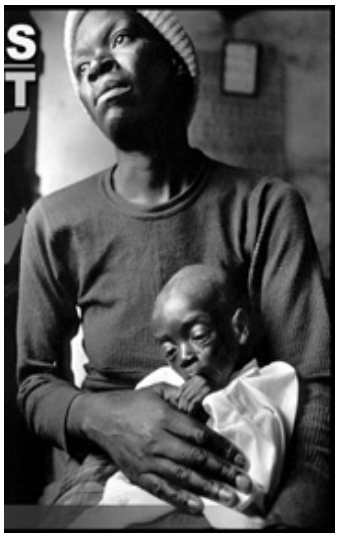
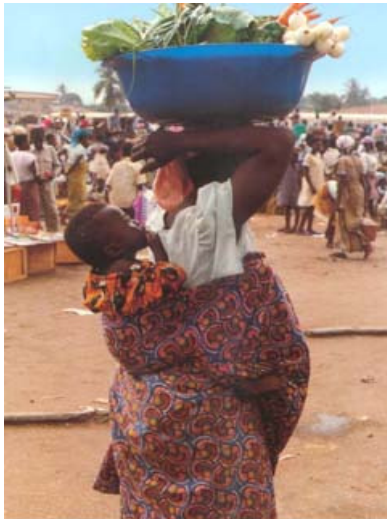


PEPFAR PMTCT Update



N. Shaffer
M. Brewinski
PMTCT/Peds TWG

Jan 9, 2009
PMTCT Expert Panel Consultation

Questions for the Panel

- Are the PEPFAR II PMTCT goals clearly defined?
  - Coverage, quality, impact
  - Non-focus countries
- Is there adequate support for PMTCT in PEPFAR II to achieve these goals?
  - Funding
  - Management, monitoring and accountability
  - HQ, country, district and facility levels
- Is there adequate coordination between PEPFAR and other key agencies, donors, implementers?
- Is the strategy appropriate to achieve the goals?
- Is PEPFAR supporting sustainable, national programs?

Overview

- Background and context
- Progress and limitations to date
- Key program elements
- Integration (within PEPFAR, other partners, MCH programs)
- Program quality, evaluation and impact
- Indicators, monitoring and reporting
- Systems and sustainability
- FY 09 COP Review
- PEPFAR II: Targets and national scale-up
- Issues and recommendations for panel

Key Messages

- PMTCT has made significant progress but still lagging behind program goals and ART scale-up
- High PMTCT coverage and impact is achievable soon, but only with clear targets and priority focus
- HAART for treatment-eligible women and combination prophylaxis regimens is essential for high-impact PMTCT – *increasing role for HAART likely in new intl guidelines under revision*
- PEPFAR programs should intensify focus on pregnant women and families as key entry-point to achieve PEPFAR II prevention, care and treatment goals
- New guidelines on early pediatric treatment (<12m) emphasize linkages, f/u and continuity of programs
- *PMTCT, ART and care programs need to be unified and better coordinated* in comprehensive approach

Background and Context

- PMTCT is a critical program area for HIV/AIDS prevention, care, and treatment
- Original USG Initiative and UNGASS goals were ambitious but only partially achieved
- PMTCT is an international effort

Magnitude of Need

Annually in 15 PEPFAR focus countries:

- 18 million women deliver
- 13 million women receive ANC (70%)
- ~1.3 million HIV+ women deliver

  HIV prevalence range: 0.4-36%, median: 7%

- ~390,000 infants become HIV-infected*

  (>50% of worldwide perinatal infections)

  *Without effective interventions, based on MTCT rate of 30%

Objectives for USG MTCT Initiative (2002)

In 5 years:

- Reach up to
  1 million women
  annually

- Reduce mother-to-child HIV transmission by up to 40% among women treated

International Support for PMTCT

1998: UNICEF pilot programs
1999: EGPAF Call to Action program
2000: Boerhinger-Ingelheim NVP drug donation
2000: WHO: PMTCT as standard MCH care
2001: UNGASS PMTCT goals
2002: "MTCT-PLUS" (Columbia U.)
2002: Global Fund
2002: President's Initiative for PMTCT
2003: WHO 3X5
2003: PEPFAR ("2-7-10")

UNGASS Global PMTCT Goals

- 2005
  - 50% of women have access to PMTCT
  - 20% reduction in new pediatric infections
- 2010
  - 80% of women have access to PMTCT
  - 50% reduction in new pediatric infections
- New global goals of “Universal Access” and virtual elimination of pediatric AIDS

International Support for PMTCT

Increasing international support and funding

Clinton Foundation

UNITAID

CIDA

New guidelines and best practices

Revised WHO PMTCT ARV guidelines (2006)

Provider-Initiated testing & counseling (2007)

