WHO Regional orientation meeting on the validation of elimination/pre-elimination of mother-to-child transmission of HIV and Syphilis in the African region,

VICTORIA FALLS, Zimbabwe, 21 to 22 August 2016

MEETING REPORT

1. Introduction

The African Region bears the highest global burden resulting from mother to child transmission of HIV (MTCT), with more than 90% of new HIV infections among children (0-14) with Twenty-one countries in the region accounting for more than 70% of new HIV infections globally. An estimated 1 million pregnant women are infected with syphilis globally each year, the majority of these women are in Africa. Untreated maternal syphilis results in congenital syphilis in over half of affected pregnancies and can lead to early fetal loss, premature birth, stillbirth, low birth weight (LBW), complications from infection, and neonatal death. Syphilis diagnosis and treatment is one of the most cost-effective and feasible interventions in low-resource settings. The key goal of the Global Plan and the Regional Framework was to eliminate MTCT of HIV and Syphilis as a public health threat.

By the end of 2015, most of the 21Global Plan priority countries in the Africa region had made good progress in the area of PMTCT, and globally new HIV infections among children had been reduced by 60%. An estimated 1.6 million of new infections in children have been averted. A growing number of countries in the Africa region are showing interest in undergoing validation for the elimination of Mother-to-Child Transmission of HIV and that of Syphilis. WHO/AFRO has therefore established a regional mechanism to support the process in African Region. An orientation meeting was organized in Victoria Falls, Zimbabwe 21-22 August, 2016

2. Objectives of the meeting:

- Orient participants on the criteria, processes and other requirements for MTCT elimination/pre-elimination validation
- Share lessons learned from ongoing experiences with countries from other regions that have been validated as well as with other programs in AFRO such as EPI, IVD, NTD, etc.
- Review and discuss MTCT elimination/pre-elimination country assessment tools and checklists.
- Discuss role and responsibilities for the Regional Validation Team as well as the working process and action plan to validate pipeline countries
- Discuss and agree on the next steps including technical assistance needs for the validation process

3. Highlights in the meeting

A total of 37 participants from selected countries (Botswana, Rwanda, Seychelles South Africa and Zimbabwe), regional validation secretariat (WHO, UNICEF, UNAIDS, UNFPA) and some Regional Validation team experts fully attended and showed enthusiasm in this meeting. The meeting was open through WEBEX to external participants and Regional Validation Team members who were not in Victoria Falls.

The regional validation secretariat is a multi-agency team lead by WHO Regional office established to coordinate and support the regional validation process. Current members are from UNICEF, UNAIDS, UNFPA, WHO and EGPAF. A roster of 15 experts called "Regional Validation Team" was established to assist with country validations in African region. Members include public health experts, HIV/STIs or PMTCT programme managers, Obstetricians, Gynaecologists, Paediatricians, Laboratory scientist, Academia, researchers and people living with HIV. Six of them attended the regional meeting in Victoria Falls.

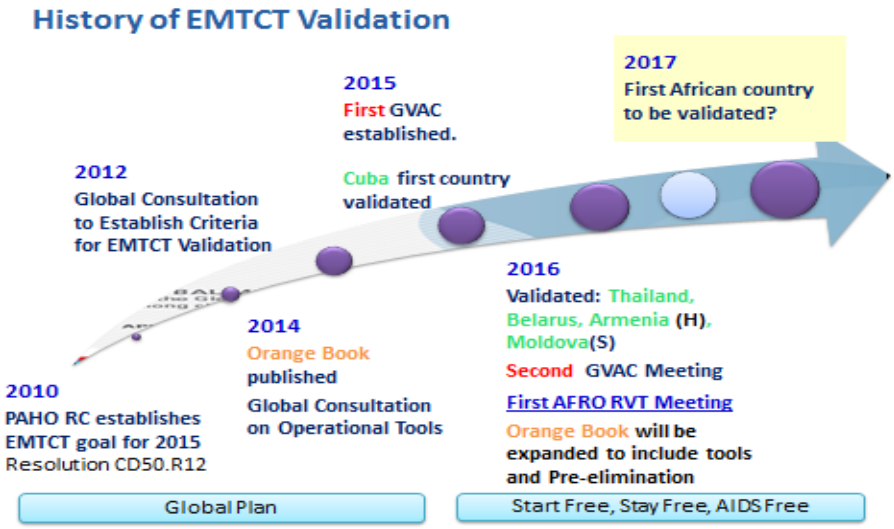
Prior to the main meeting with country teams, a half-day session was organized as a first face-to-face meeting between Regional Validation Secretariat and the Regional Validation Team.

