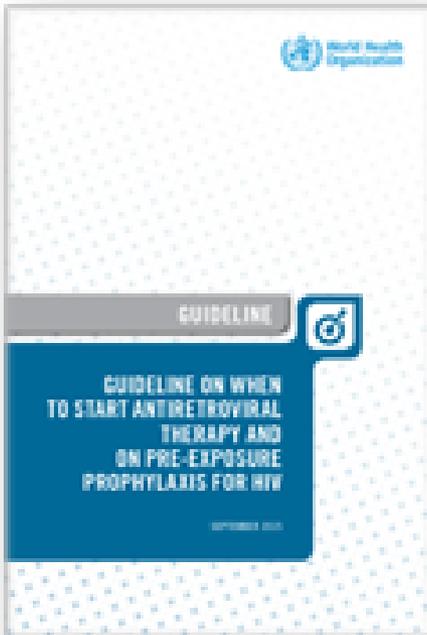


# The Early Release Guidelines on When to start antiretroviral therapy and on pre- exposure prophylaxis for HIV



Meg Doherty, MD, PhD, MPH  
2 Oct 2015  
IAPAC Summit, Paris





# Acknowledgements

Special thanks to all the external experts who contributed as members of the Guideline Development Groups, and to those who contributed to the GRADE systematic reviews and supporting evidence which informed the guidelines process. Thank you to IAPAC for opportunity to share these guidelines.

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**JHU**

**Pangaea, APN+, AHF, ITPC, EATG, AFROCAB, Via Libre**

**leDEA Collaboration**

**The Global Network of People living with HIV/AIDS**

**PEPFAR**

**CDC**

**USAID**

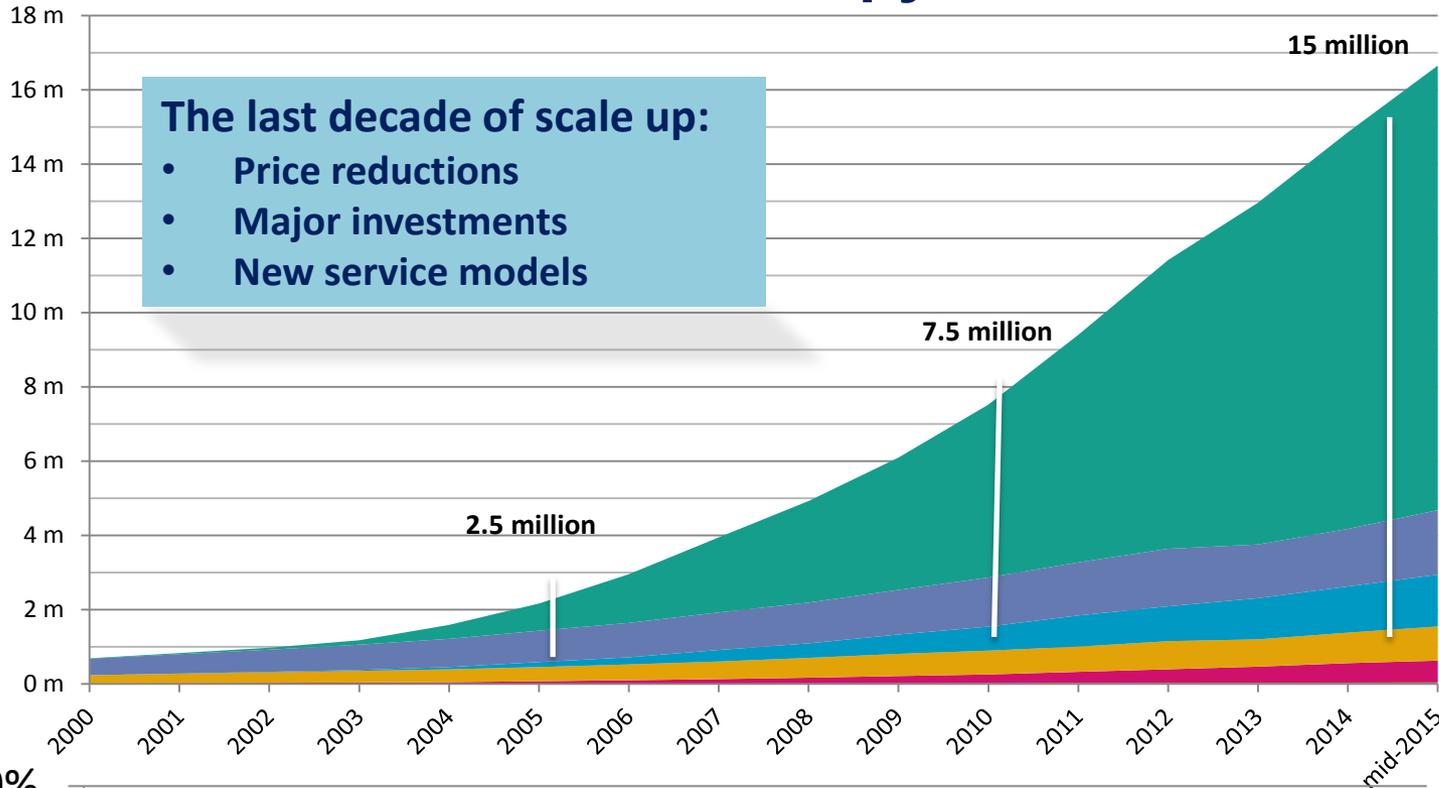
**Bill and Melinda Gates Foundation**



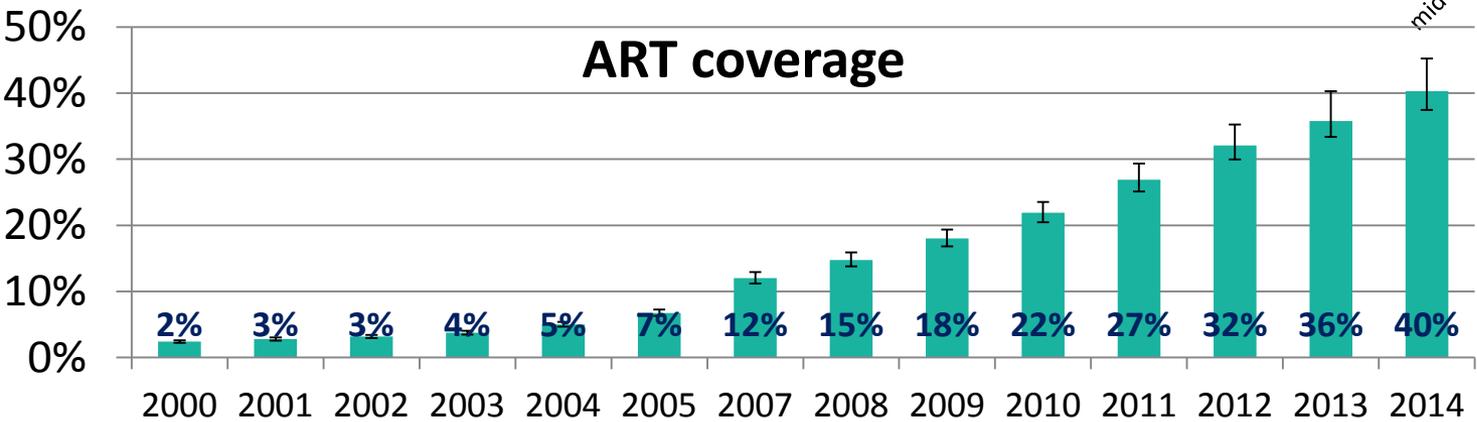


# Progress in access to antiretroviral therapy: 2000–2015

## HIV TREATMENT

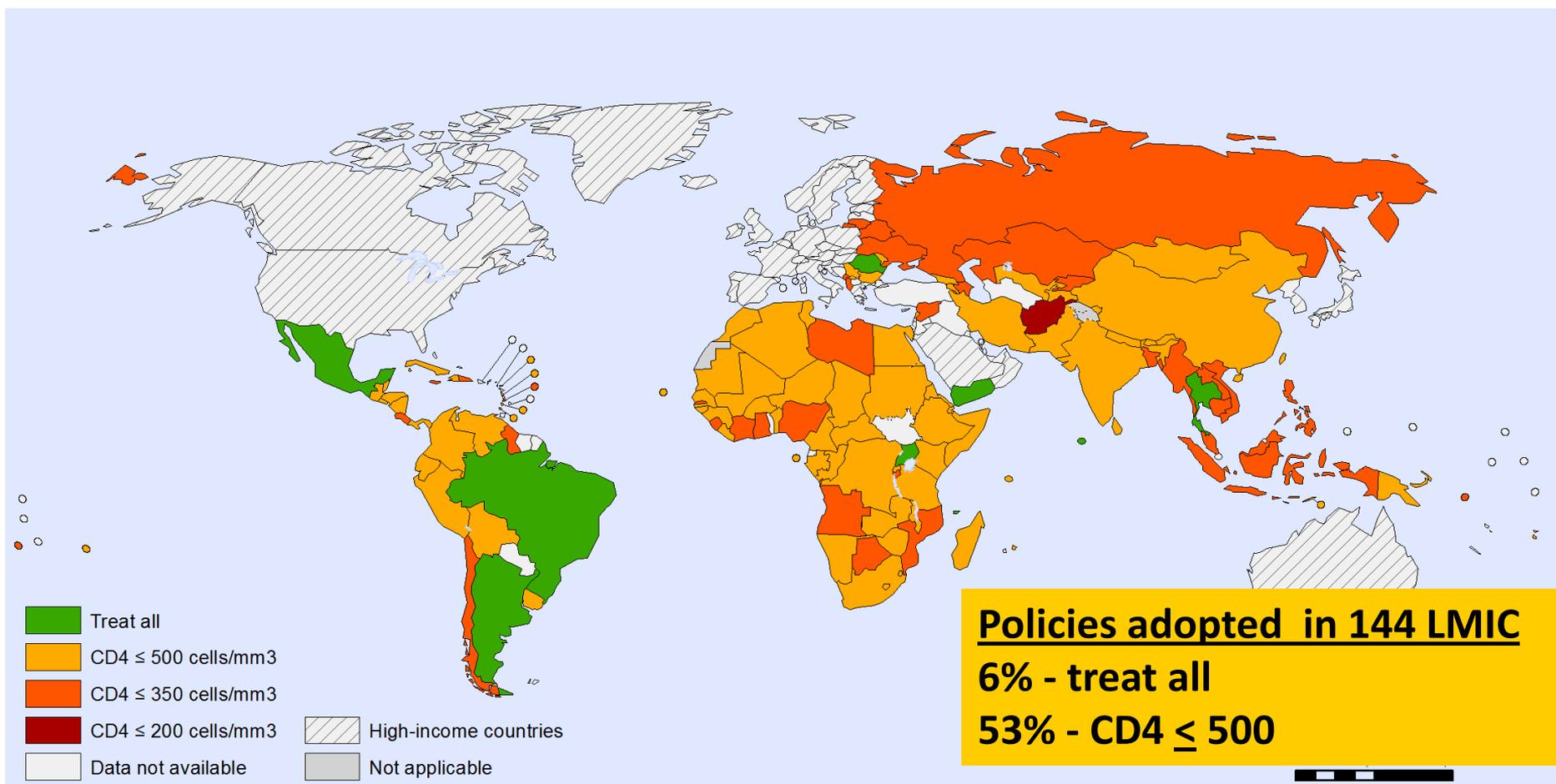


- Africa
- Americas
- South-East Asia
- Europe
- Western Pacific
- Eastern Mediterranean



**“15 BY 15”**  
**A GLOBAL TARGET ACHIEVED**

# Uptake of WHO policy for initiation threshold among adults and adolescents living with HIV in low- and middle-income countries (situation as of end 2014)



