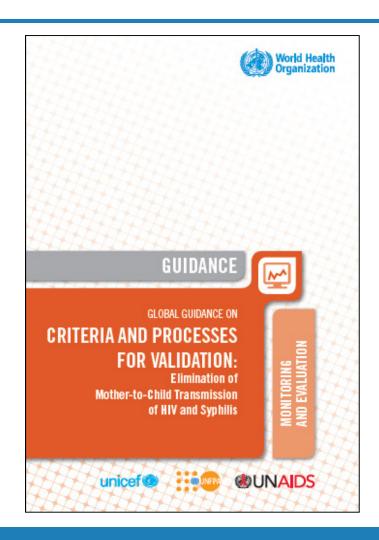


### **Validation of EMTCT:**

Summary of Global Criteria and Activities WHO HIV and RHR Department

Chika Hayashi





## Background





## MTCT of HIV and Syphilis without Treatment

### MTCT transmission:

HIV: around 1/3 (15-45%)

Syphilis: >1/2 (52-90%, depending on maternal stage)

### Without treatment:

HIV: ~1/3 with HIV die <12 months ~1/2 die by <24 months

Syphilis: 52% perinatal deaths, 31% congenital disease,

12 % preterm or low birthweight (at risk for infant death)



### Preventable Burden

Burden

HIV: estimated 240,000 MTCT infections in 2013

<u>Syphilis</u>: estimated 350,000 adverse outcomes in 2012 (including 143,000 perinatal deaths)

Interventions exist

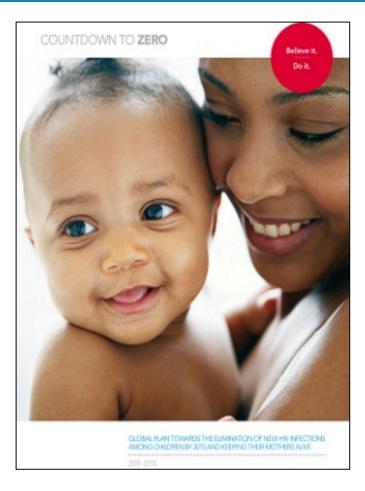
HIV: early and continued ART can reduce transmission from 15-45% <2% or <5%

Syphilis: Screening and treatment of syphilis-infected mothers < 30 days before delivery can prevent perinatal morbidity and mortality

Target pregnant women and similar control measures

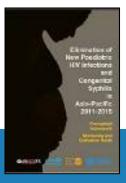


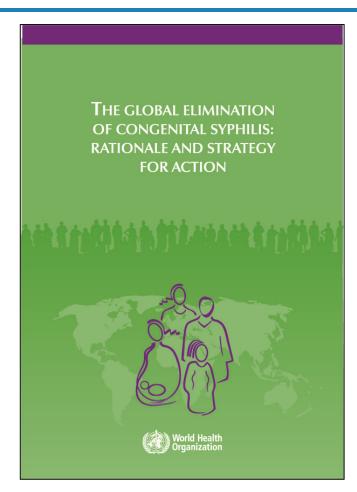
# Global initiatives for EMTCT of HIV/AIDS and syphilis













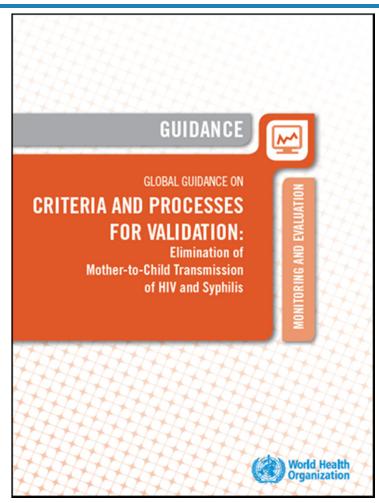
# CRITERIA & PROCESS for EMTCT Validation



## 2012 Consultation on Global Guidance for EMTCT Validation

- Standardized Criteria
- Process
- Secretariat

- WHO, UNAIDS, UNICEF, UNFPA
- Based on country pilots
- Common systematic approach for dual elimination





## Terminology and Definition

### Certification

### **Eradication**

 Permanent reduction to zero of the worldwide incidence of infection

### **Elimination**

 Reduction to zero of the incidence of disease or infection in a defined Certification/ geographical area
 Verification

### Control

 Reduction in the incidence, prevalence, morbidity or mortality of an infectious disease to a locally acceptable level

Dowdle WR.1998. The principles of disease elimination and eradication. Bull World Health Organ 1998;76 Suppl 2:23-5.

