

**IATT Webinar: Cuba Validation of Elimination of Mother-to-Child Transmission of HIV and Syphilis
July 13, 2015**

Summary of Key Points

Global Validation Criteria and Process, WHO

- Standardized criteria developed and discussed for validation regardless of epidemiological context in global consultation meeting hosted by WHO, UNICEF and UNFPA in 2012 and informed by country pilots

Definition of Terms:

- Eradication = Permanent reduction to zero of the worldwide incidence of infection (i.e. polio from the Americas)
- Elimination = Reduction to zero of the incidence of disease or infection in a defined geographical area; Elimination as a public health problem
- Control = Reduction in the incidence, prevalence, morbidity or mortality of an infectious disease to a locally acceptable level

Global Criteria

- Aligned to the *Global Plan Towards the Elimination of New HIV Infections Among Children and Keeping Mothers Alive*

MTCT of HIV Targets

- Rate mother-to-child transmission (MTCT) of HIV to 2% or less.
- Incidence of MTCT of HIV to 0.3 cases or less per 1,000 live births.

Syphilis Targets

- Incidence of congenital syphilis to 0.5 cases or less (including stillbirths) per 1,000 live births.

For more information on the process indicators for validation, please see the [WHO Guidance on Criteria and Processes for Validation of EMTCT of HIV and Syphilis](#)

Case Rate

In countries with large numbers of births and HIV-positive pregnant women, even if we are able to reduce MTCT to <2%, there will still be a high number of new HIV infections among children. Overall, HIV prevalence among pregnant women must be reduced to achieve EMTCT of HIV, which underscores the importance of primary prevention and addressing the unmet need for family planning among women of reproductive age. Although syphilis has a lot in common with HIV, it is an opportune time to link up the elimination of these two diseases. As we look to eliminate congenital syphilis, treatment will be key. This is because syphilis is a disease with a high transmission rate (up to 52%), if there is no treatment. Treatment, if given 4 weeks before delivery is 100% effective. Even in low prevalence settings, high detection and treatment rates are needed to achieve the case rate required for elimination. Countries with prevalence rates >2% will need to reduce prevalence among mothers.

The global case rate is higher to account for the number of countries where breastfeeding is common practice, but regions can set different criteria customized to their context. Low prevalence settings need to have high case rates to achieve the established case rate of 50/1,000 live births.

Qualifying requirements to apply for validation include:

- Reach process indicators for two years AND
- Impact indicator demonstrated for at least one year because impact studies may not be feasible to conduct regularly;
- Review of equity considerations, including low performance districts and high burden areas, or a particularly vulnerable groups that may be driving new infections;
- Robust monitoring and surveillance system to detect new cases; and
- EMTCT of HIV met with basic human rights considerations

In 2014, tools and checklists developed to support the validation process, including human rights and costing.

Three levels of validation:

- National: Collects, reviews and decides on the national documentation through consultations
- Regional: Reviews country reports and country surveillance system comply with global minimum validation standard and regional standards
- Global: Reviews country/RVC reports to ensure consistency and compliance with the minimum global criteria

Maintaining validation over time is important to sustain the validation status. WHO will continue to collect data on the EMTCT validation process through the global reporting processes. There is some discussion to develop more rigorous criteria, as more countries start reaching validation for EMTCT of HIV.

Global validation committee is comprised of global experts, the Secretariat and regional representatives. Pre-validation benchmarks and activities are being developed in recognition of efforts made in high prevalence settings to reduce MTCT of HIV, which is contributing to the global reductions that have been observed.

Regional Validation Criteria and Process, PAHO

- Methodology developed prior to 2012 to conduct country assessments that was purely qualitative which was the starting point to establish a reliable and valid methodology to verify country achievements. In collaboration with WHO, a more precise and quantitative methodology was piloted in the PAHO region and informed global validation tools and methodology
- Regional validation committee (RVC) developed in 2014, convened by the PAHO director and regional experts from the UN agencies, CDC and implementing partners
- Roster of regional experts to support validation process because RVC not able to respond to all country requests for validation anticipated in the next few years
- Disseminated validation guidance in the region to the ministries of health and developed standardized templates for key tasks to guide review of country reports

In November 2013, Cuba submitted first validation request in the region, which gives a sense of the duration of the process. Going forward, it is not expected to take as long, as this request was processed in parallel with the development of regional mechanisms for validation.