Advocacy and International Mobilization

Guidance on Global Scale-Up of PMTCT (2007)

High Level Global Forums for PMTCT

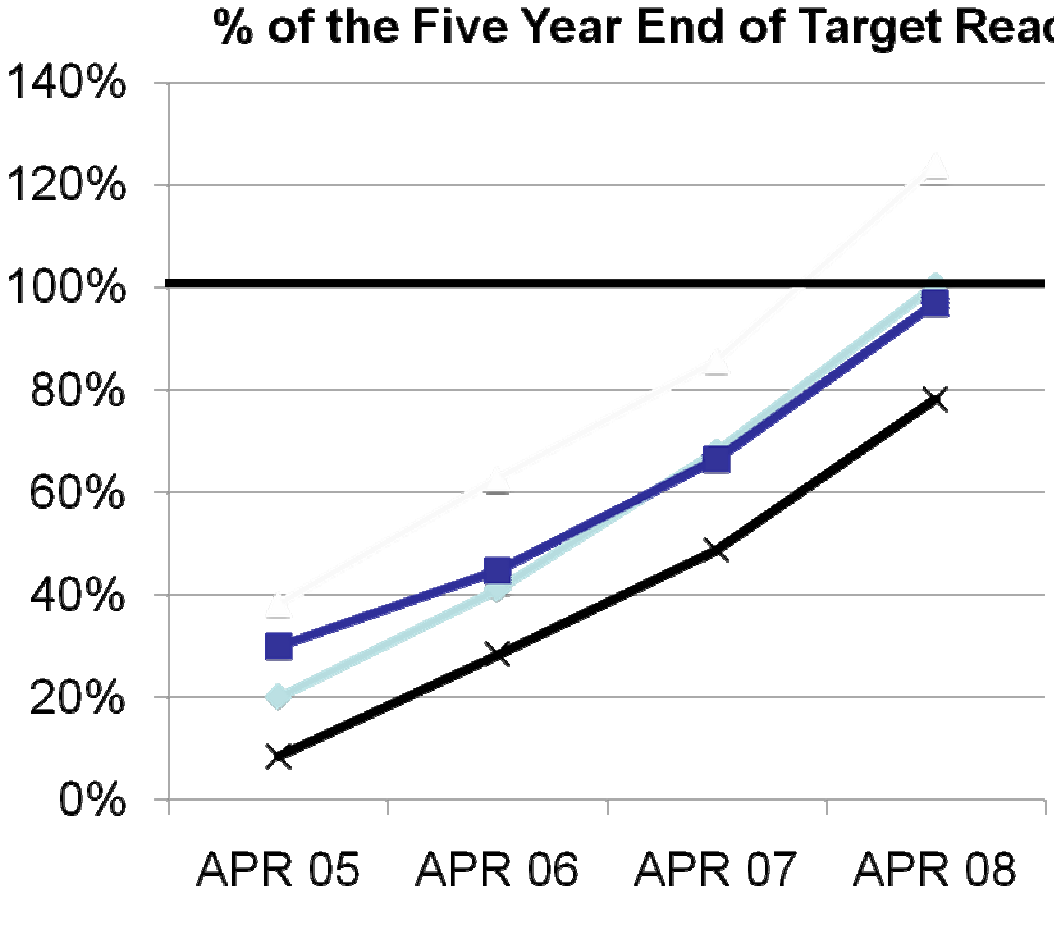
Expansion of the PMTCT IATT

Universal Access Monitoring and Reporting

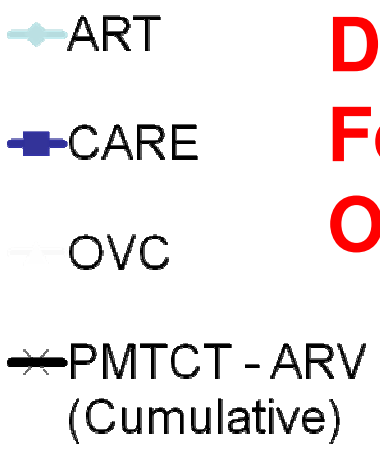
Progress and Limitations

- We have not achieved goals of MTCT Initiative or PMTCT PEPFAR I goals
- However, several countries have achieved coverage goals and nearly all PEPFAR focus countries are making significant progress
- We are just beginning to assess quality and impact of programs

Focus Countries: Progress towards Goals and Population Coverage



Program Area	5-Year Goal	Result	Population Coverage
ART	2,000,000	2,007,864	38%
PMTCT -ARV	1,438,455	1,125,211	44%
CARE	10,000,000	9,693,800	
OVC	3,192,611	3,959,129	



DRAFT For USG Only.