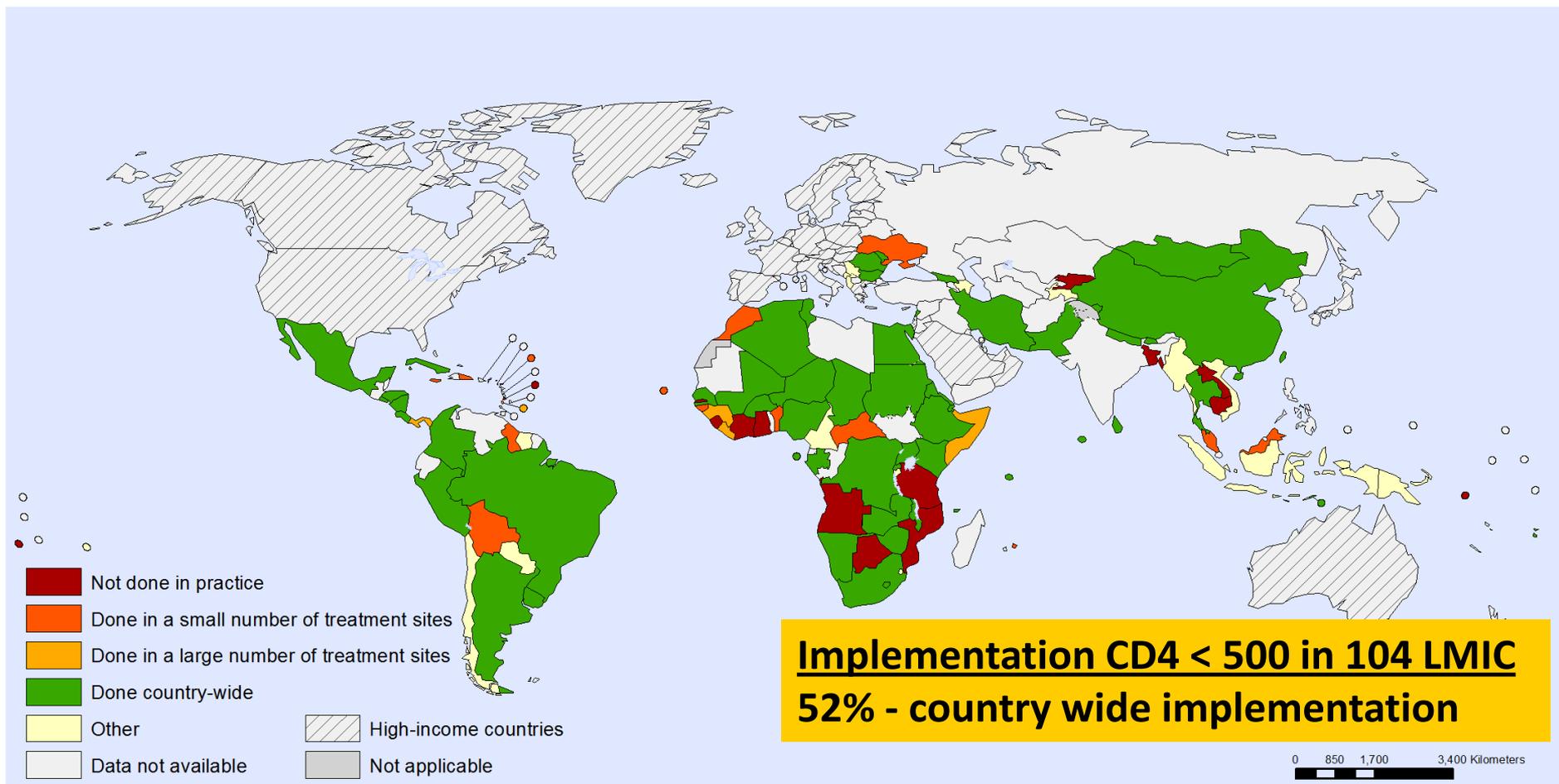
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization  
 Map Production: Health Statistics and Information Systems (HSI)  
 World Health Organization



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# Implementation and practice of initiating ART at a CD4 threshold of 500 among adults and adolescents living with HIV in low- and middle income countries (situation as of end 2014)



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization  
 Map Production: Health Statistics and Information Systems (HSI)  
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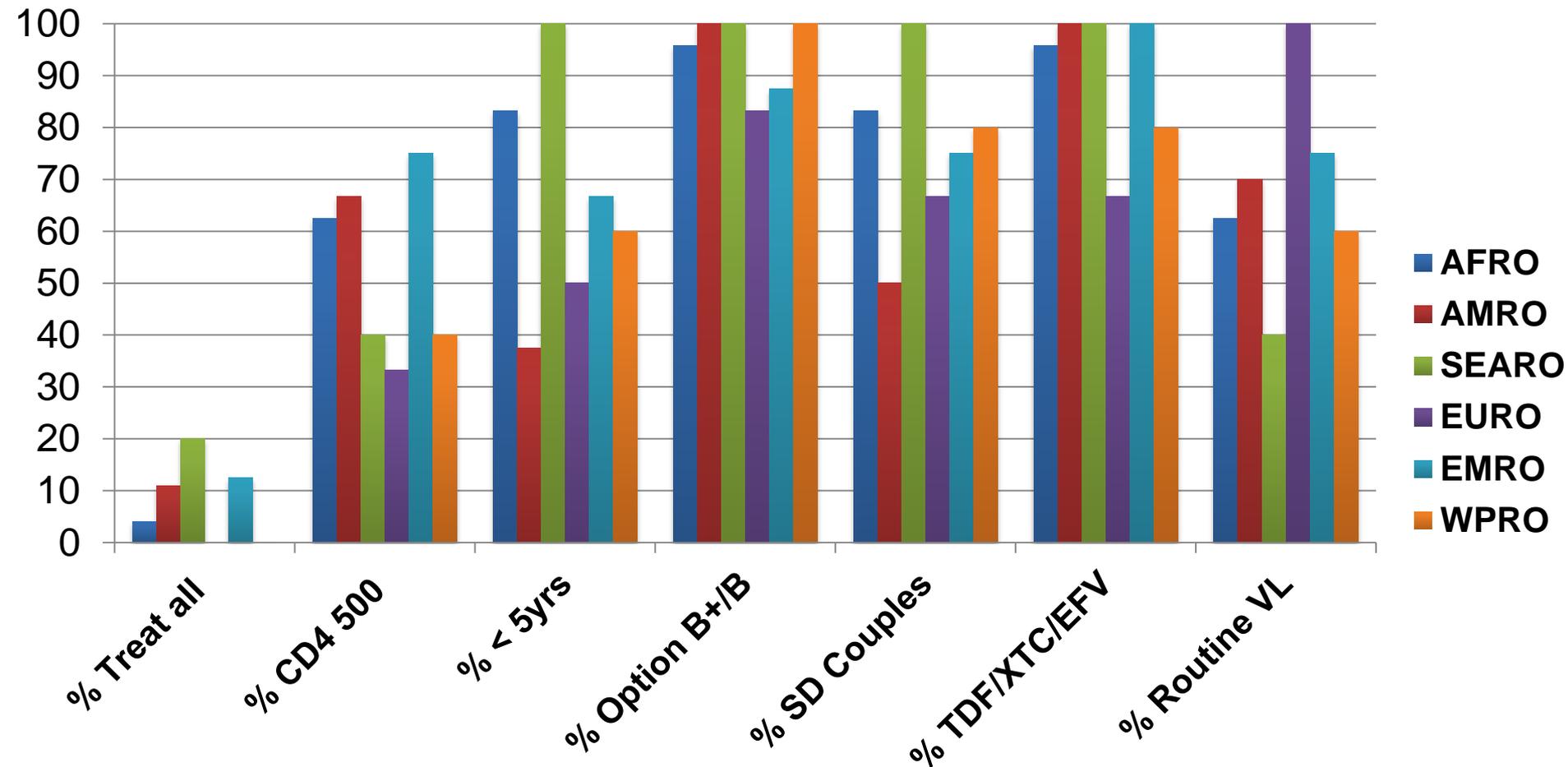


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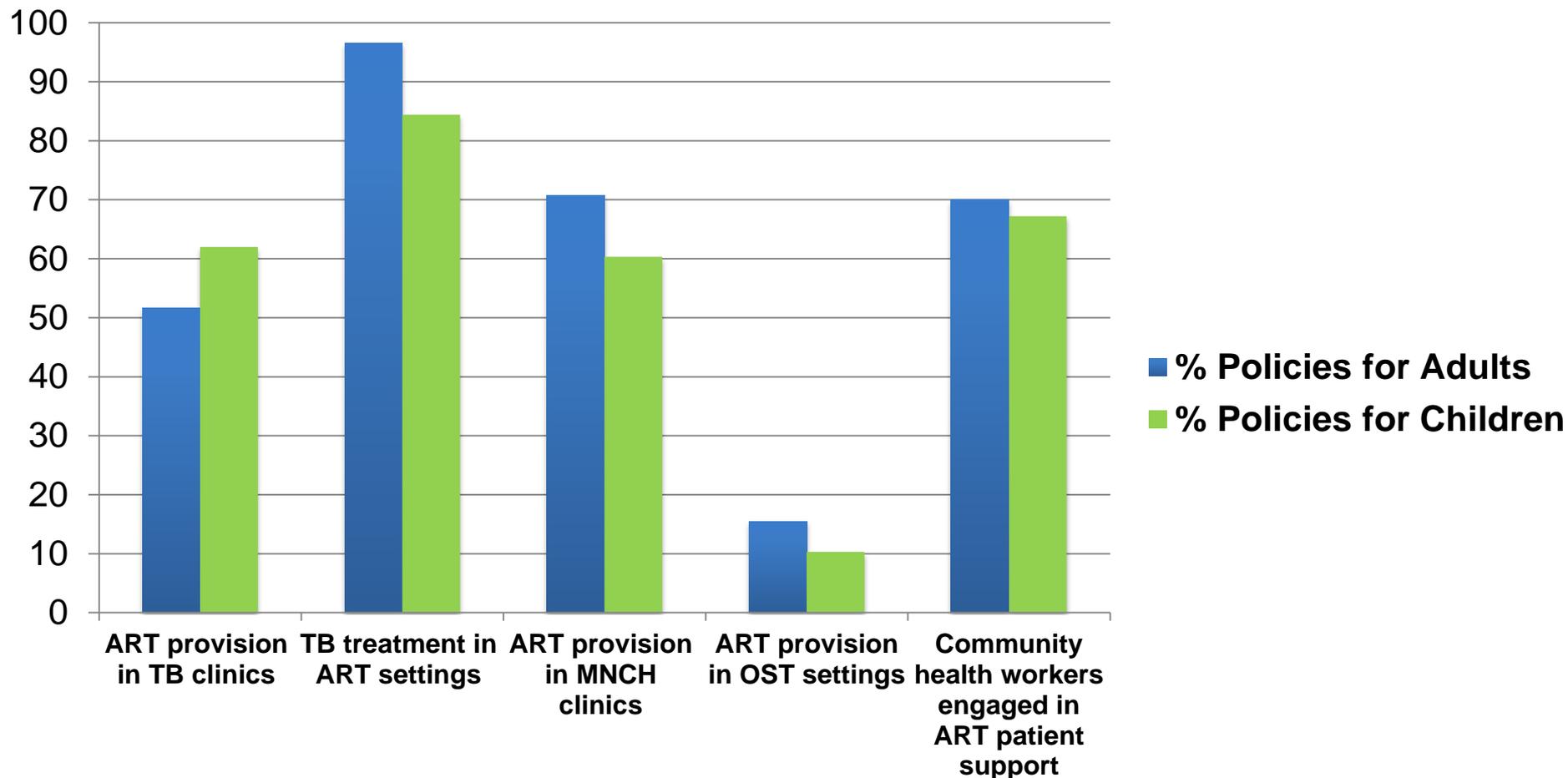
# WHO 2013 Consolidated ARV Guidelines