### Elimination of MTCT Mode of Transmission

**Validation** 

 EMTCT: eliminating as a public health problem, to a very low level (below threshold, achieve global targets)

#### HIV

### **Impact indicators**

Mother-to-child transmission (MTCT) HIV case rate of ≤50 new paediatric HIV infections per 100 000 live births

MTCT of HIV of <5% in breastfeeding populations

OR

MTCT of HIV of <2% in non-breastfeeding populations

### **Process indicators**

Antenatal care (ANC) coverage (at least one visit) of ≥95%

Coverage of pregnant women who know their HIV status of ≥95%

Antiretroviral (ARV) coverage of HIV-positive pregnant women of ≥90%

### Congenital syphilis

### **Impact indicator**

Incidence of congenital syphilis ≤50 cases per 100 000 live births

#### **Process indicators**

ANC coverage (at least one visit) of ≥95%

Coverage of syphilis testing of pregnant women of ≥95%

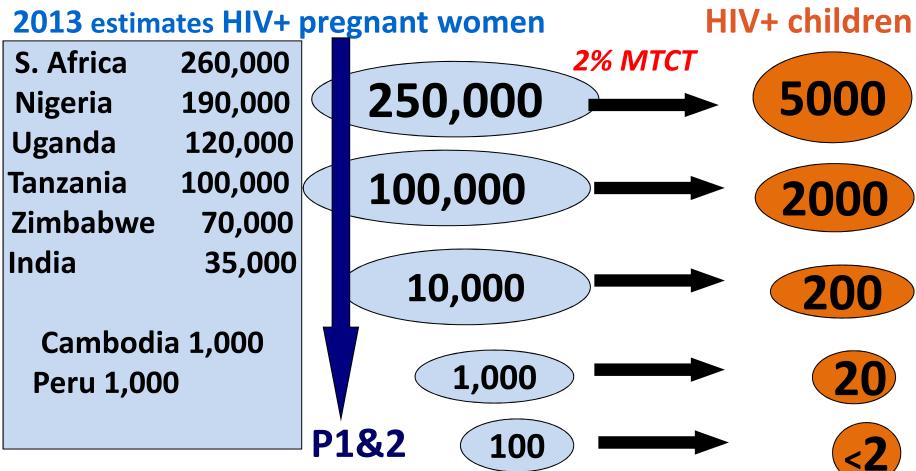
Treatment of syphilis-seropositive pregnant women ≥95%

**GP** 

**GP** 



## HIV: Vertical Transmission not enough for EMTCT Validation



• Even if we interrupt vertical transmission, child HIV infections due to MTCT is not getting close to zero unless we reduce prevalence/number of HIV+ pregnant women



### **Case Rate - HIV**

	NUITAD	ING VND	EVALUATION
пти и	UNIIUK	ING AND	EVALUATION

HIV	Live Births	HIV-exposed	New CI	nild HIV	Case Rate per 100,000 livebirths if:			
Prevalence		Births	2%	5%	2%		5%	
0.50%	27000000	135000	2700	6750	10		25	
0.50%	10000	50	1	2.5	PAHO 10	Global	25	
1%	27000000	270000	5400	13500	<30 20	Global <50	50	
1%	10000	100	2	5	20		50	
2%	27000000	540000	10800	27000	40		100	
2%	10000	200	4	10	40		100	
5%	27000000	1350000	27000	67500	100		<b>250</b>	
5%	10000	500	10	25	100		<b>250</b>	
10%	27000000	2700000	54000	135000	200		<b>500</b>	
10%	10000	1000	20	50	200		500	
15%	27000000	4050000	81000	202500	300		<b>750</b>	
15%	10000	1500	30	75	300	World He Organiza	ealth ati <b>r</b> n <b>50</b>	

## HIV MONITORING AND EVALUATION Case Rate - Syphilis

syphilis	Births	syphilis- exposed	Case rate per 100,000** Detection and Treatment					
Prevalence		Births	95%	75%	50%	20%		
0.3%	100000	300	7	34	68	108		
1%	100000	1000	23	113	225	360		
2%	100000	2000	45	225	450	720		
5%	100000	5000	113	563	1125	1800		
6%	100000	6000	135	675	1350	2160		
8%	100000	8000	108	900	1800	2880		

52% of births affected if no detection/treatment 30 days prior to delivery

Gomez et.al. 2013





# Qualifying Requirements for EMTCT Validation

- 1. National EMTCT validation indicators
  - Process indicator targets achieved for <u>2 years AND</u>
  - Impact indicator targets achieved for 1 or more 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