This regional team was oriented and was given the opportunity to contribute to the objectives and structures of the Africa Regional mechanism, membership, roles and responsibilities as well as working processes and communication channels.

3.1.1. Orientation on the criteria, process and other requirements for MTCT Pre-elimination and Elimination of MTCT HIV and Syphilis.

An overview of PMTCT including trends, issues and opportunities was presented including the ***'Super-Fast Track to End AIDS for children, adolescent, young women and expectant mothers'*** which is the way forward after the Global Plan for the elimination of mother-to-child transmission 2011-2015.

The history of the validation process was presented as elucidated in the orange book on the global guidance, criteria and processes for validation of elimination of mother-to-child transmission (EMTCT) of HIV and syphilis which was released by WHO in 2014. A second version will be disseminated by the end of 2016. However, the validation process was contextualized to the Africa Region as it is meant to address the Africa specific situation.



Based on the most recent data, some countries in African region are making good progress to achieve the elimination targets. However, it is very unlikely that any high HIV burden country could meet the case rate criteria of elimination of Mother-to-child transmission of HIV because of the large pool of HIV positive mothers resulting in high paediatric HIV case rate. Due to this peculiar situation of high HIV burden countries, WHO came up with the concept of Pre-elimination to attempt to specifically recognize the progress made in PMTCT in high burden countries. The Pre-elimination concept outlines the benchmarks that need to be met and processes to be followed for eligibility to be recognized by WHO as having achieved Pre-elimination status. Criteria for elimination and pre-elimination status are shown in the Table 1.

Table 1: Criteria for Elimination of MTCT of HIV & Syphilis and Pre-elimination of MTCT of HIV

Indicators	Elimination		Pre-elimination
	HIV	Syphilis	HIV
Impact indicators	• MTCT < 2% or < 5% in Breast Feeding populations • Case rate ≤ 50 per 100,000 live births	• Case rate ≤ 50 per 100,000 live births	MTCT < 2% or < 5% in Breast Feeding populations (No case rate minimum)
Process indicators	• ANC coverage ≥ 95% • Testing coverage ≥ 95% • ART coverage ≥95%	• ANC coverage ≥ 95% • Testing coverage ≥ 95% • Treatment coverage >95%	• ANC ≥ 90% • Testing in ANC ≥ 90% • ART coverage ≥90%

Participants had detailed and extended discussions on the concept of pre-elimination and raised a number of issues and recommendations. Issues raised included the following:

- Is "pre-elimination" the right terminology, given that many years may pass between pre-elimination and elimination?
- How will this concept be explained to Ministers of Health and donors to galvanise political buy-in and necessary support towards elimination?
- Should there be an absolute case rate as part of the criteria?
- Should the plan target a reduction in the case rate or an absolute case rate?
- The model that has been adopted is flawed because it is usually used for diseases with a cure where treatment leads to a reduction of prevalence, but for HIV the treatment actually increases the prevalence

The meeting agreed that the terminology of pre-elimination might be inappropriate in this context and that discussions on the process towards the validation should be continued in the region.
The meeting made recommendations and next steps to move forward including mapping countries according a typology for high burden and low burden in the validation process and the revision of the terminology of pre-elimination.

Tools for assessing elimination at country level were introduced to participants and shared.