## Policy uptake in 58 WHO focus Countries End 2014

(% responding yes, by region)



# % Uptake of Service Delivery Integration Policies in the 58 WHO focus countries, end 2014





# 2015 WHO Consolidated ARV Guidelines



## WHAT TO DO?

- When to start
- What to use for children, adolescents, pregnant women
- How to monitor
- **Co-infections**
- **HIV and MH & NCDs**
- **PrEP, PEP**

Clinical

Operational & Service Delivery

Programmatic Prioritization

## HOW TO DECIDE?

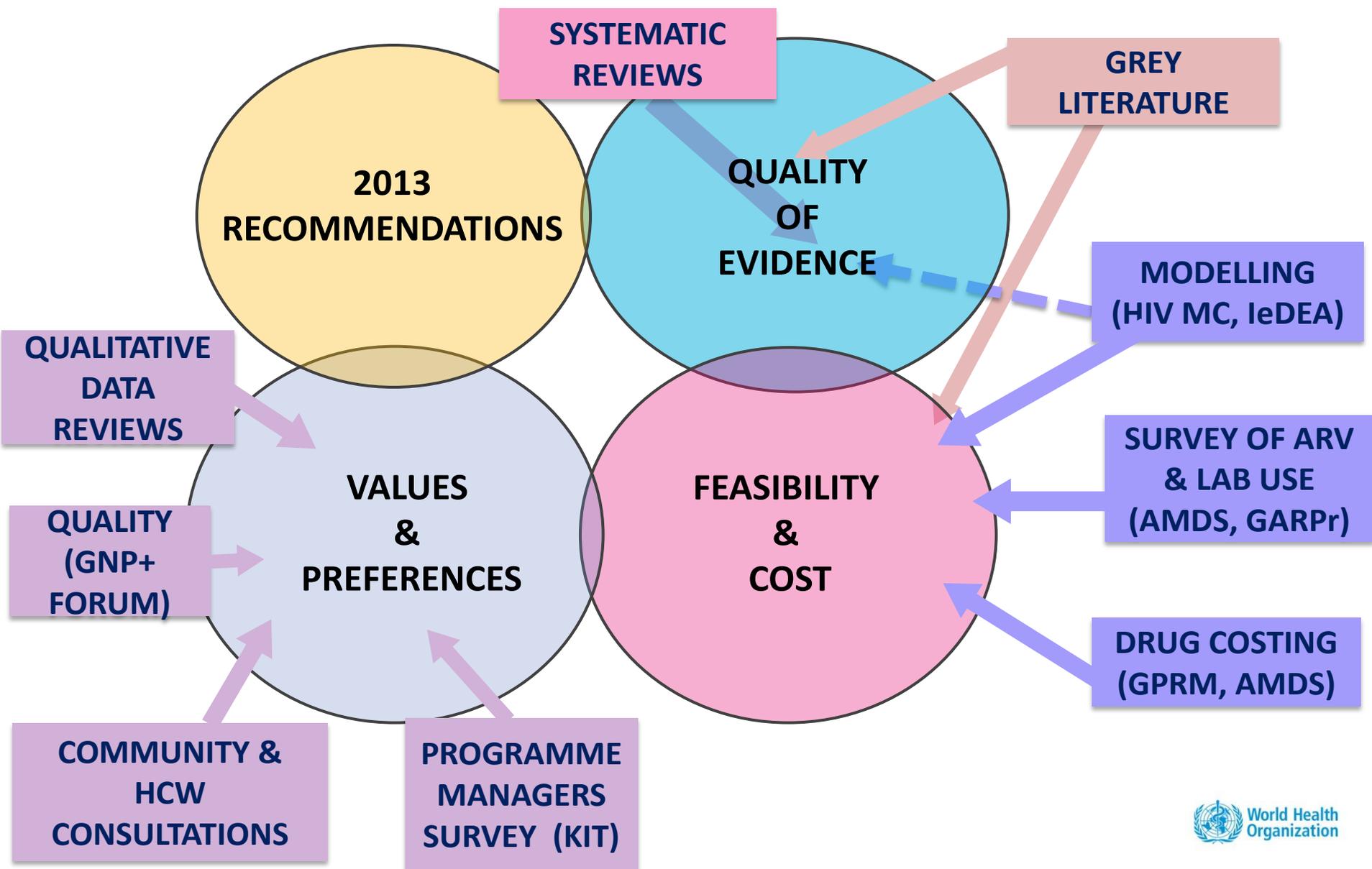
- **Approaches to prioritization & sequencing**
- **Tool kits for country adaptation and implementation**

## HOW TO DO IT WELL?

- **Care Packages (Differentiated /Adaptive Care)**
- Linkages, Retention, Adherence
- **Quality of care**
- **Diagnostics**
- **Supply chain**



# 2015 ARV Guidelines Process





# ART eligibility: 5 policy scenarios

Estimated millions of people eligible for ART (2014)



30 m.

36.9 m.

1

CD4 ≤ 200

Recommended since 2003

2

CD4 ≤ 350

Recommended since 2010

3

CD4 ≤ 350 + TasP

Incremental approach 2012

4

CD4 ≤ 500

+ indications for ART at any CD4

5

All HIV+

Treat ALL

2013 guidelines

2015 guidelines

# WHEN TO START - 2015 RECOMMENDATIONS

Target Population	Specific Recommendation	Recommendation Strength	Quality of Evidence	
Adults	ART initiation at any CD4	Strong	Moderate	<b>NEW</b>
	ART initiation if WHO clinical stage III/IV or CD4 $\leq$ 350 as priority	Strong	Moderate	
Pregnant/BF women	ARV initiation at any CD4 and continued lifelong (Option B+)	Strong	Moderate	<b>REVISED</b>
Adolescents	ART initiation if 10-19 years-old	Conditional	Low	<b>NEW</b>
	ART initiation if WHO clinical stage III/IV or CD4 $\leq$ 350 as priority	Strong	Moderate	
Children	ART initiation if 1-10 years-old	Conditional	Low	<b>NEW</b>
	ART initiation if < 1 year-old	Strong	Moderate	
	ART initiation if < 2 years-old or WHO clinical stage III/IV or CD4 < 25% (< 5 years) or $\leq$ 350 (>5 years) as priority	Strong	Moderate	

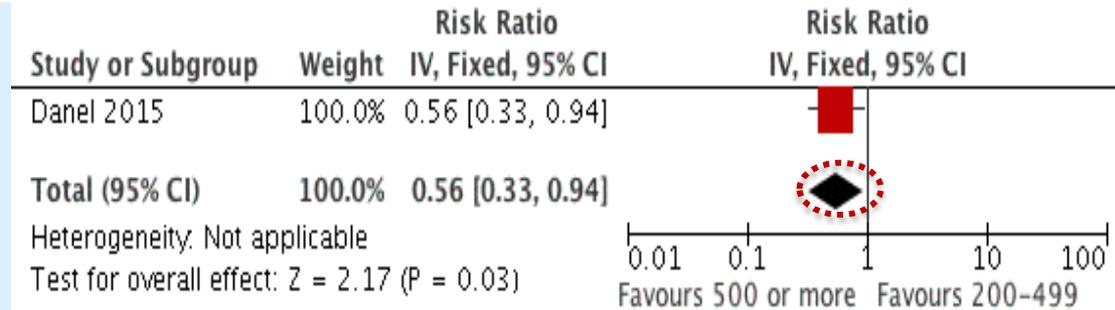
# Evidence Summary: When to Start in Adults

- **Systematic Review of 18 eligible studies** (1 RCT and 17 observational cohorts )
- Some observational studies reported **results from a single cohort** (6 studies)
- **Outcomes reported:**
  - ✓ Mortality
  - ✓ Severe HIV disease
  - ✓ HIV disease progression
  - ✓ AIDS events
  - ✓ Non-AIDS events
  - ✓ Malignancy ( AIDS and non AIDS)
  - ✓ Tuberculosis
  - ✓ HIV transmission
  - ✓ SAE and lab abnormalities
  - ✓ Severe HIV disease or malignancy or mortality (combined outcome)

# Evidence Summary: Risk of death, severe HIV disease or HIV disease progression

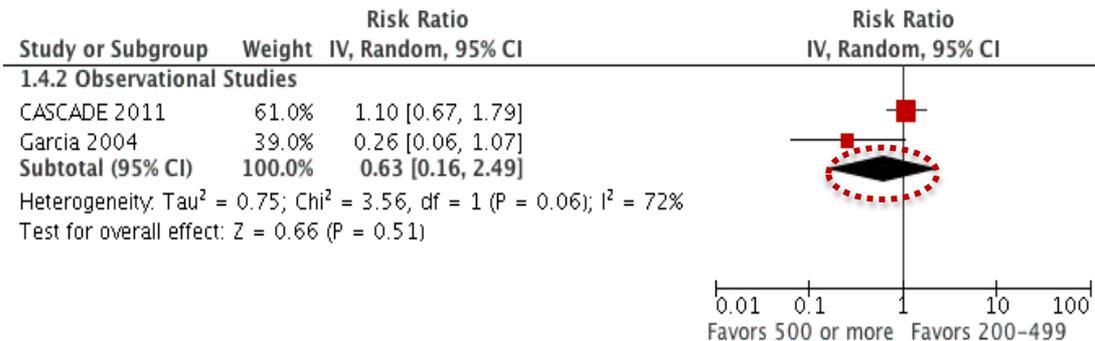
## Clinical trials

Moderate quality evidence for lower risk of **death, severe HIV disease or malignancy** compared to those deferring treatment **(1 study)**



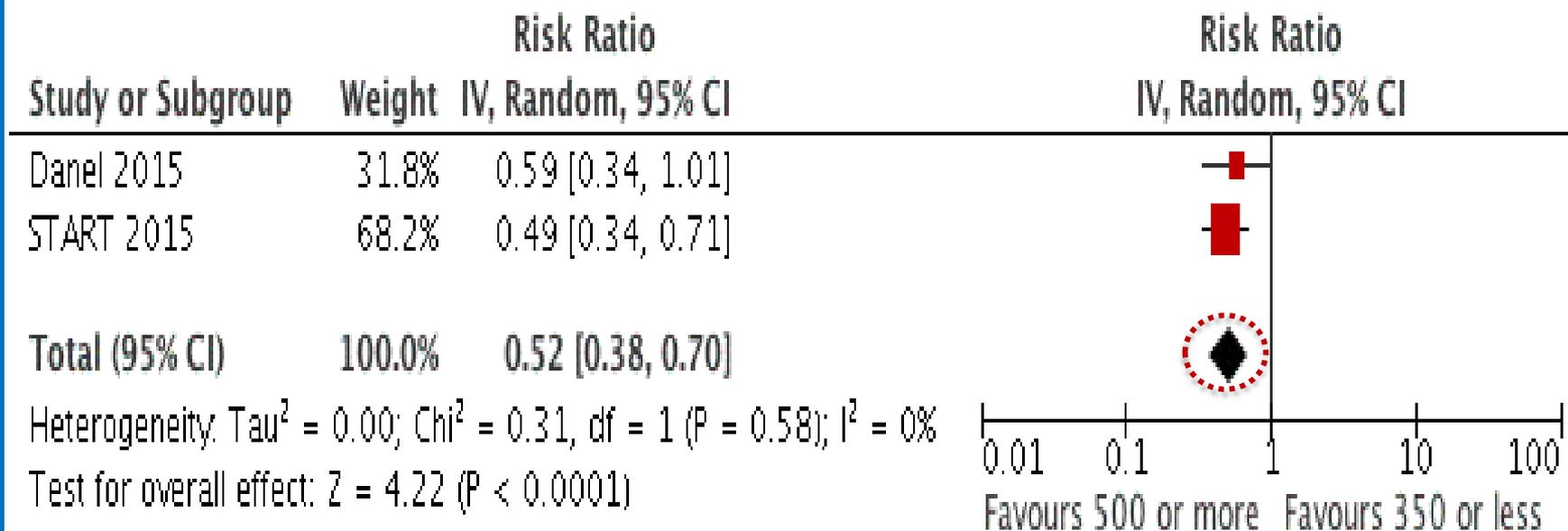
## Observational studies

Very low quality evidence for lower risk of **death or progression to AIDS** compared to those deferring treatment **(2 studies)**