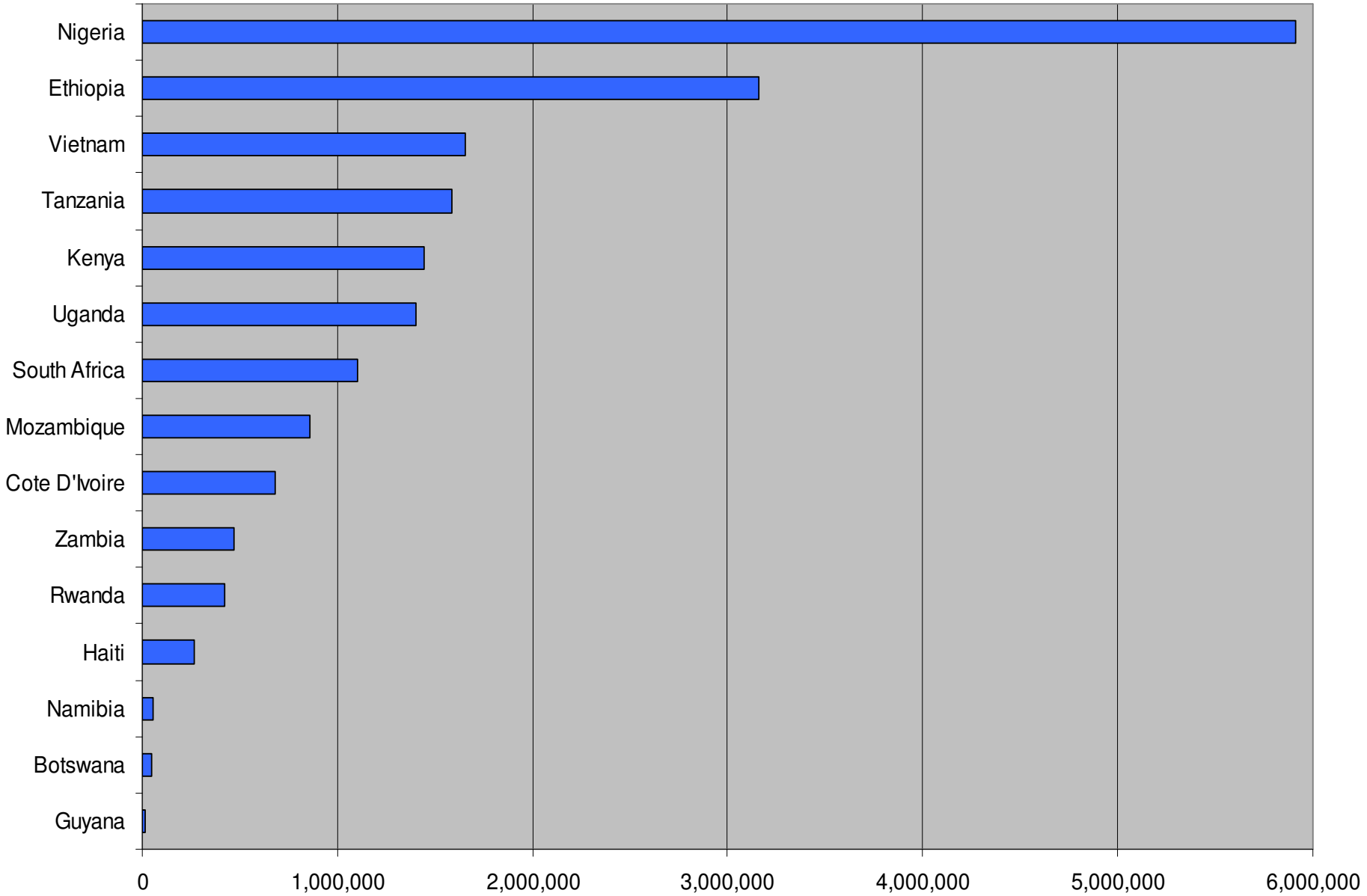
Notes for % of Target Reached: Numerators are APR Results. Denominators for ART, Care and OVC targets are Five-Year End of Plan targets. Denominator for PMTCT ARV is the sum of annual country-set targets. **Notes for Coverage**: Numerators are APR 08 Results. ART Denominator is estimated number eligible for ART (2007 need estimates) PMTCT-ARV Denominator is Estimated number of HIV+ pregnant women needing ARVs for PMTCT (2007). Both denominators are from *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Heath Sector, Progress Report, 2008*. WHO.