Guidance for countries wishing to apply for validation of Elimination or pre-elimination:

Countries that wish to apply for validation of elimination and have reached the reqiured impact and process indicators are eligible to apply for validation of Elimination or Pre-elimination. The procedure for applying for validation of Elimination follows a series of steps:

- The Ministry of Health should submit a request for validation to the WHO country office
- The Ministry of Health convenes a National Validation Committee (NVC) to assess the national programme. A set of 4 tools have been developed by WHO and made available to facilitate the process of validation in country:
    - Program assessment tool
    - Data quality assessment checklist
    - Laboratory quality assessment checklist
    - Human Rights and Community engagement checklist
- The National Validation Committee will develop the Country Report
- The Country Report should be reviewed by the appropriate Regional Validation Committee (RVC). Where there is no standing RVC, it is the WHO Regional Office which serves the function of the RVC and convenes an independent Regional Validation Team (RVT) to evaluate the Country Report.

3.1.2. Experiences from elimination/eradication of Polio, Dracunculosis, Onchocerciasis, Tetanus/Measles in African region

The regional meeting provided an opportunity to clarify some public health concepts regarding elimination, eradication and control of communicable diseases. A panel of experts

presented their experiences on eradication on Polio, Dracunculosis, Onchocerciasis, Tetanus/Measles in African regional and raised the following key issues:

- Elimination as a public health problem is a term related to both infection and disease. It is defined by achievement of measurable global targets set by WHO in relation to a specific disease. The elimination is the reduction to zero of incidence in a defined geography zone.
- When reached, continued actions are required to maintain the targets and/or to advance the interruption of transmission. The process of documenting elimination as a public health problem is called validation.
- Eradication is a permanent reduction of case or incidence to zero worldwide. Certification in the context of polio Eradication is an Independent verification of the eradication of wild poliovirus
- Control is the reduction the incidence to a locally acceptable level

This critical panel session highlighted the trigger points for a country to start the process of elimination/eradication validation, the in-country process, issues and challenges based in the respective areas:

Elimination of Maternal and Neonatal Tetanus

- No formal structures were put in place for validation of elimination
- Process driven by the secretariat jointly managed by WHO and UNICEF
- Used programmatic data and field survey
- Criteria for elimination : 1 case per 1000 live births
- No national committee
- Country which has been validated can lose validation status if there is a new cluster of cases observed
- Challenge is absence of committed resources from global partners

Elimination of Measles

- Elimination is less than 1 case per 1 million population and 95% coverage of immunisation in routine EPI and 95% coverage in campaigns
- No regional or National verification structures in place. However, a framework for processes has been proposed by WHO.
- Countries are categorised for programmatic purposes including for prioritisation of technical assistance

Eradication of Polio

- Success due to high level of commitment through the Global Polio Eradication Initiative (GPEI)
- Certification is part of country strategic plans
- Verification for certification is done independently
- Certification is done by region and not by country
- National certification committee (NCC) oversees certification process at country level
- The Africa Regional Commission for Certification of polio Eradication (ARCC) is the only body to declare the country polio free and to certify the region polio free.
- NO CERTIFICATE is given to countries declared polio free, but a polio free status declaration letter is send by Chair-person of the ARCC to government through the Ministry of health (MOH) to congratulate the country highlighting achievements and remaining gaps to be addressed.

Elimination of Onchocerciasis and Dracunculosis

- National committee oversees the validation process
- Independent international committee with no national membership locals makes recommendations to WHO HQ and DG certifies
- Post-elimination yearly surveillance continues
- In addition for dracunculosis, there is community based surveillance system

Among major recommendations from this panel, the following was noted:

i) For candidate countries there is a need to strengthen monitoring systems and improve data quality assurance;
ii) Regional level to verify country readiness using an independent body.

3.1.3. Overview of validated or certified countries in 2015-2016 and some reflections concerning GVAC

Five certified countries so far: Cuba (Latin America); Moldova, Belarus and Armenia (Europe); and Thailand (Asia). Four out of the five countries had very low HIV prevalence among the population.
The related experience was shared by the members of the Global Validation Committee (GVAC) and WHO headquarters around the following aspects:

- Process and duration of the validation: national, regional, global
- Issues and challenges
- The lessons learned were highlighted for application where useful in the African Region.
- Strategies to maintain the elimination status in the 5 countries