CI confidence interval; df, degrees of freedom; IV, inverse variance; RCT, randomised controlled trial

# Severe HIV morbidity on TEMPRANO & START studies



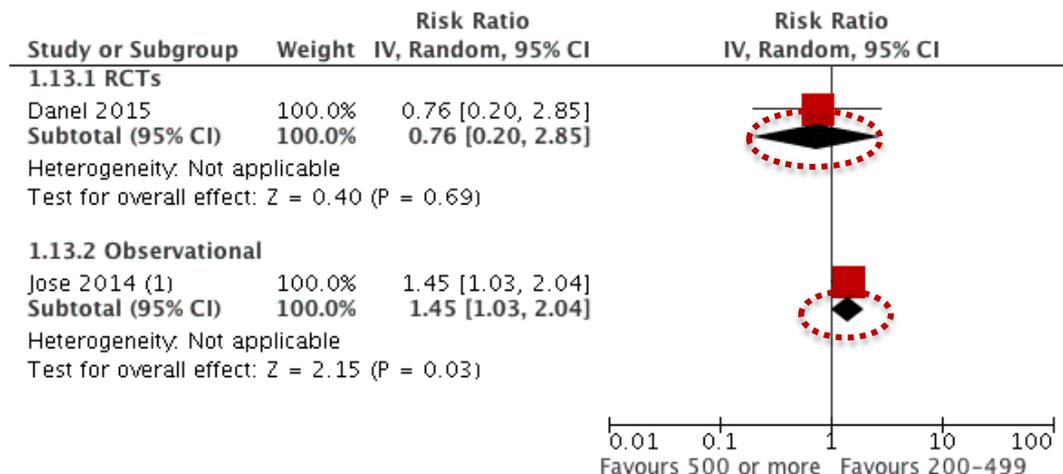
CI confidence interval; IV, inverse variance; RCT, randomised controlled trial

# Evidence Summary: Risk of Hepatic and Renal SAE

## Hepatic SAE

### Clinical trial

Low quality evidence for no increased risk of hepatic and renal SAE between early vs deferred treatment **(1 study)**



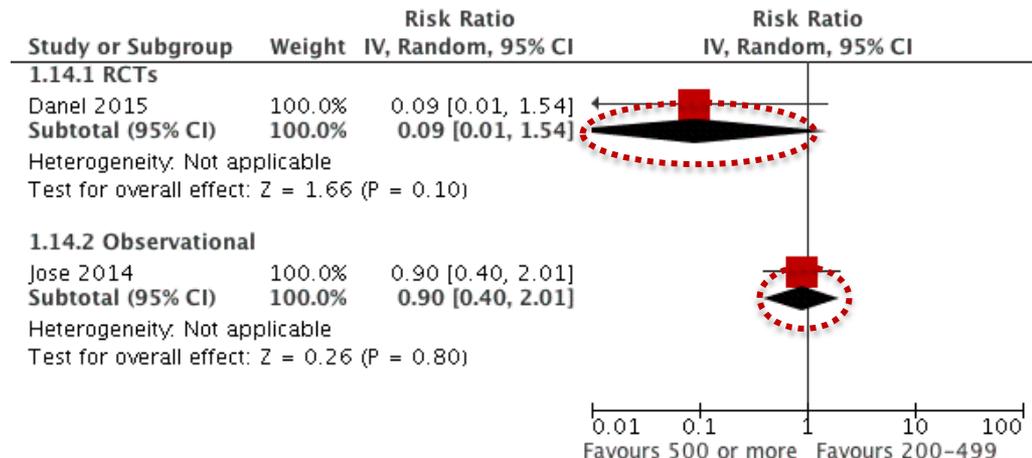
(1) 500+ vs <350

## Renal SAE

### Observational studies

Low quality evidence for increased risk of hepatic SAE compared to those deferring treatment but no increased risk for renal SAE

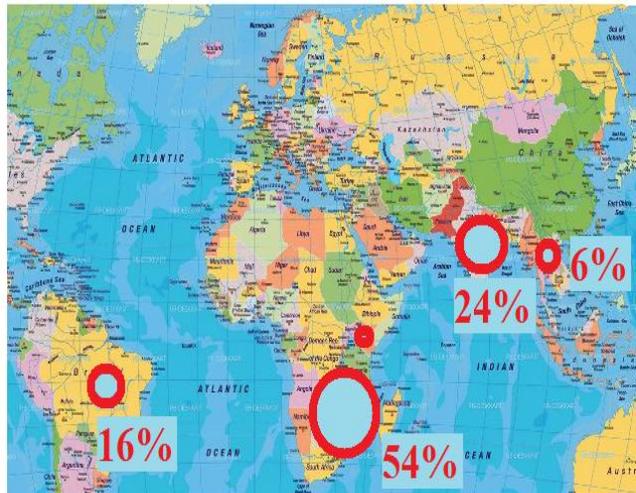
**(1 study)**



# When to Start in Adults: Evidence Summary

- Evidence show clinical benefits of ART initiation over 500 CD4 to all PLHIV compared with < 500 CD4 initiation, with reduction of severe HIV morbidity, HIV disease progression and HIV transmission, without increase in grade III/IV adverse events.
  - Quality of evidence for the combined outcome of death, severe HIV disease or malignancy was of **moderate quality**
  - Quality of evidence for any Grade 3 or 4 laboratory abnormalities was also of **moderate quality**
  - Quality evidence for HIV disease progression and HIV transmission was **very low**
  - All other outcomes showed evidence of **low to very low** quality, including mortality, incident malignancies , tuberculosis, non-AIDS events, and specific SAEs

# Number of participants and location



## HPTN052

- Total: 1761
  - Africa 54%

## TEMPRANO

- Total: 2056
  - Africa 100%

## START

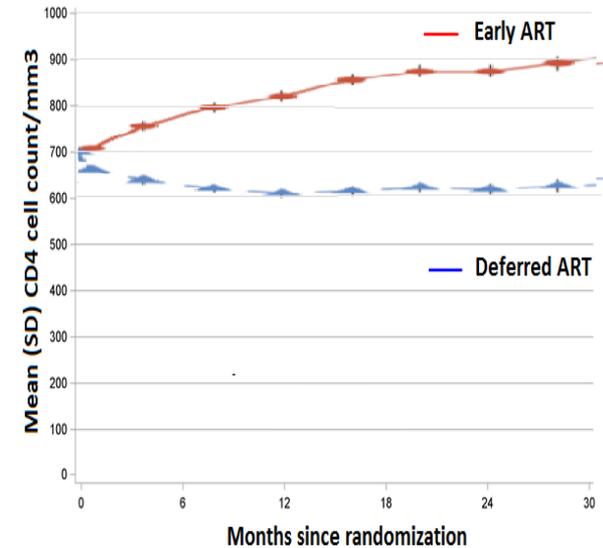
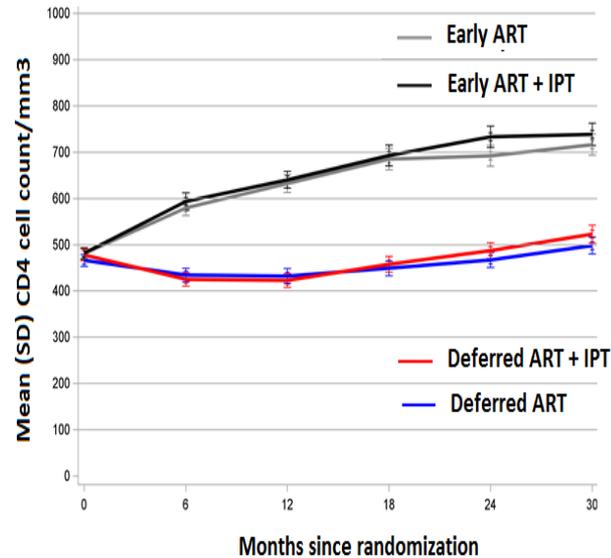
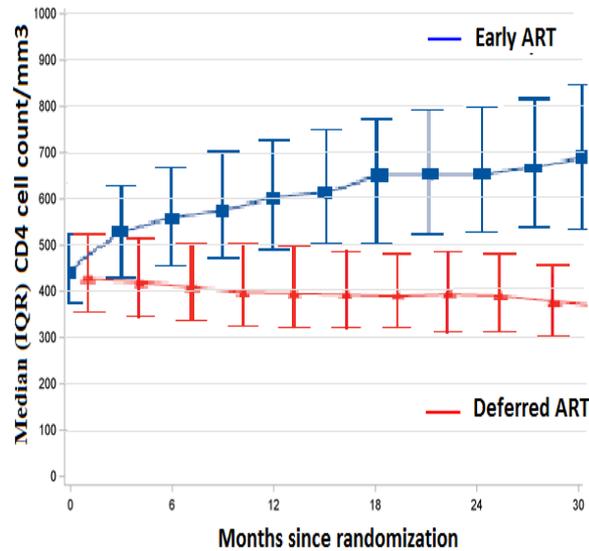
- Total: 4651
  - Africa 21%

**HPTN052:** Grinsztejn, *Lancet Infect Dis* 2014; 14:281-90

**Temprano:** Temprano study group, *NEJM* 2015; 373:808-22

**START:** INSIGHT START study group, *NEJM* 2015; 373:795-807

# CD4 Inclusion Criteria



## HPTN052

- Inclusion : 350-550
- Initiate ARV: < 250

## TEMPRANO

- Inclusion : 250-800
- Initiate ARV: < 250  
< 350  
< 500

## START

- Inclusion : >500
- Initiate ARV: < 350

# Primary outcomes

## HPTN052

- Death
- WHO Stage 4
- Tuberculosis
- Cancers non-AIDS
- Severe bacterial infections
- CVD
- Diabetes

## TEMPRANO

- Death
- WHO Stage 4
- Tuberculosis
- Cancers non-AIDS
- Severe bacterial infections

## START

- Death
- AIDS (except oral candida and invasive HSV)
- Tuberculosis
- Cancers non-AIDS
- CVD
- Renal insufficiency
- Severe hepatic insufficiency

# Hazard ratio of primary outcome by study

	Early treatment (n=886)	Delayed treatment (n=875)	Hazard ratio (95% CI)	p value
Any serious clinical event	57 (6%)	77 (9%)	0.73 (0.52-1.03)	0.074
Any AIDS event	40 (5%)	61 (7%)	0.64 (0.43-0.96)	0.031
Tuberculosis	17 (2%)	34 (4%)	0.49 (0.28-0.89)	0.018
Severe bacterial infection*	20 (2%)	13 (1%)	..	..
Any WHO stage 4 event (excluding tuberculosis)	9 (1%)	19 (2%)	..	..
Non-AIDS event	12 (1%)	9 (1%)	1.35 (0.57-3.19)‡	0.50
All deaths	11 (1%)	15 (2%)	0.73 (0.34-1.59)‡	0.43

	Early ART			Deferred ART			Adjusted Hazard Ratio (95% CI)
	no. of patients	person-yr	rate	no. of patients	person-yr	rate	
Death or severe HIV-related illness (primary outcome)	64	2313	2.8	111	2248	4.9	0.56 (0.41-0.76)
Death	21	2520	0.8	26	2502	1.0	0.80 (0.45-1.40)
Death or AIDS	50	2333	2.1	84	2288	3.7	0.58 (0.41-0.83)
AIDS	33	2333	1.4	65	2288	2.8	0.50 (0.33-0.76)
Tuberculosis	28	2337	1.2	55	2298	2.4	0.50 (0.32-0.79)
Invasive bacterial diseases	14	2358	0.6	36	2332	1.5	0.39 (0.21-0.71)