## Sept 2014 Consultation Sept 2014 Consultation

## **Operational Tools for EMTCT Validation**

- Data Quality Checklist: to review data quality and impact assessments in a systematic way
- Lab Quality Checklist: to verify reliability of test results
- Human Rights Checklist: to support discussion and review of key human rights considerations

### In addition, not covered in consultation:

- Costing Tool: to facilitate costing of validation
- Programme Assessment Tool: to gather information on programme and service delivery



## PROCESS for EMTCT Validation





### 3 Levels

T Va

National Validation Committee (NVC)

 Collects, reviews and decides on the national documentation through consultations

E A M

Regional

 Reviews country reports and country surveillance system comply with global minimum validation standard and regional standards

NVT and RVT:
data collection
and analysis,
in-country
visits.

Global Validation Committee (GVC)

Reviews country/RVC reports to ensure consistency and compliance with the minimum global criteria.



## Summary of processes for

## validation of EMTCT of HIV and/or syphilis

**p.17** 

http://www.who.int/hiv/p ub/emtct-validationguidance/en/

#### MOH submits a validation request to the regional secretariat. MOH and the RVC jointly establish an NVC. NVC decides whether to establish an NVT. Country NVC (or NVT where active) collects, assesses, and summarizes pre-validation national data for pre-validation report. NVC reviews pre-validation report and submits to the RVC. RVC selects RVT for each candidate country. RVT reviews country pre-validation report. RVT and NVT conduct in-country validation visit and Country interviews with key stakeholders. validation RVT prepares and submits national validation report to the regional secretariat. Regional secretariat convenes RVC. RVC reviews national validation report for compliance with minimum regional and global criteria. Regional If approved, RVC prepares and submits regional validation validation report to the global secretariat. If not approved, RVC notifies NVC and provides clear recommendations. Global secretariat convenes GVC. · GVC reviews regional validation report for compliance with minimum global criteria. Global GVC prepares global validation report and submits to global validation secretariat. Global secretariat issues letter officially notifying the candidate country of validation status and recommending follow-up actions for maintenance of validation status. Official validation

#### Maintenance of validation

- Global secretariat monitors maintenance of validation indicators through existing annual global reporting systems.
- Global secretariat reports any concerns noted to RVC for follow-up and more in-depth assessment.

## Tracking maintenance of validation



# Global Reporting

	Indicator 1: Percentage of antenatal care attendees tested for syphilis			Indicator 2: Percentage of antenatal care attendees tested who are positive for syphilis				Indicator 3: Percentage of antenatal care attendees who tested positive for syphilis and who received treatment				
WHO Region	2008		2013		2008		2013		2010		2013	
	Number of reporting countries	Median value reported	Number of reporting countries	Median value reported	Number of reporting countries	Median value reported	Number of reporting countries	Median value reported	Number of reporting countries	Median value reported	Number of reporting countries	Median value reported
African Region	18	59%	23	58%	30	2.3%	30	2.2%	15	100%	16	96%
Region of the Americas	14	73%	25	83%	14	0.9%	26	0.6%	16	85%	18	82%
Eastern Mediter- ranean Region	3	-	4	-	4	_	7	0.0%	0	-	2	-
European Region	9	100%	13	99%	9	0.3%	14	0.1%	3	-	9	100%
South- East Asia Region	3	-	8	75%	6	1.3%	5	0.3%	3	_	4	-
Western Pacific Region	4	-	11	96%	8	0.3%	12	0.2%	7	98%	4	_
Global	51	78%	84	84%	71	1.4%	94	0.6%	44	99%	52	94%

The regional median is not shown if fewer than five countries reported.





## June 2015 First Meeting

## **Global EMTCT Validation Committee**

- Composed of technical experts + regional representation
- Agreed on TOR
- Reviewed Cuba report, assessed whether criteria were met, and recommended EMTCT validation to WHO
- Decided on establishment of pre-validation benchmarks and activities, especially for high burden countries making good progress in controlling MTCT of HIV and syphilis
- WHO Secretariat works with key partners (UN and CDC) and supports operation of GVC. Annual workplan discussed, including further development and update of guidance, tools, templates and regional/country support.



### **Acknowledgements**

WHO: Lori Newman, Maura Laverty, regional focal points

**CDC:** Mary Kamb

**UNAIDS:** Karusa Kiragu

**UNICEF:** Priscilla Idele

**UNFPA: Lynn Collins** 

CDC: Thu-Ha Dinh

Various other contributors!

For more information:

www.who.int/reproductivehealth/topics/rtis/syphilis/en/index.html

http://www.who.int/hiv/pub/emtct-validation-guidance/en/

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