The situation of Thailand with high HIV prevalence 2.3%, high population, and high MTCT rate 10.3% in the early 2000 is the most relevant for the Africa region. The preparation of the validation process, submission and improvement of Thailand took two years

Lessons learned from the first five countries certified:

In European countries, human rights were of a particular concern because there are still laws on the books which criminalize transmission of HIV including vertical transmission. Although no prosecutions have ever taken place, the GVAC felt that the country should address these laws and they should be revoked as soon as possible. While there were no reports of forced sterilization and forced abortion for HIV positive women, the GVAC felt that these issues continue to be addressed annually. These countries were validated with the caveat that GVAC recommendations include these concerns, and that the GVAC would follow up with the country in one year to establish whether these concerns were addressed. The key conclusion was that AFRO countries can learn from Thailand with generalized epidemic and should consider securing resources for sustainability after certification.

In addition, GVAC "Modus operandi" and activities were shared to inspire the Regional Validation Team for African region.

3.2. Countries perspectives

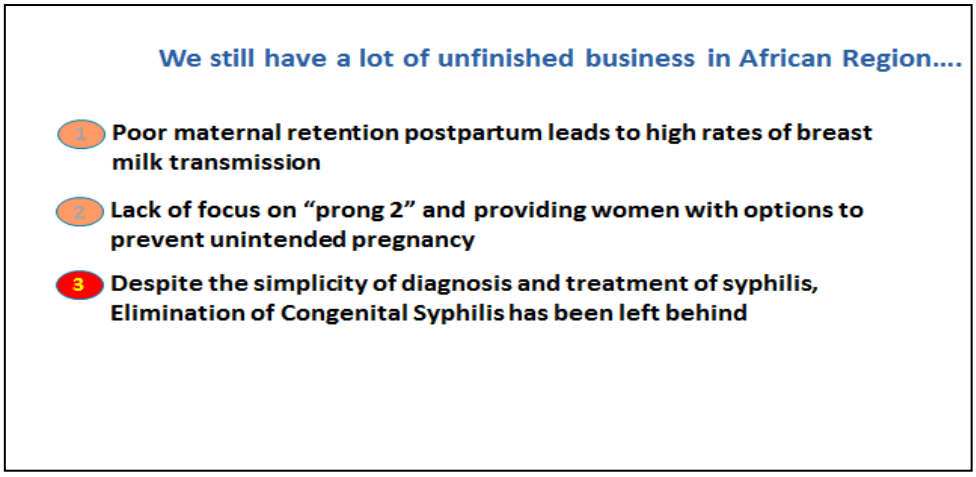
Five countries which have expressed their interest to undergo the process of elimination validation were selected for this meeting (Rwanda, South Africa, Seychelles, Botswana and Zimbabwe). They made presentations on their current progress, issues, way forward and technical assistance needs. These included successes and challenges experienced by each in their PMTCT national programme.

All the five countries have a successful PMTCT programme and have met the required process and impact indicators for pre-elimination except Zimbabwe. Two countries (Botswana and Zimbabwe) have already identified members for the National Validation Committee. Seychelles has notified zero case of HIV in new-born for the past two years. Seychelles and Botswana are almost ready to start the validation assessment. Botswana is planning to host the first national committee meeting in September 2016. Rwanda is planning to start beginning next year 2017.

However, the most challenging in the five countries is to get data on syphilis from health facilities and to reach the case rate required (50/100,000 lives birth) mainly for HIV. Data analysis, monitoring and evaluation systems are a major issue in all countries.

4. Key considerations and recommendations

- The meeting recognized that although the burden of HIV is still very high in Africa, a number of countries have made tremendous achievements under the 4 prongs and therefore need to be recognized. However, we still have an unfinished business including effective retention on ART, syphilis management and implementation of PMTCT prong 1&2.



- Countries should strengthen quality maternal and child health services including capacity to generate and collect data on syphilis management in maternal settings.
- There is need to take into consideration the HIV context and epidemic in Africa compared to other regions of the world and continue the discussion the appropriate process and indicators especially for high burden countries.