	Immediate-Initiation		Deferred-Initiation		Hazard Ratio
	no.	no./100 person-yr	no.	no./100 person-yr	
Composite primary end point	42	0.60	96	1.38	0.43 (0.30-0.62)
Serious AIDS-related event	14	0.20	50	0.72	0.28 (0.15-0.50)
Serious non-AIDS	29	0.42	47	0.67	0.61 (0.38-0.97)
Death from any cause	12	0.17	21	0.30	0.58 (0.28-1.17)
Tuberculosis	6	0.09	20	0.28	0.29 (0.12-0.73)
Kaposi's sarcoma	1	0.01	11	0.16	0.09 (0.01-0.71)
Malignant lymphoma	3	0.04	10	0.14	0.30 (0.08-1.10)
Cancer not related to AIDS	9	0.13	18	0.26	0.50 (0.22-1.11)
Cardiovascular disease	12	0.17	14	0.20	0.84 (0.39-1.81)

## Hazard Ratio pour le critère de jugement principal

### HPTN052

- 0.73 (0.52-1.03)

### TEMPRANO

- 0.56 (0.41-0.76)

### START

- 0.43 (0.30-0.62)

# When to Start Children and Adolescents

- ART should be initiated in all adolescents with HIV regardless of WHO clinical stage and at any CD4 cell count (***conditional recommendation, low-quality evidence***).
- ART should be initiated in all children infected with HIV, regardless of WHO clinical stage or CD4 cell count
  - Infants diagnosed in the first year of life (***strong recommendation, moderate-quality evidence***)
  - Children infected with HIV one year to less than 10 years of age (***conditional recommendation, low-quality evidence***).

Age	When you start
10 years to less than 19 years	<p><b>Treat all adolescents</b></p> <p>Individuals with WHO clinical stage 3 or 4 and with CD4 count <math>\leq</math> 350 cells/mm<sup>3</sup> as a priority</p>
1 year to less than 10 years	<p><b>Treat all children</b></p> <p>(children <math>\leq</math> 2 years or with WHO stage 3 or 4 or CD4 count <math>\leq</math> 750 cells/mm<sup>3</sup> or <math>&lt;</math>25% in younger than 5 years and CD4 count <math>\leq</math> 350 cells/mm<sup>3</sup> in 5 years and older as a priority)</p>
Infants ( $<$ 1 year)	<p><b>Treat all infants</b></p>



- **Lack of direct evidence** in support of earlier initiation (particularly for horizontally infected adolescents)<sup>1</sup>
- Indirect evidence suggests **reduction in mortality and improvement in growth** (particularly in children 5-10 years with CD4 >500)<sup>2</sup>
- A growing body of evidence demonstrates the **positive impact of ART** on growth<sup>3</sup>, neurodevelopment<sup>4</sup>, immunological recovery<sup>5</sup> and in preventing pubertal delays<sup>6</sup>
- Gains appear to be limited for vertically infected **adolescents**<sup>2,5</sup>

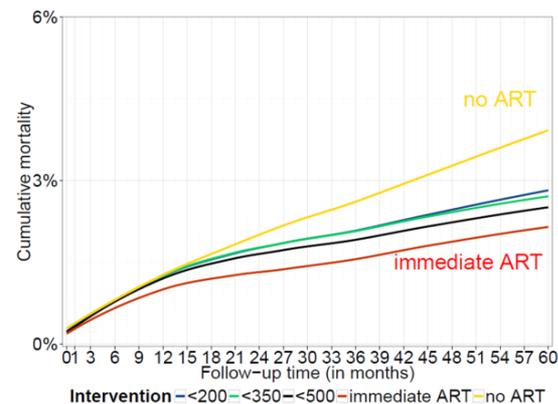
References:

1. Sigfried et al 2014  
2. leDea network 2015

3. McGrath et al 2011  
4. Loughton et al 2012

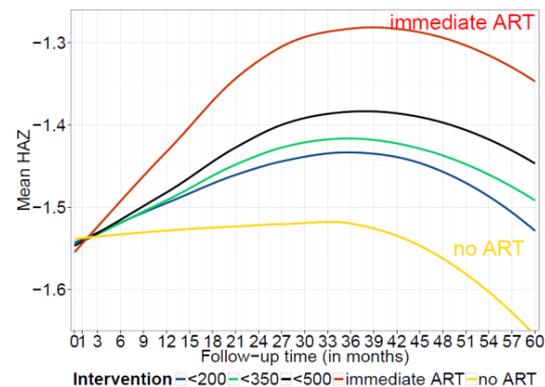
5. Picat et al 2013  
6. Szubert et al 2015

Mortality – age 5-10 – present with CD4 > 500



Difference 'immediate ART' to '< 500':  
0.4% (0.02%; 0.6%)

Growth - age 5-10 – present with CD4 > 500



Difference 'immediate ART' to '< 500':  
0.10 (0.07; 0.12)



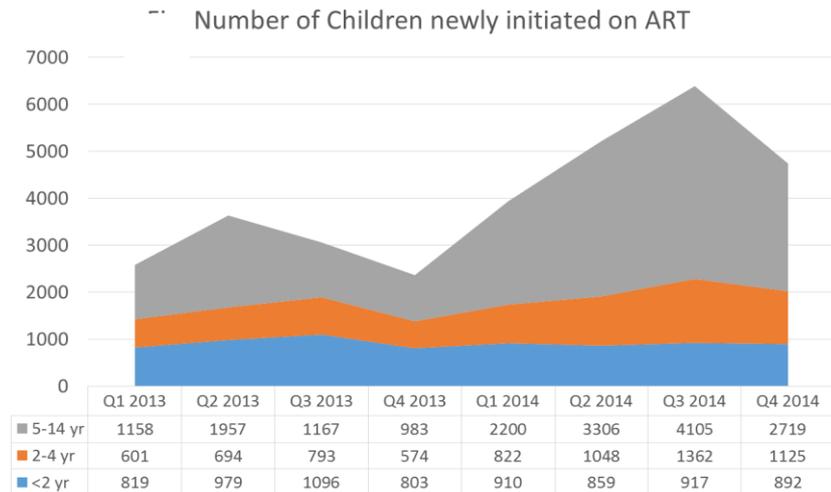
# Programmatic Rationale Children and Adolescents

Only ~20% are not eligible based on existing criteria

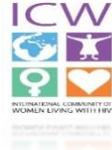
- **Eliminates the need** for determining CD4 count to initiate ART
- **Avoids delaying** ART in settings without access to CD4 testing.
- **Simplifies** paediatric treatment and facilitate expansion of paediatric ART (task-shifting and decentralization)
- Improves **retention** in care compared to pre-ART



**However...need adherence support (particularly in adolescents), careful planning, strengthening laboratory services and improvement of procurements and supply of key commodities**



# Community – led Global Consultation:

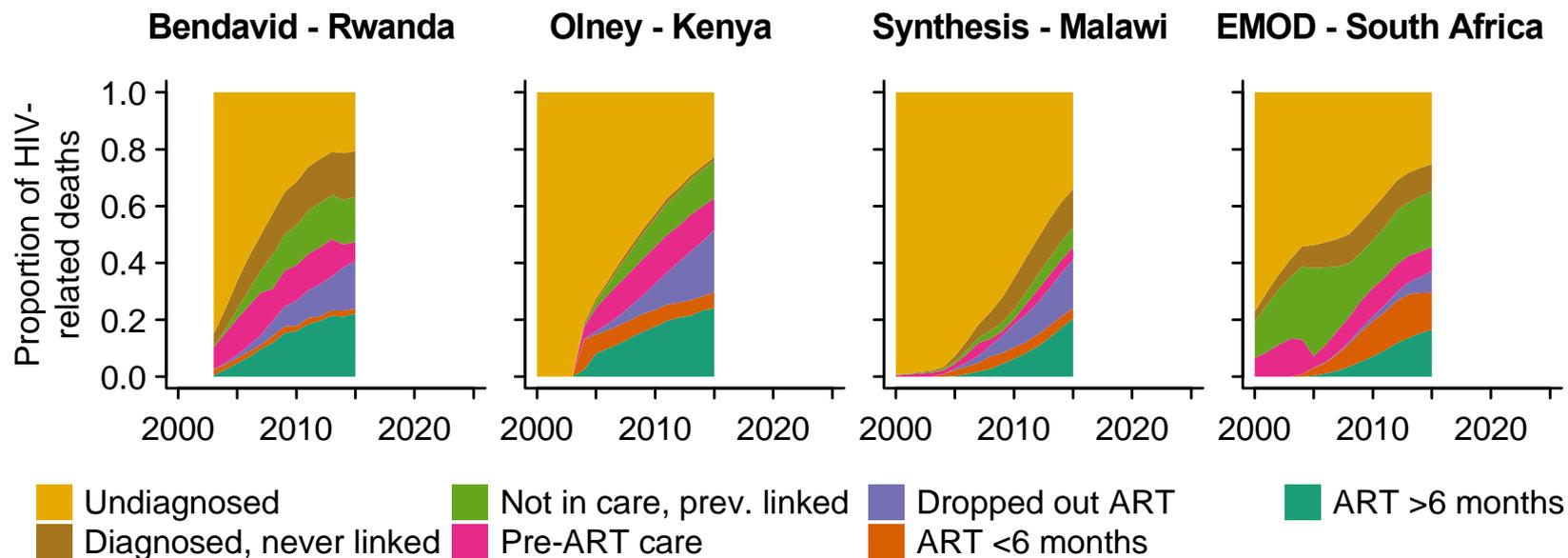






## Acceptability of Earlier Initiation of ART

- 24 workshops, 8 countries, 8 sub populations, 206 people living with HIV, 74 service providers.
- Earlier initiation was deemed **acceptable**, specific considerations were highlighted
- **Collaborative decision-making** with the ultimate decision to initiate ART being client-driven
- The requirement for **comprehensive and accurate information** to ensure an informed decision as well as readiness
- Initiating ART is relatively easy however **maintaining adherence is challenging**
- **Stigma and discrimination** were uniformly raised as fundamental concerns by all and seen to constrain treatment access and adherence



- More HIV-related deaths are among people on ART, but projections indicate that there will still be **25-40% of HIV deaths** among persons never initiated ART.
- Deaths among persons **disengaged from ART** care will **increase** to be a substantial proportion of HIV deaths (purple).
- Only **10-30%** of HIV deaths will be among adults stable on ART.

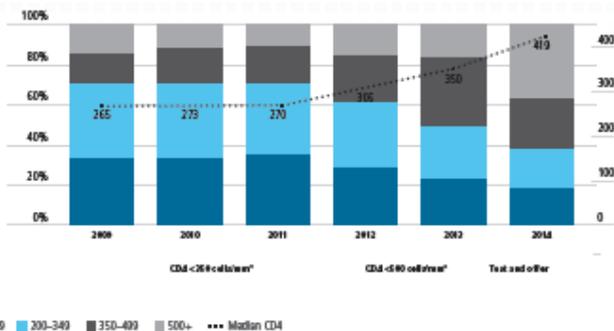


# Countries are leading the way

Examples from five countries implementing Treat All or Treating All in specific populations:



Fig. 2. Median pre-treatment CD4 count and proportion of people living with HIV in Brazil who initiated ART according to the last CD4 count result before initiating ART, by year, 2009–2014

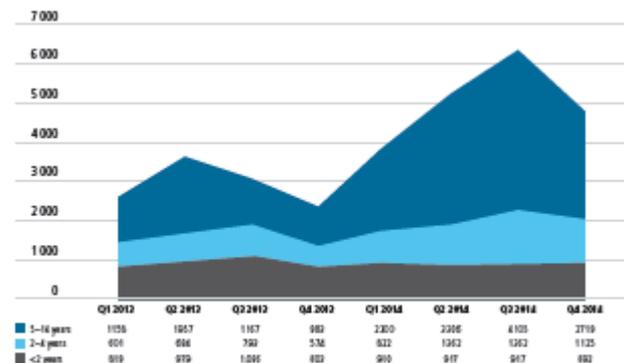


Source: Ministry of Health, Brazil, Department of STD, AIDS and Viral Hepatitis, 2015.