In March 2014, following extensive discussions Cuba established a National Validation Committee, led by the MOH and in October 2014 submitted the country report for validation. Global guidance provides recommended content to justify the case for validation.

Regional secretariat shared by PAHO and UNICEF. Technical advisors on the Secretariat reviewed and provided feedback on the report.

Pre-validation visit to Cuba conducted in December 2014 for an in-depth review of the pending questions in the validation report, to orient the Cuba team on the validation process and prepare for the actual validation mission scheduled for March 2015.

There were validation questions for each programme component that was reviewed including the programme and service delivery, laboratory capacity, data and impact assessment and human rights, gender equality and community engagement. The questions and process are detailed in the presentation.

Selecting the regions and sites to be visited to comply with global requirement of equity was challenging. Defining the lowest performing sub-national units considered multiple variables including, population size/density; process/coverage indicators and impact indicators. This was challenging due to the high coverage of essential services in Cuba (i.e. ANC attendance) and the number of cases of both paediatric HIV and congenital syphilis was very low. The main criteria consisted of where the most recent transmissions occurred and geographical variance among urban v. rural settings. First, regions were selected, then municipalities and specific health facilities (maternal houses, hospitals, FP clinics, etc).

Based on the above factors, the RVC felt that Cuba complied with the validation criteria and recommended their request to the global validation committee.

EMTCT of HIV and syphilis in Cuba: MOH, Cuba

The MOH provided an overview of the history of the PMTCT and syphilis programmes. In the early years, dermatologists provided care for STIs. In 1972, the syphilis control programme was established and prioritized, with a focus on case notification, research and epidemiological analysis and service provision at community level clinics. Each pregnant woman receives 10 interventions for PMTCT and follow-up care is provided, which includes HIV and syphilis testing to pregnant women as well as their sexual partners. Nearly all pregnant women give birth at health facilities. Annually, Cuba conducts nearly 1.5 million tests for syphilis, including 300,000 pregnant women, with 99% coverage. Since 1990, the annual rate for congenital syphilis has met criteria for validation, ranging from 0 to 0.04/1,000 live births.

In the early 1980's Cuba established an operational team for the HIV response. This group consists of social sector representatives, civil society and the health sector to ensure a cross-sectoral approach to the response at the national, provincial and municipal levels. The technical commission on HIV/AIDS provided technical support and the national response was informed by public health approaches. In particular, we built on the experience from the control of STIs and early diagnosis, notification of sexual partners, patient education and organization of services for prevention, care and treatment of those affected. To sustain the programme, the network of scientific centers invested in research, human resources, and technology to ensure access to diagnosis and care and treatment services.

Since the beginning of the epidemic there have been 21,922 people diagnosed with HIV, 3,652 deaths and currently there are a total of 18,270 people living with HIV/AIDS. National HIV prevalence among people ages 14-49 year old is 0.25%. For PMTCT, the programme implemented and adapted to the national context based on emerging scientific evidence. HIV testing in ANC, delivery using cesarean section and the suspension of breastfeeding were the main prevention measures used in

the 1980's, when the transmission rate exceeded 40%. HIV testing is provided on a quarterly basis, partner testing, combined with the provision of ART. Viral load (VL) monitoring, delivery via cesarean section, as well as infant prophylaxis and diagnosis are all components of our national PMTCT strategy. The MTCT rate of HIV has been equal to or lower than 2% for the past three years. Care and treatment for people living with HIV (PLHIV) has been integrated into the health service network and primarily provided by family doctors and specialists at the polyclinic trained in HIV/AIDS. Other services are provided, including referral to secondary and tertiary levels of care, as needed.