- Consider revising the Pre-elimination terminology and come up with language which can be sold to political leaders and modify the language in the policy brief on elimination to fit the context of high burden countries.
- Categorize countries on where they are in terms of progress and set standards for different typologies as a process towards validation.
- Resolve the issue of pre-elimination and guide countries on how to move the agenda including supporting countries that are ready/almost ready to be validated including Botswana, Rwanda and Seychelles.
- Review and strengthen retention and adherence to MTCT to ensure no loss-to- follow-up.
- Engage community groups and People Living with HIV (PLHIV) on issues of human rights and gender equality as well as making resources to women support groups to support retention.
- Engage Men to reduce Gender based violence.
- Follow up on dissemination of new STIs global guidance including syphilis as well as new technologies on dual testing of HIV and syphilis

5. Next steps:

1. Countries to develop Road Maps on elimination of EMTCT and congenital syphilis aligned to national planning processes including to make sure they form National Validation
2. Countries to work more to improve syphilis activities, to strengthen data collection to include % ANC1 women tested for syphilis and % positive for syphilis treated and report on regular basis on syphilis progress along PMTCT data.
3. WHO and partners to organize a follow-on consultative meeting for African region to develop a consensus on the terminology, typology and the guidance for the validation process in the African region (AFRO)
4. Regional Validation Team to provide technical support to countries including Botswana and Seychelles ready to start the validation process by the end of 2016.

Annexes:

1. **Agenda**

SUNDAY 21st AUGUST, 2016		
Time	**Topics**	**Presenters/facilitators**
Pre-meeting, Moderator: WHO/AFRO		
14:00-15:00	**Regional Validation secretariat** Discuss the Regional mechanism, roles and responsibilities of the secretariat	Francoise, Shaffiq (WHO)
15:00 - 18:00	**Regional Validation Team meeting** *(involving RVT external participants via WebEx)*	WHO, UNAIDS, UNICEF, UNFPA
18-18.30	**feedback**	
MONDAY 22nd AUGUST, 2016		
SESSION 1: INTRODUCTION, Moderator: WHO/IST/ESA		
08.00-08.30	Registration, Administration and security advices	Patricia (WHO)
08:30-09:00	Welcome & Introductory Remarks Objectives, expected results, Adoption of the Agenda Introduction of participants	Francoise (WHO) and Biziwick (UNAIDS) Innocent (WHO)
09:00-09:45	- Overview on Trends, issues, challenges on mother-to-child transmission of HIV globally and in African region - Challenges and opportunities in congenital syphilis elimination	Shaffiq, Stephen (WHO)
09:45-10:15	Panel 1: Country status and factors of success	Laurie (UNICEF)
10:15-10:30	Coffee/Tea Break	Patricia (WHO)
SESSION 2: Orient participants on the criteria, processes and other requirements for MTCT Pre-elimination and Elimination of MTCT HIV and Syphilis,		

Moderator: UNFPA		
10:30-11:20	Global guidance, concepts of Elimination indicators and Pre-elimination including the demonstration of elimination tools	Chika, Shaffiq, , Maura
11:20-13:00	Discussions on the Global guidance, concepts of Elimination indicators and Pre-elimination including the demonstration of elimination tools + discussions (continued)	All
13:00-14:00	LUNCH	Patricia (WHO)
SESSION 3: Share lessons learned from ongoing experiences with countries from other regions that have been validated as well as with other programs in AFRO such as EPI and IVD, Moderator: UNICEF		
14:00-14:45	Lessons learnt in EMTCT from Cuba, Moldova, Thailand, Belarus and Armenia + Discussions	Angela (GVAC), Shaffiq (WHO)
14:45-15:30	Panel 2: Experiences learnt from elimination of Polio, Dracuncolosis, Onchocerciasis, Tetanus/Measles in African region + Discussions	Sanni, Francoise (WHO)
15:30-16:00	Tea Break	Patricia (WHO)
16:00-16:45	Country presentations (Progress, issues, way forward and TA needs)	Botswana, Rwanda, Seychelles, South Africa, Zimbabwe
16:45-17:00	Next steps Closure Remarks	Jane (UNAIDS) Francoise, Laurie, Biziwick, Innocent

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