- **Brazil has been treating all for one year**
- Leading to increase in median CD4 at ART initiation (265 to 419)
- Similar retention and VLS at 12 months (81% for CD4 > 500)

- **Uganda started to treat all children < 15 years in 2014**
- Seen increase in overall number children on ART
- Retention at 12 m similar; VLS = 84%

Fig. 7. Number of children newly initiating ART by age group in Uganda



Source: Implementing the test and treat policy for all HIV-infected children under 15 years of age: a rapid assessment of Uganda's experience. Kampala: Ministry of Health, Uganda, 2015.



# Why consider PrEP

## 2.1 million people infected with HIV in 2013

### Among key populations:

- Burden of HIV infection is 19 fold higher among MSM and 49 fold higher among transgender women compared with the general population.
- High rates of HIV incidence among MSM across all regions.
- High HIV prevalence among sex workers in Africa >20% in Nigeria;>50% in South Africa and Zimbabwe.
- Estimates from South Africa show a 5.6% HIV prevalence among girls aged 15–19 years, increasing to 17.4% for young women aged 20–24 years.



**Demonstrated need for more prevention options**

**HIV incidence in 18-35 year women in this community:**

**9.1%**

**9.1 per 100 women-yrs  
(95% CI: 7 - 12)**

*Source: Abdool Karim Q et al, Science 2010*

## **HIV in pregnant women in rural**

**South Africa (2001-2013)**

<b>Age Group (Years)</b>	<b>HIV Prevalence (N=4818)</b>
------------------------------	------------------------------------

<b>≤16</b>	<b>11.5%</b>
------------	--------------

<b>17-18</b>	<b>21.3%</b>
--------------	--------------

<b>19-20</b>	<b>30.4%</b>
--------------	--------------

<b>21-22</b>	<b>39.4%</b>
--------------	--------------

<b>23-24</b>	<b>49.5%</b>
--------------	--------------

<b>&gt;25</b>	<b>51.9%</b>
---------------	--------------

*Source: Abdool Karim Q, Int J Epi, 2014*

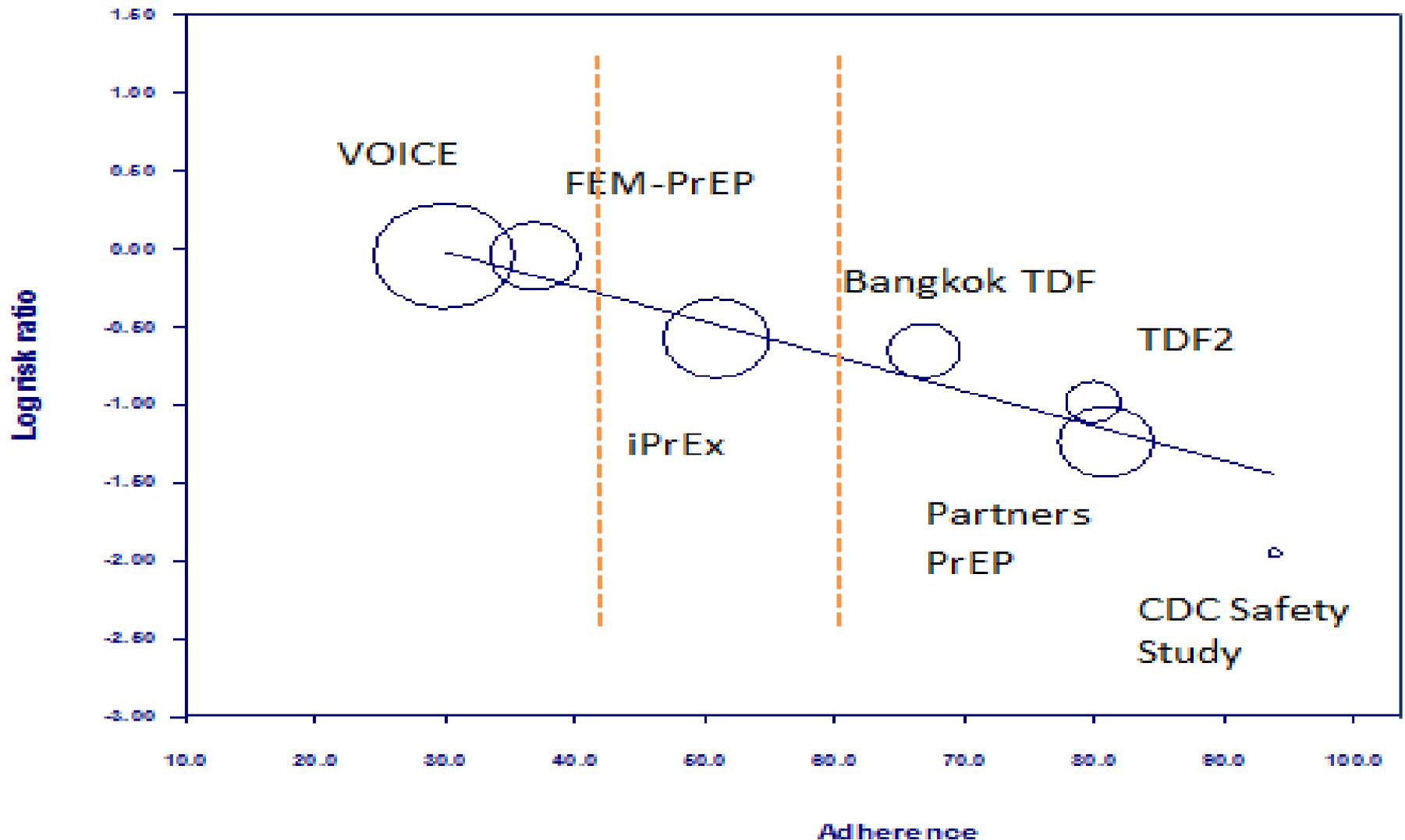
# PrEP Systematic review results

Analysis	No. of studies	Sample Size (N)	Risk Ratio (95% CI)	p-value	I <sup>2</sup>	P-value (meta-regression)
<b>RCTs comparing PrEP to placebo</b>						
Overall	10	17424	0.49 (0.33-0.73)	0.001	70.9	--
Adherence						
High (>70%)	3	6150	0.30 (0.21-0.45)	<0.0001	0.0	<0.0001
Moderate (41-70%)	2	4912	0.55 (0.39-0.76)	<0.0001	0.0	0.009
Low (≤40%)	2	5033	0.95 (0.74-1.23)	0.70	0.0	<i>ref</i>
Mode of Acquisition						
Rectal	4	3167	0.34 (0.15-0.80)	0.01	29.1	
Vaginal/penile	6	14252	0.54 (0.32-0.90)	0.02	80.1	0.36
Biological sex <sup>1</sup>						
Male	7	8706	0.38 (0.25-0.60)	<0.0001	34.5	
Female	6	8716	0.57 (0.34-0.94)	0.03	68.3	0.19
Age <sup>2</sup>						
18 to 24 years	3	2997	0.71 (0.47-1.06)	0.09	20.5	0.29
≥25 years	3	5129	0.45 (0.22-0.91)	0.03	72.4	
Drug Regimen						
TDF	5	4303 active	0.49 (0.28-0.86)	0.001	63.9	
FTC/TDF	7	5693 active	0.51 (0.31-0.83)	0.007	77.2	0.88
Drug Dosing						
Daily	8	17024	0.54 (0.36-0.81)	0.003	73.6	
Intermittent	1	400	0.14 (0.03-0.63)	0.01	0.0	0.14
<b>RCTs comparing PrEP to no PrEP</b>						
Overall	2	720	0.15 (0.05-0.46)	0.001	0.0	NA

<sup>1</sup> The iPrEx trial included 313 (13%) transgender women. <sup>2</sup> Includes only studies that stratified age by <25 and ≥25.

# PrEP Adherence and effectiveness

Regression of Log risk ratio on Adherence



# GRADE table: HIV infection

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Oral PrEP (containing tenofovir)	Control	Relative (95% CI)	Absolute		
<b>HIV Infection--PrEP vs. Placebo--Adherence &gt;70%</b>												
3	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	39/3866 (1%)	79/2284 (3.5%)	RR 0.30 (0.21 to 0.45)	24 fewer per 1000 (from 19 fewer to 27 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL
<b>HIV Infection--PrEP vs. Placebo--Adherence 40-70%</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	53/2455 (2.2%)	97/2457 (3.9%)	RR 0.55 (0.39 to 0.76)	18 fewer per 1000 (from 9 fewer to 24 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL
<b>HIV Infection--PrEP vs. Placebo--Adherence &lt;40%</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	146/3002 (4.9%)	95/2031 (4.7%)	RR 0.95 (0.74 to 1.23)	2 fewer per 1000 (from 12 fewer to 11 more)	⊕⊕⊕⊕ HIGH	CRITICAL
<b>HIV infection--PrEP vs. no PrEP</b>												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	3/367 (0.82%)	22/353 (6.2%)	RR 0.15 (0.05 to 0.46)	53 fewer per 1000 (from 34 fewer to 59 fewer)	⊕⊕⊕⊕ HIGH	CRITICAL

# WHO guidance on PrEP (2012, 2014, 2015, 2016)



**2012. Guidance for MSM & Serodiscordant Couples in the context of demonstration projects *to encourage countries to conduct such demonstration projects***



**201. Consolidated KP Guidelines**

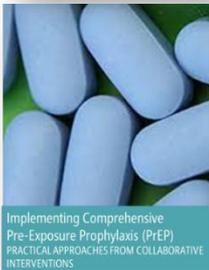
*Recommendation for MSM*

Among men who have sex with men, PrEP is recommended as an **additional HIV prevention choice** within a comprehensive HIV prevention package (*strong recommendation, high quality of evidence*).