15 Focus Countries

Wide variations in:

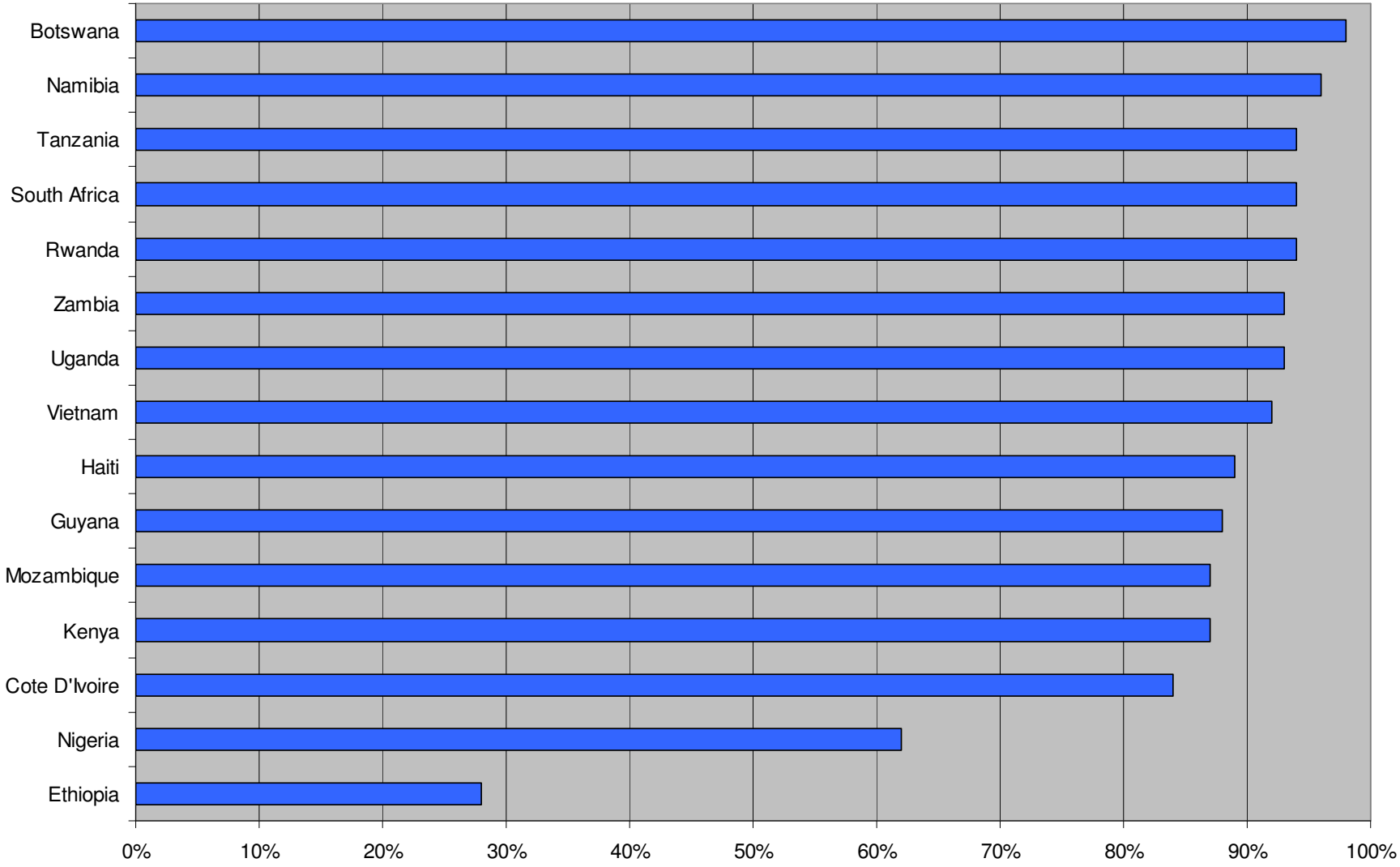
- # Annual births
- ANC attendance
- Facility deliveries
- Seroprevalence
- Level of development / MCH capacity
- Govt commitment and program management
- Program policies

Estimated number of annual births by focus country[1]



