation targets and indicators; explains the operation of validation committees and secretariats; and reviews the validation procedure.

The global guidance proposes a validation structure consisting of global, regional and national mechanisms as below.⁵

- **Global Validation Secretariat** – WHO HQ in partnership with UNAIDS, UNFPA, and UNICEF: appoints the global validation committee (GVC); coordinates GVC and regional secretariats; and provides official notification of validation.
- **Global Validation Committee (GVC)**: reviews regional validation report to ensure consistency and compliance with the minimum global criteria.
- **Regional Validation Secretariat (RVS)**: establishes, convenes and coordinates the regional validation committee (RVC) and the regional validation team (RVT) and provides oversight to regional and national validation processes and activities.
- **Regional validation committee (RVC)**: appoints RVT as needed to carry out country reviews; reviews national validation reports; ensures compliance with regional and global criteria; and prepare regional validation report.
- **Regional Validation Team (RVT)**: reviews country data; conducts in-country validation visits with the national validation team (NVT); and prepares national validation report.
- **National Validation Committee (NVC)**: convened by the Ministry of Health; initiates validation process and prepares national validation report.
- **National Validation Team (NVT)**: formed as necessary, collects and analyses national data for national validation report (NVC could choose to play this function directly).

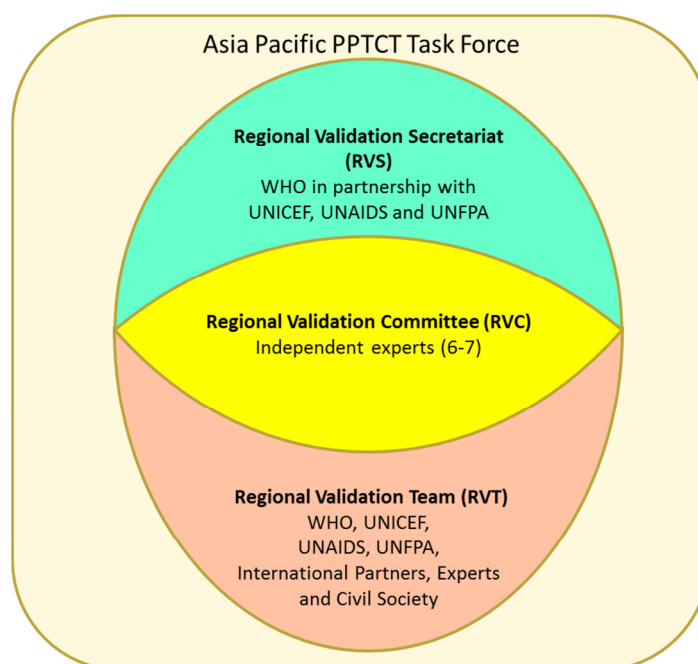
2. **Regional Mechanism of Validation in the Asia and Pacific**

The regional validation mechanism will be built on the existing platform of the Asia Pacific PPTCT Task Force (Figure 1). Below is a brief description of roles and structures of the mechanism. More detailed description of each role will be found in *Global Guidance on Criteria and Processes for Validation for EMTCT of HIV and syphilis*.⁵

- **Asia-Pacific Regional Validation Secretariat**
The regional validation secretariat (RVS) takes overall responsibility for the regional validation process. The RVS will be provided by the WHO Regional Offices for South-East Asia and the Western Pacific, and its functions will be performed in partnership with UNICEF, UNAIDS and UNFPA. The RVS will establish and convene the regional validation committee (RVC) and the regional validation team (RVT).
- **Asia-Pacific Regional Validation Committee**
The main task of the regional validation committee (RVC) is to review and determine whether candidate countries' achievements in EPTCT of HIV and syphilis can be recommended for the global validation. The committee shall consist of between 6 and 7 independent experts and its activities will be supported by the RVS and PPTCT task force core group members, namely WHO, UNICEF, UNAIDS, UNFPA, international partners, and civil society.

- **Asia-Pacific Regional Validation Team**
A regional validation team (RVT) will be formed to support the RVC and activities related to validation. Team members will be identified from and through PPTCT task force core group members. The members of RVC may be a part of the team. The RVT reviews national validation report; conducts in-country validation visits with the national validation team (NVT) and the national validation committee (NVC); and submits national validation report to RVS.
- **National Validation Committee and Team**
The national validation committee (NVC) takes overall responsibility for the national validation process. The NVC is convened, chaired and led by the Ministry of Health of the country. It gathers evidence and prepares the national validation report; coordinates internal validation processes; and ensures strong communication with the MOH and stakeholders. The NVC may convene a national validation team (NVT) as a subset of the NVC membership to perform its tasks.