**2015**

**Oral PrEP (containing TDF) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches (Strong/High Quality)**



**2016**

**Implementation guidance, package of implementation tools for a variety of implementers and populations forthcoming  
Implementation tool / guidance, *forthcoming***

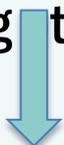


# Who might benefit from PrEP – people at 'substantial' HIV risk

**Step 1.** consider an incidence in a community/population of  $\approx 3$  per 100 person-years



**Step 2.** Within a population with incidence  $\approx 3\%$  there will be significant heterogeneity. Not all people will have high HIV risk. Simple screening questions will help identify those at most risk within this population or community and those who are *not* using other effective HIV prevention methods

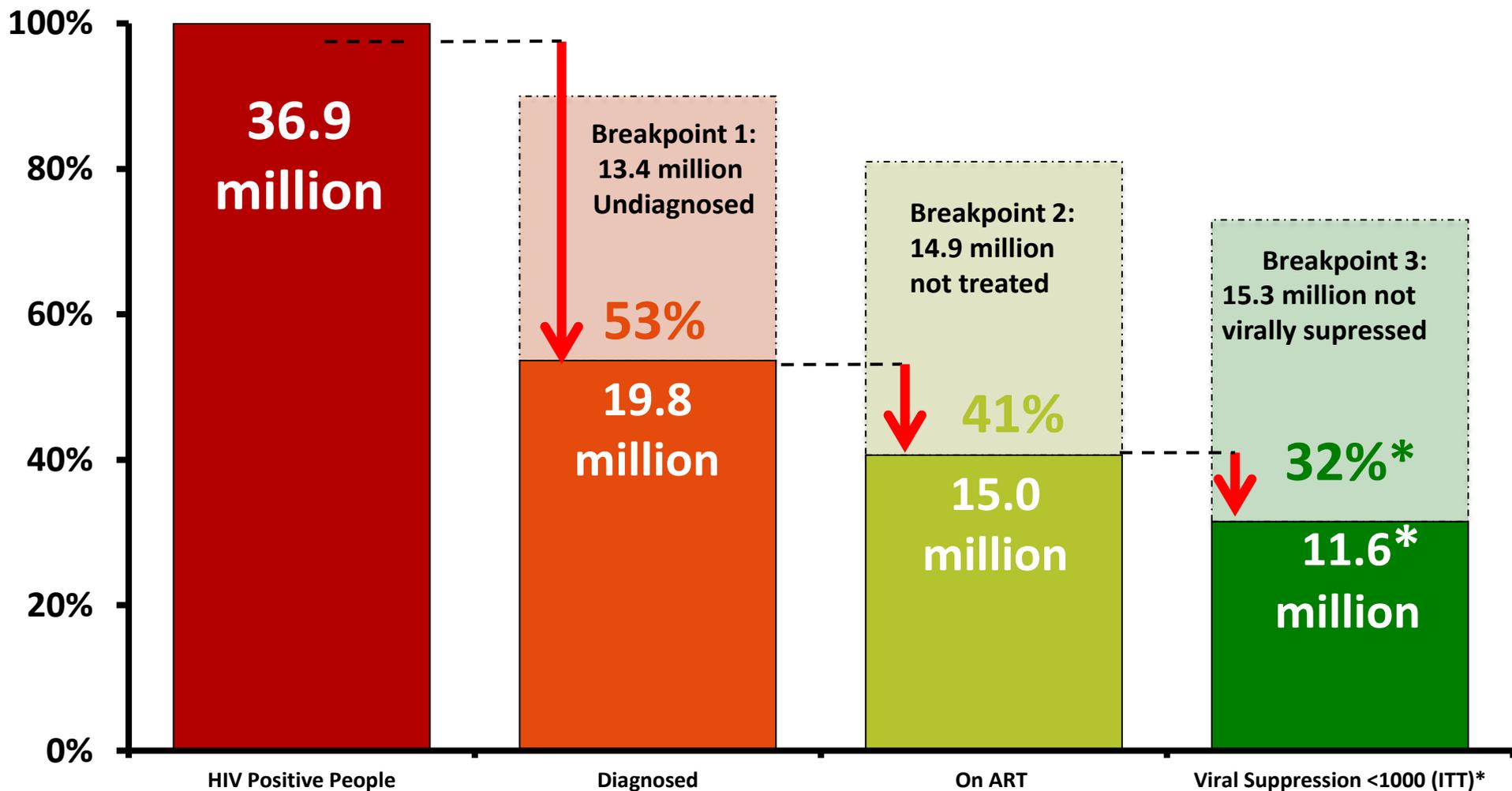


**Step 3.** Those who are identified at highest HIV risk and a would welcome and want to take an additional prevention option





# Global estimates (2014-2015) vs the gap to reach 90-90-90 targets in 2020



Ref: On ART = March 2015. How Aids Changed Everything. Fact Sheet. UNAIDS 2015. MDG 6: 15 YEARS, 15 LESSONS OF HOPE FROM THE AIDS RESPONSE July 2015. \* Average viral suppression% Intention to Treat LMIC rate from a Systematic Review by McMahon J. et al. Viral suppression after 12 months of antiretroviral therapy in low-and middle-income countries: a systematic review." *Bulletin of the World Health Organization* 91:5 (2013): 377-385.





# Critical issues addressed in New HTS Guidelines

- **New approaches**

- Trained lay providers testing (*new recommendation*)
- Test for Triage (*new testing strategy*)
- HIV self-testing (*push for implementation and monitoring*)

- **Better linkage**

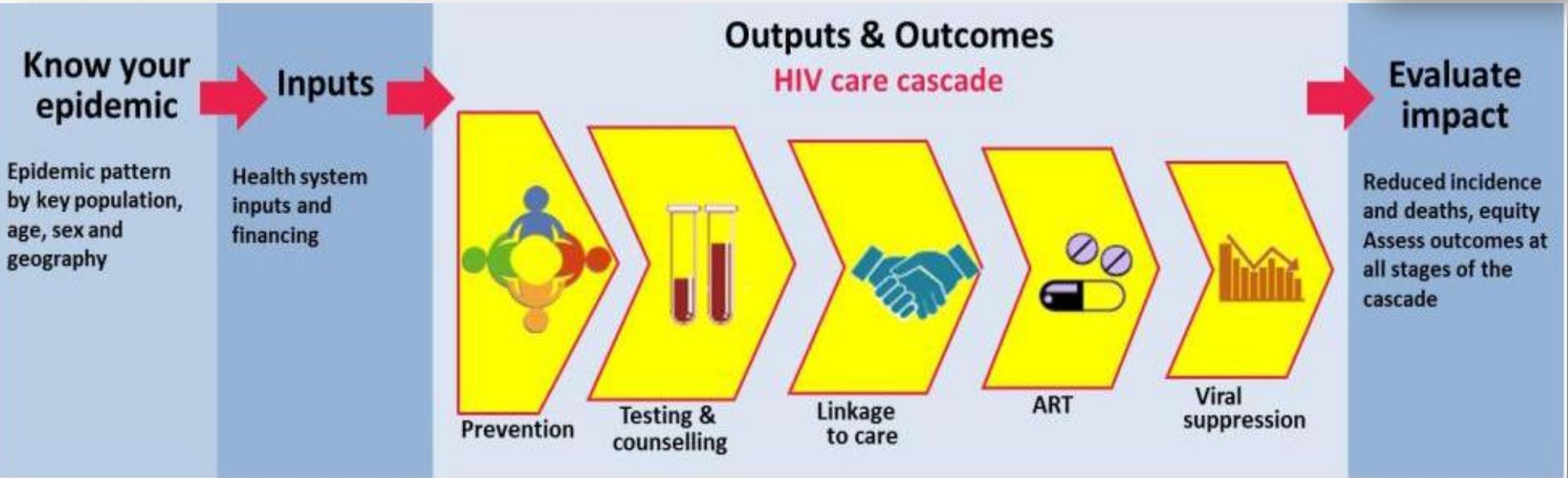
- **Preventing misdiagnosis**

- Focus on QA
- Re-emphasise re-testing all +ve before ART initiation

- **Strategic choices**



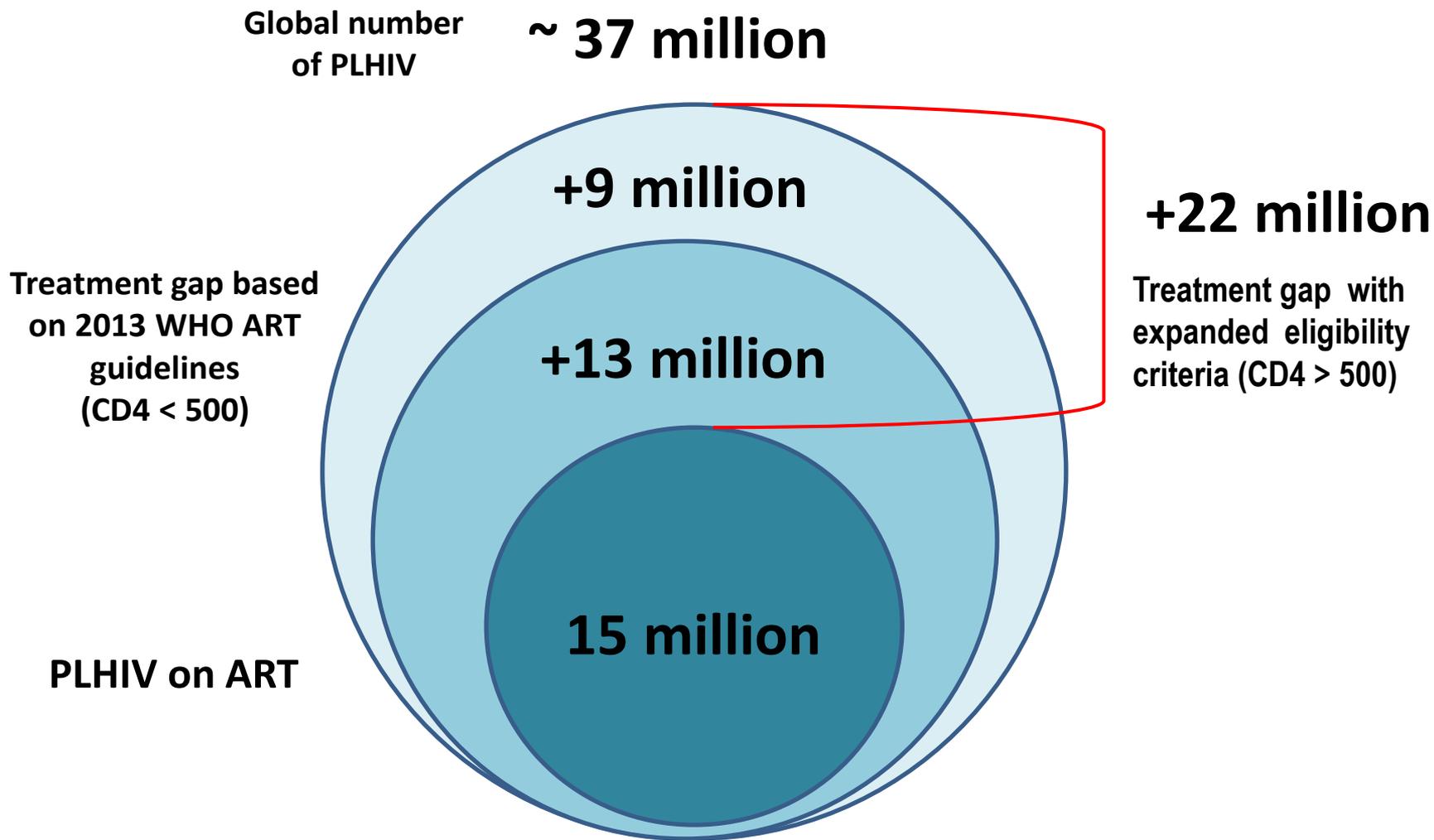
# Consolidated Strategic Information Guidance



<p><b>(1) People with HIV</b> Number and % of people living with HIV (PLHIV)</p>	<p><b>(2) Domestic finance</b> % of HIV response financed domestically</p>	<p><b>(3) Prevention by key populations</b> % condom use among key populations or needles per PWID</p>	<p><b>(4) Knowing HIV status</b> % of PLHIV who have been diagnosed</p>	<p><b>(5) Linkage to care</b> Number and % in HIV care (including ART)</p>	<p><b>(6) Currently on ART</b> % on ART</p> <p><b>(7) ART retention</b> % retained and surviving on ART</p>	<p><b>(8) Viral suppression</b> % on ART virally suppressed</p>	<p><b>(9) HIV deaths</b> Number and ratio of HIV-related deaths</p> <p><b>(10) New infections</b> Number and % of new HIV infections</p>
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**10 Global Indicators**