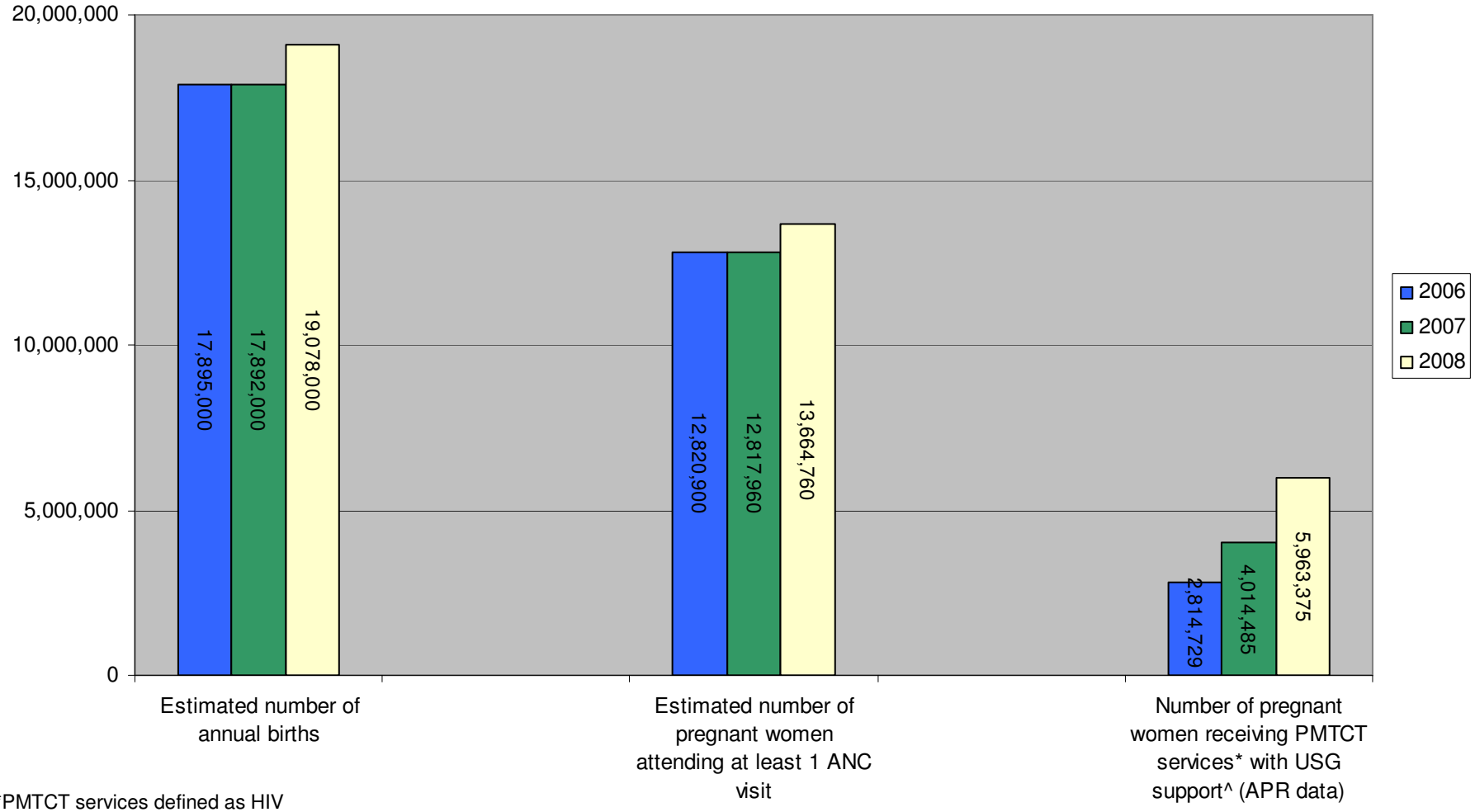
[1]From the UNICEF report "State of the World's Children 2008: Child Survival" Report, http://www.unicef.org/publications/index_42623.html