In collaboration with the GFATM, we have built the capacity to ensure access to special studies on follow-up care. We have 9 laboratories for phlebotomy and 5 laboratories for VL testing and monitoring. Cuba has made great strides to achieve EMTCT of HIV, including the research development and the local development of medicines as well as care provided by the national health care system and the technical support provided by partners. Today, there are 13,075 Cuban men and women living with HIV receiving ART.

In response to the commitment of PAHO in 2010, Cuba embarked on the validation process for EMTCT of HIV and congenital syphilis. A formal request was submitted to PAHO in 2013. As a result, we were able to mobilize the national team, hold workshops, organize monitoring visits, develop tools, train teams and using an instrument that was locally tested. Once the country report was finalized, we organized a validation visit by the RVC. During this visit, regional experts assessed the reliability of the report, exchanged information with the local team and planned for the global validation visit in March 2015. The RVC consisted of representatives from WHO, UNAIDS, UNICEF, UNFPA, CDC, and ICW, among others. In addition to visiting health facilities, we also interviewed programme managers as well as people living with HIV benefitting from these services. The process concluded with the recognition that Cuba achieved dual elimination of MTCT of HIV and syphilis.

Linkages to the Global Plan, UNAIDS

- Global, worldwide charge for EMTCT of HIV which has focused heavily on 22 countries that contribute to 90% of new HIV infections among children, but it is really a global responsibility
- Baseline for the Global Plan (GP) targets is data from 2009, which was the best data available when the GP was developed.
- Cuba's validation represents an important opportunity since 85 countries have fewer than 50 new cases of HIV infections among children in 2014
- Since 2005, there has been a downward trend in the number of new HIV infections among children and in 2009 through 2013 and acceleration in the rate of decline which showed as countries placing emphasis on EMTCT. We hope this acceleration curve will continue and many countries are doing an extraordinary job of working toward these targets.
- The Global Plan is supportive of WHO validation process. The GP is an acceleration for action, while validation is a measure of the achievement of EMTCT of HIV and work hand-in-hand.
- Elimination occurs along a continuum and countries are at different places along this line: a hyper-epidemic phase with a larger number of new infections and low case detection rate; followed by a narrowing of the gap between new infections and the case detection rate; moving on to what may be considered a pre-elimination phase identifying most, if not nearly all of the new infections and able to intervene; to an elimination phase and then potentially eradication. High burden countries may have significant numbers of infections, but may have made tremendous progress in reducing the MTCT rate of HIV.
- Inclusion of human rights is the first time this dimension has been included in an elimination of a disease (i.e. smallpox or polio). To develop this criteria, multiple meetings with groups of women living with HIV, community members, and human rights experts were held to

determine what is most important from a public health perspective to require as part of the validation process.

- EMTCT of HIV is one part of the broader goal of ending the HIV epidemic by 2030.

Next Steps and Future Directions

- Cuba's validation marks the beginning of the end of HIV epidemic
- First time the impact of the HIV response has been validated regionally and globally
- Opportunity to consolidate the validation agenda among partners
 - Maintaining the movement across partners, which links to the SGDs
 - Deepen and widen the validation agenda, including more countries and secure funding necessary to do this – scale-up to 10, 20, 40 countries. Challenge to extend this to Africa
 - Streamline the process and clarify global and regional roles so there is one validation step and reduce overlap in roles
 - Extend the agenda to better include the great progress in Africa where hundreds of thousands of infections are being eliminated on a yearly basis
 - Include pre-validation phase to recognize countries which have achieved MTCT of HIV rates of <5% and develop progress plans in these countries
- Priorities for the Global Validation Committee include:
 - Consolidate and simplify tools and link to ongoing country programme reviews and other assessments
 - Strengthen stages of pre-elimination/impact stage to bring in countries with high caseloads, but that have documented major progress; pilot this in an Africa country
 - Firm up the sustaining stage of elimination
 - Work on the pipeline of countries from each region to strengthen this agenda and conduct the readiness analysis
 - Resource mobilization to support validation activities to include more countries
 - Maintain the validation structure
 - Celebrate lessons learned from the validation process in Cuba and what has been achieved