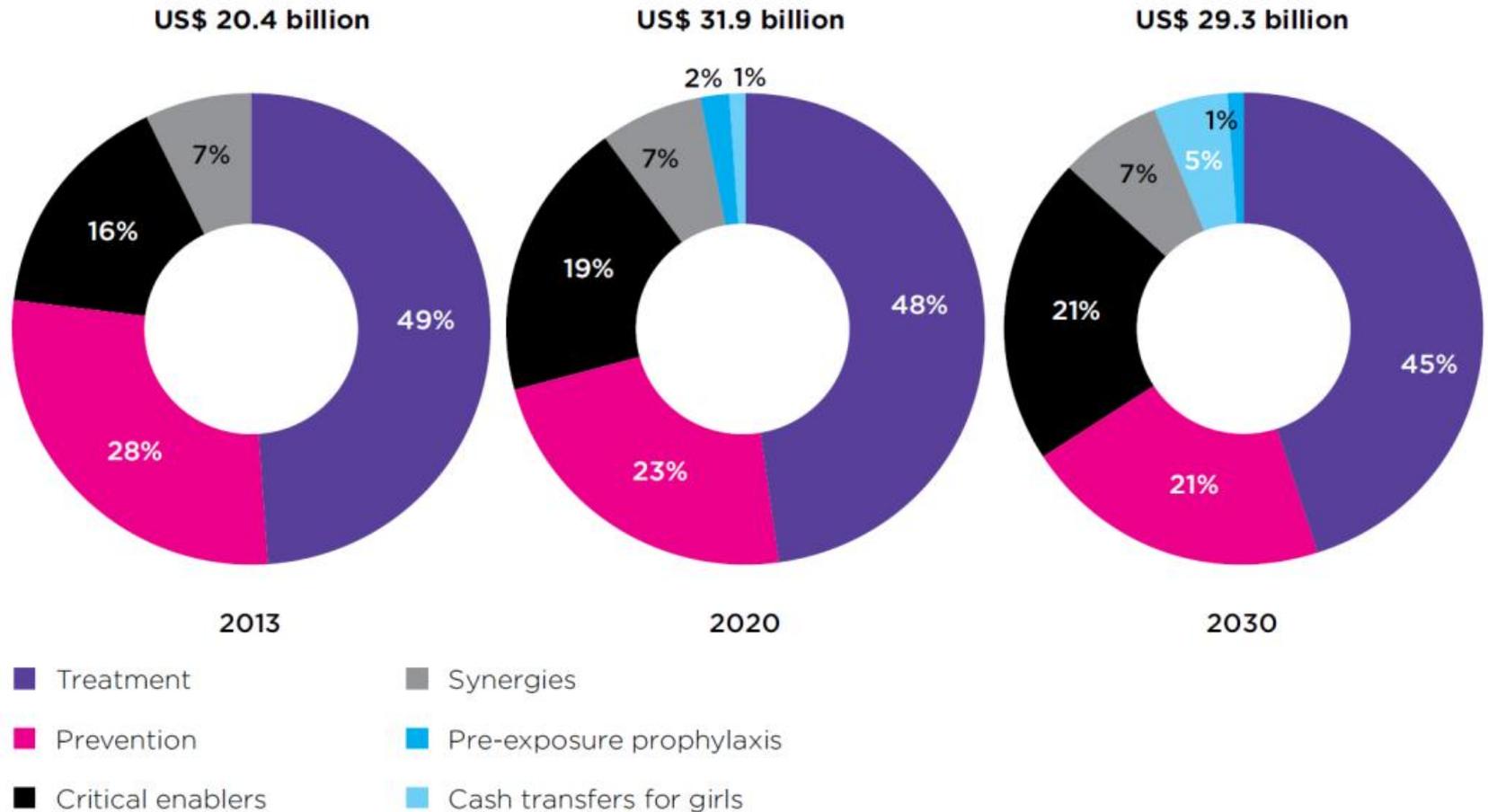
# The estimated gap between treatment targets & actual numbers of PLHIV on ART according to eligibility criteria



Concerns from countries/donors on how to address immediate increased cost and service demand

# From UNAIDS Fast Track Modeling

## Resources and investment portfolio, 2013-2030



Source: Based on GARPR reports through 2015 and on Fast-Track: ending the AIDS epidemic by 2030. Geneva: UNAIDS; 2014.

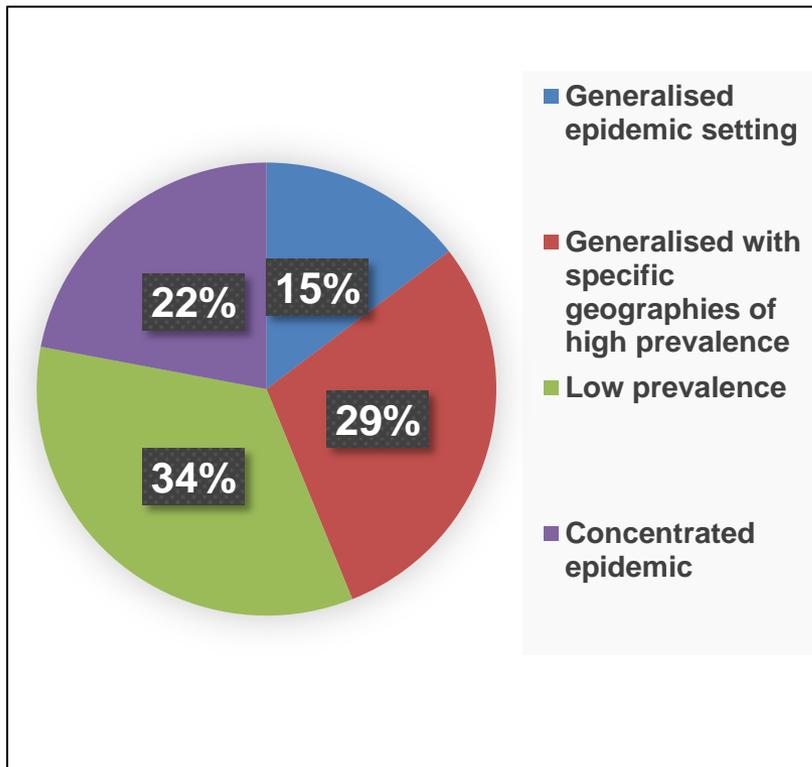


# MDG results & new targets...

Key parameters	2005	2015	2020	2030
New HIV infections	3 million	2 million [↓ 35%]	500,000	200,000
AIDS-associated deaths	2.4 million	1.2 million [↓ 50%]	400,000	200,000
PLHIV accessing ART	1.5 million	15 million [↑ 10x]	30 million	ALL
Investments for global HIV response (US\$)	7 billion	20 billion [↑ 3x]	32 billion	29 billion

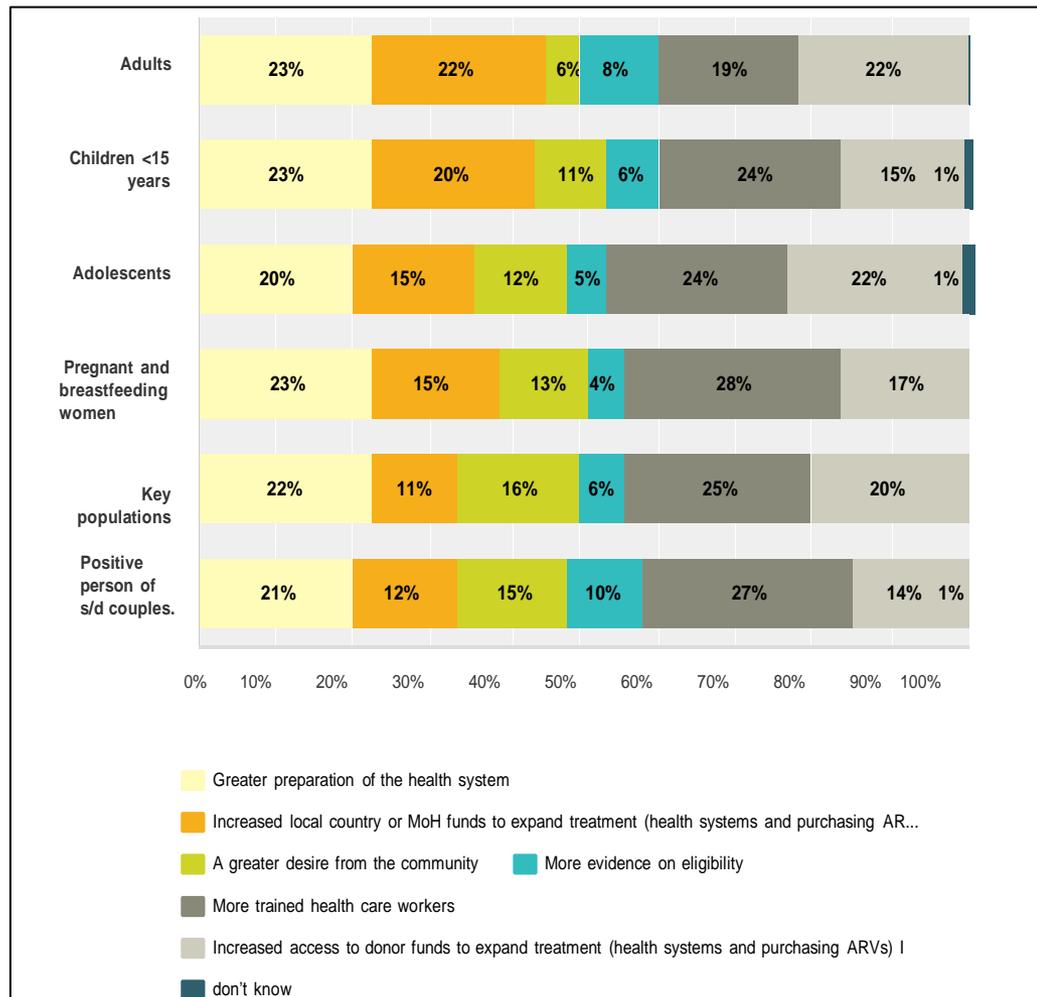
# Results: Programme Managers Survey

Figure 1: Country HIV epidemic settings of survey respondents (N=41)



Source: National ART Programme managers perspectives' on implementing HIV interventions, KIT 2015

Figure 2: Top 3 requirements to enable your country to expand ARV treatment initiation criteria for each of the groups stated (N=33)





**Michel Sidibé, Executive Director, UNAIDS**

“Everybody living with HIV has the right to life-saving treatment. The new guidelines are a very important step towards ensuring that all people living with HIV have immediate access to antiretroviral treatment.”



**Deborah L. Birx, U.S. Global AIDS Coordinator & U.S. Special Representative for Global Health Diplomacy**

“These are transformative to epidemic control. Short of an HIV vaccine or cure, this gives us the critical tools we need to create an AIDS-free generation utilizing the FAST TRACK strategy. We have no excuses - it is up to us to seize this moment...”

**Mark Dybul, Executive Director, The Global Fund**

“The two recommendations are critically important to moving us towards the fast-track treatment and prevention goals.... We must embrace ambition if we are going to end HIV as a public health threat.”



# What is new in the Early release guideline?

- Treat all (at any CD4) - people living with HIV across all ages
- The sickest remain a priority (symptomatic disease and CD4 < 350)
- New age band for Adolescents (age 10-19)
- Option B not taken forward; Option B+ as the new standard
- PrEP recommended as an additional prevention choice for all people at substantial risk of HIV infection (> 3% incidence)



# 2015 ARV : Timeline



**Evidence retrieval:**  
 Systematic reviews  
 Values and preferences  
 Community consultations  
 Modelling  
**Dec 2014 – May 2015**

**Key recommendations preview**  
**July 19 2015**

**Launch Full Updated 2015 Consolidated ARV Guidelines**  
**Dec 1 2015**

**Core group**  
**July 23-24 2015**

**Supplement launch WAD**  
**Dec 1 2014**

**GDG Clinical/ Operational**  
**June 1-5 2015**  
**June 16-19 2015**

**Launch Interim Guidelines on when to start and pre-exposure prophylaxis**  
**Sept -Oct 2015**

**Core group**  
**Oct 20-21 2014**





# Acknowledgements

Special thanks to all the external experts who contributed as members of the Guideline Development Groups, and to those who contributed to the GRADE systematic reviews and supporting evidence which informed the guidelines process. Thank you to IAPAC for opportunity to share these guidelines.

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**leDEA Collaboration**

**The Global Network of People living with HIV/AIDS**

**PEPFAR**

**CDC**

**USAID**

**Bill and Melinda Gates Foundation**