ANC attendance rates by focus country



Source: Measure DHS surveys

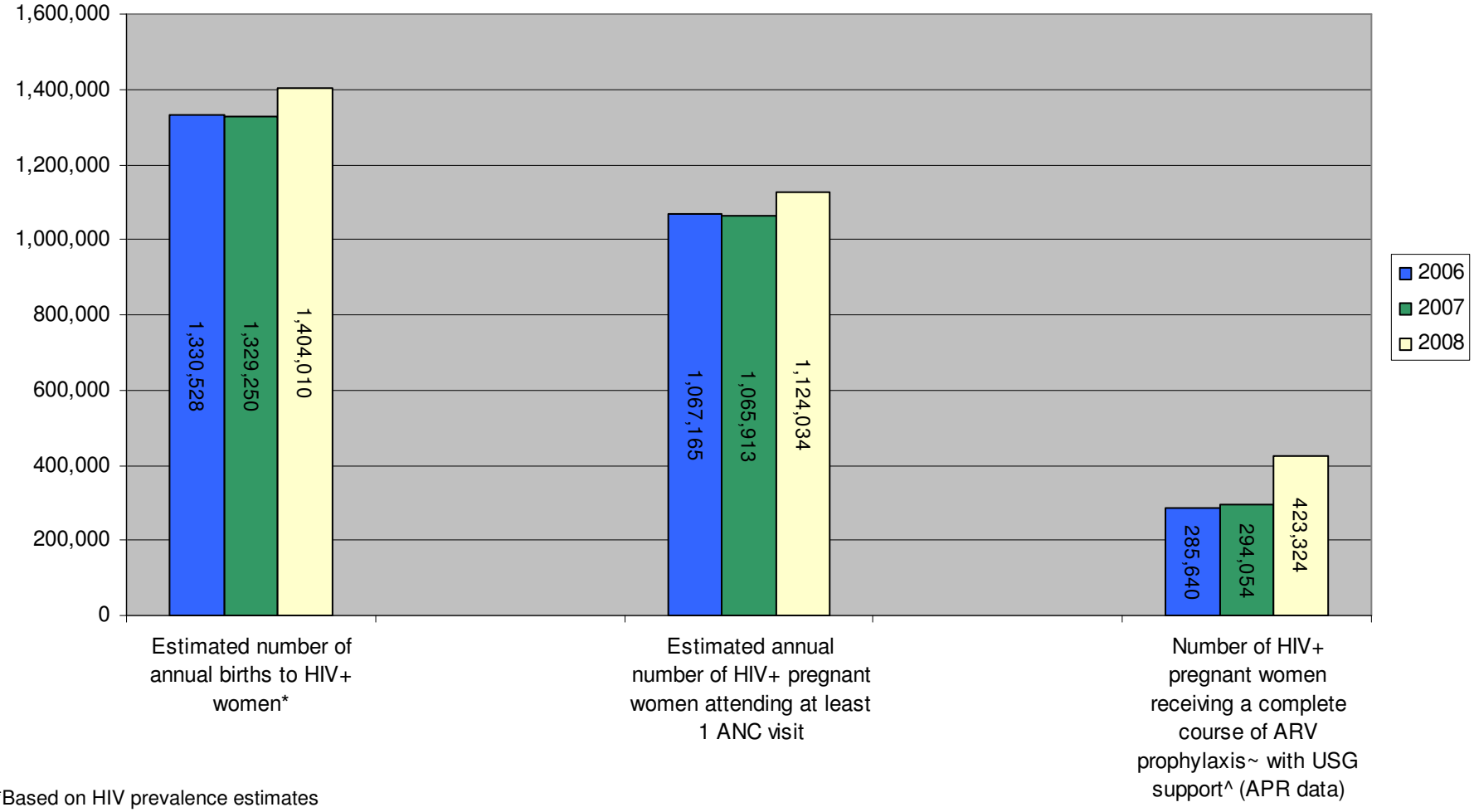
Coverage of HIV counseling and testing in PMTCT settings - all focus countries, FY06 through FY08