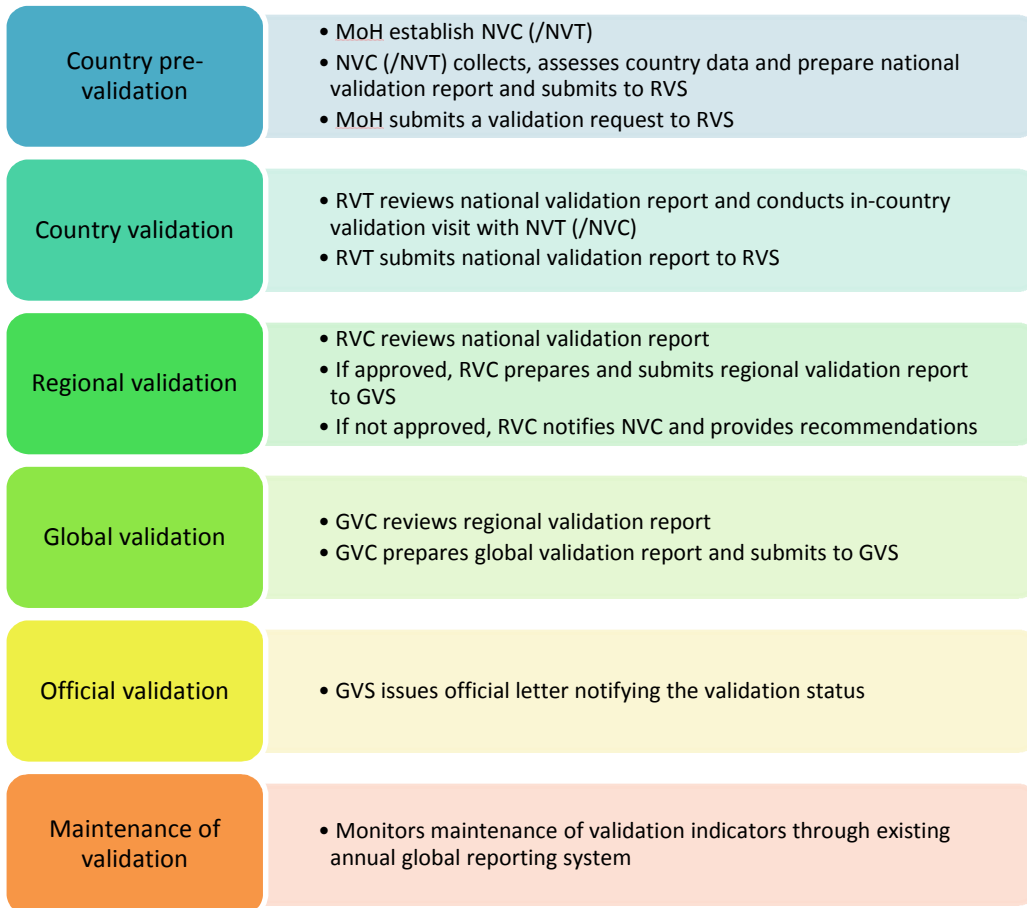
Figure 1. Regional mechanisms of validation in Asia-Pacific



Annex 3

3. Process of Validation

Below describes the process of validation. More detailed description of each step will be found in *Global Guidance on Criteria and Processes for Validation for EMTCT of HIV and syphilis*.⁵



TERMS OF REFERENCE
FOR THE ASIA PACIFIC REGIONAL VALIDATION COMMITTEE
FOR ELIMINATION OF PARENTS-TO-CHILD TRANSMISSION
OF HIV AND SYPHILIS

1. Functions

The mission of the Asia-Pacific regional validation committee (RVC) for elimination of parents-to-child transmission of HIV and syphilis (EPTCT) will be to contribute to the validation of EPTCT in the Region by reviewing whether candidate countries' achievements can be recommended for the global validation.

It will have the following functions:

- 1.1. Assist countries to assess progress of elimination and readiness for validation.
- 1.2. Assist development of regional operational tools for validation.
- 1.3. Assist countries to prepare, initiate and complete validation.
- 1.4. Review national validation reports and determine national compliance with regional and global criteria for validation of EPTCT of HIV and/or syphilis in consultation with the National Validation Committee.
- 1.5. Prepare a regional validation report that will inform national and global partners whether the country meets regional and global minimum criteria for validation.
- 1.6. Ensure that the regional report includes clear explanations and suggestions for the areas requiring improvement if a candidate country does not meet the validation criteria.
- 1.7. Submit a regional validation report to the global validation secretariat.
- 1.8. Assist updating regional data and development of progress reports.

These functions will be carried out with support from the Regional Validation Secretariat (RVS) and the Regional Validation Team (RVT).

2. Membership

Members of the RVC shall be appointed by the Regional Directors of WHO Regional Office for South-East Asia and Regional Office for Western Pacific Region for the duration of three (3) years.

Annex 3

- 2.1. The committee shall consist of between 6 and 7 independent experts and its activities will be supported by the RVS in partnership with the Asia Pacific United Nations Prevention of Parents-to-Child Transmission (PPTCT) Task Force Core Group members, namely WHO, UNICEF, UNAIDS, UNFPA, international partners, and civil society.
- 2.2. The members shall be nominated through the RVS after a broad consultation with the countries and stakeholders including the members of the PPTCT Task Force.
- 2.3. The RVC membership should bring together expertise in the following disciplines and areas:
 - Epidemiologists and/or statisticians who can strengthen data systems, and who may assist with pre-assessment before starting validation process.
 - Public health practitioners including national managers and programme officers of maternal and child health, HIV and STI
 - Laboratory scientists
 - Representative of civil society and nongovernmental organizations including and women and men living with HIV, and community members
 - Experts on HIV and other STIs
- 2.4. Optimum diversification in terms of professional background, gender, geographical representation, international standing and affiliations will be considered.
- 2.5. Replacement of RVC members will take place on a rolling schedule. For the first replenishment, 50% of the members will be replaced after three years, and the other 50% after four years, to ensure continuity and preservation of institutional memory.
- 2.6. The Chair and Co-Chair will be appointed by the Regional Directors selected from among the members and the position of Chair should be rotated every 3 years.
- 2.7. Each RVC member will be asked to sign a confidentiality and conflict of interest statement. RVC members should not have any salary, bonuses or other compensatory elements tied to their RVC membership or actions.

3. Frequency and cost of activities

- 3.1. The frequency of activities will depend on the progress made by countries and the number and timing of validation requests submitted by countries.
- 3.2. WHO, UNICEF, UNAIDS, UNFPA and the other partners will mobilize resources to support operational costs for the RVC, including travel costs of the RVC members.
- 3.3. In addition to the validation exercises, the RVC will meet as needed (annually or less frequently) for periodic stock-taking.



World Health
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