Question & Answer Transcript

Question # 1: What type of strategy did MOH of Cuba use in terms of mass media campaigns and what type of messaging was included? (E.g. Radio, TV)

The MOH representative, MOH, Dr. Katia noted that since the HIV program started in 1986, mass media campaigns have been used to expose Cubans to health promotion messages, using the media as an educational tool, including radio, TV and the printed press. Media also played a very important role in creating awareness and decision-making. Over the past 10 years have been aimed at targeting the most vulnerable groups. Although we have a long way to go, we have made headway in addressing the needs of vulnerable populations, which has had an impact on the trajectory of the HIV epidemic.

Question # 2: What kind of incentives has been used by Cuba to maintain volunteers?

In Cuba, we encourage volunteerism. There is no monetary compensation for the volunteers are people from the community who have received orientation on HIV and support the education component of the work. However, the MOH offers certificates of recognition and hand-written notes for the volunteers' efforts. Despite being unpaid, so far the results have been encouraging.

Question # 3: Are all the volunteers HIV positive or is anyone from the community irrespective of their HIV status able to be a volunteer?

Dr. Katia stated that anyone from the community irrespective of their HIV status can become a volunteer. In Cuba, volunteers are a mix of people living with HIV as well as community members who are not HIV-positive. Many are people affected by HIV, for example family members or co-workers of people living with HIV.

Question #4: How is Cuba dealing with HIV-related stigma and discrimination?

Since the inception of the HIV programme in Cuba, the government has worked with and toward empowering people living with HIV. Dr. Katia also added that the MOH works closely with local health care teams at the grass-roots level. However, there are specific incidents of stigma at the local or interpersonal level and those are addressed by the district or territory where the incident has occurred. We still have a long way to go, but over time we have made progress in reducing stigma and discrimination.

Question # 5: What are the strategies used by Cuba to improve or increase partner testing?

Partners are asked if they would like to be tested based on informed consent and HIV positive individuals are also informed about the risk of transmission to their partner.

Question #6: How does Cuba plan to maintain the elimination status?

In her statement, Dr. Katia noted that achieving elimination was a boost for the HIV programme and that the validation process fostered much learning. There are different monitoring mechanisms that have been adopted, and additionally Cuba is currently in the process of empowering districts that weren't included in the validation exercise to enable them to adopt the same monitoring mechanisms in order to maintain the elimination status. We have also developed an action plan based on the recommendation of the regional validation committee.

Question #7: How is Cuba dealing with task shifting in order to allow nurses to initiate and manage ART?

Dr. Jose Juanes Fiol responded that in Cuba family doctors are responsible for managing ART and nurses are only required to control and follow up adherence to treatments.

Question #8: How do you maintain mothers and children in care- so you don't lose them?

Mothers and their children who are living with HIV or syphilis are systematically followed up under the national programme as any other person living with HIV. Mothers and children living with HIV often support the educational component of our work. For example, the family doctor and nurses work together to follow up on the health, as well as, social conditions of women and children.

Question #9: What types of community engagement strategies were used, in addition to using a large number of volunteers?

The educational strategy under the HIV national program works with CSOs, women, and adolescents. There is also a focus on reaching people engaging in transactional sex and MSM, each of these groups have representatives in different institutions, including work places, community associations and other cultural institutions, which help to identify individuals most at risk of acquiring HIV and to refer those who are HIV positive to the programme people into the programme.

Question #10: When is the final status of children determined, is it at 4-6 weeks, and does that mean breastfeeding is not allowed in Cuba?

Dr. Katia states that according to the Cuban protocol, pregnant women who are known or identified as HIV positive in ANC or who become HIV positive during pregnancy are discouraged from breastfeeding.

Question #11: Given that a number of countries are trying to implement specific process for validation is there a repository for tools that are currently being used or is it possible to share those that have been used in Cuba so other countries can adapt them?

WHO agreed to discuss with PAHO in making the repository available to share with other countries.