*PMTCT services defined as HIV counseled and tested and received results

^Includes both direct and indirect USG support

Coverage of ARV prophylaxis for PMTCT - all focus countries, FY06 through FY08

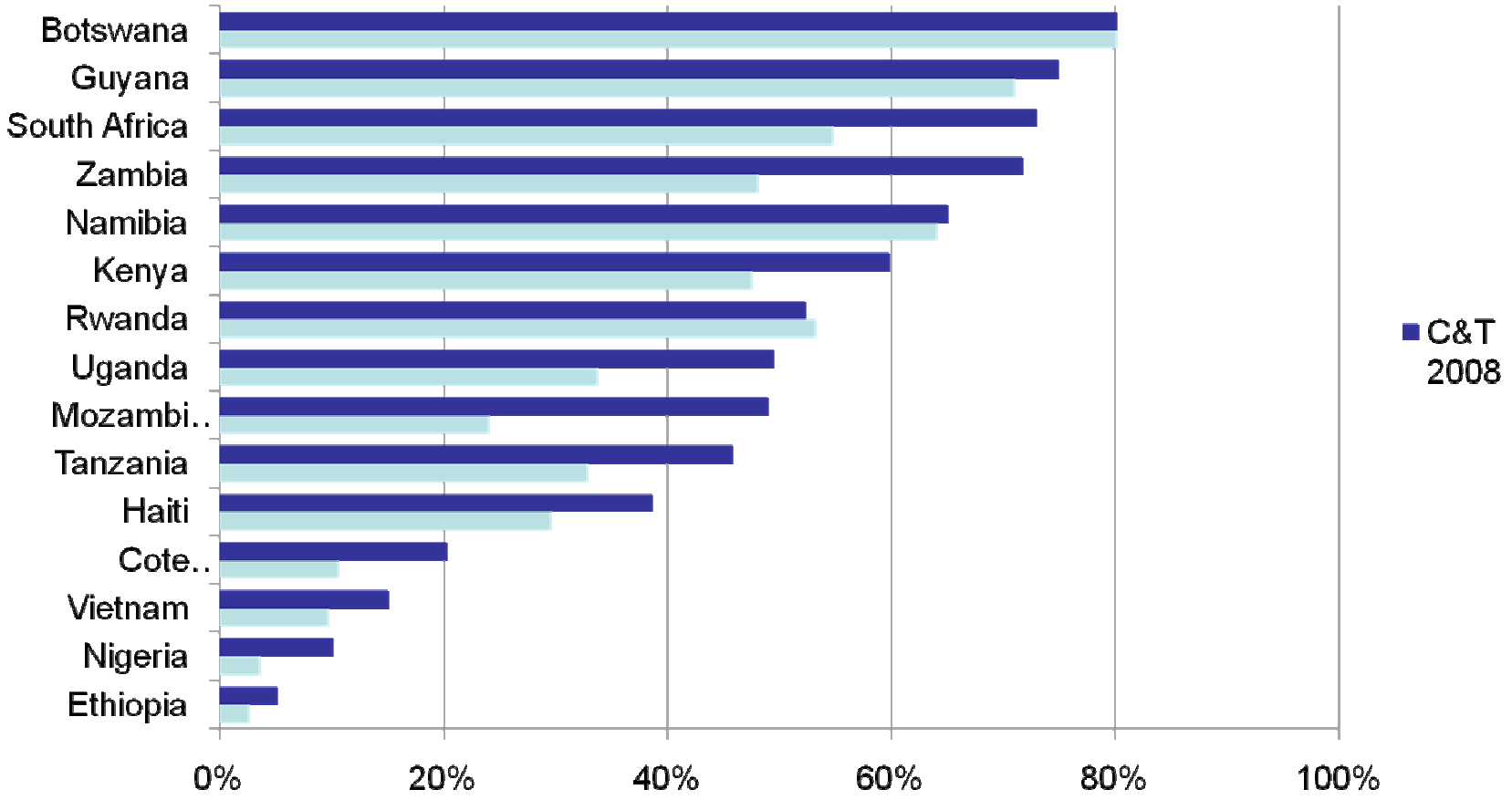


*Based on HIV prevalence estimates among pregnant women

~Any PMTCT ARV regimen

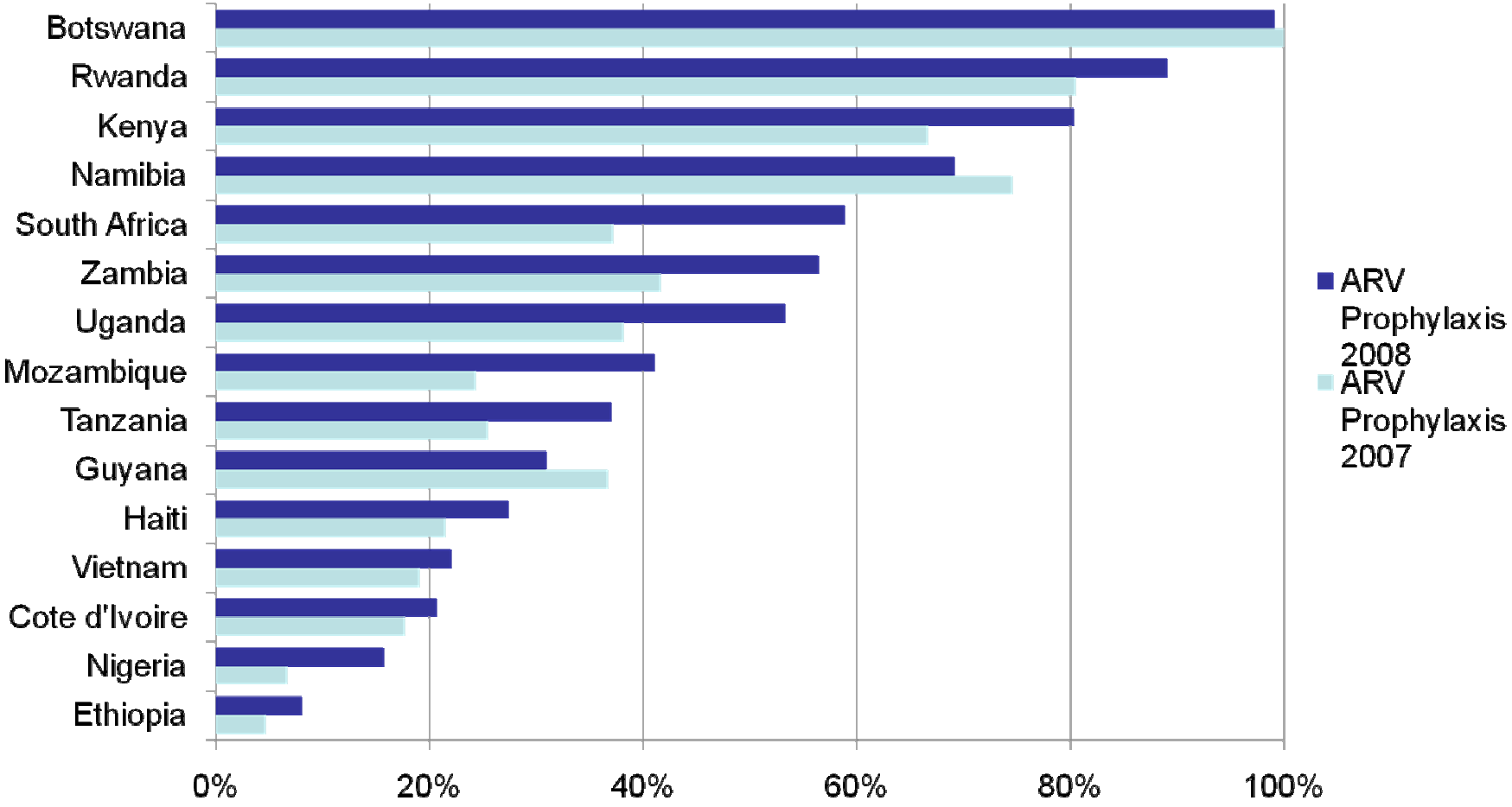
^Includes both direct and indirect USG support

Coverage: Counseling and Testing among Pregnant Women



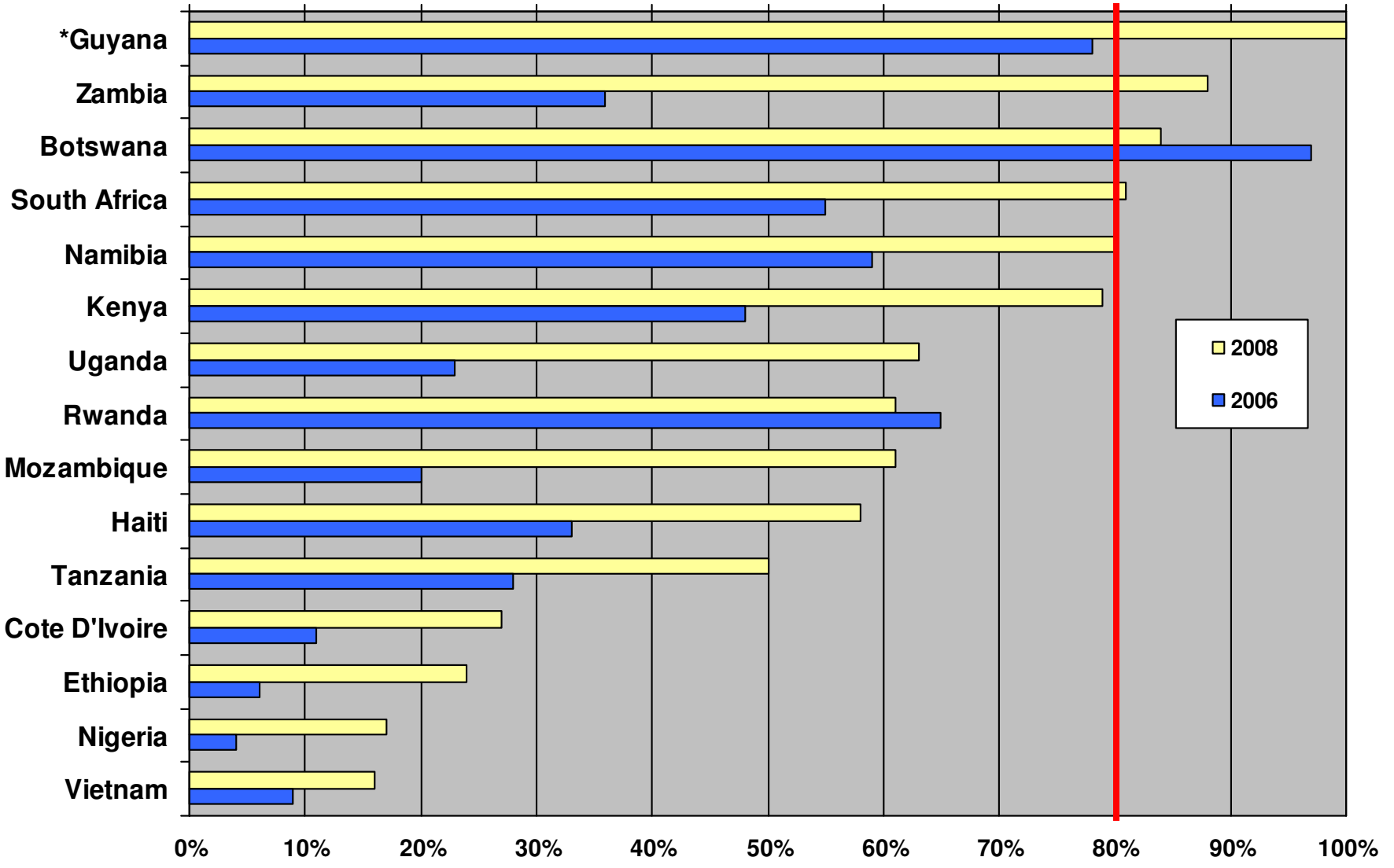
Numerator: PEPFAR 2007 and 2008 APR; Denominator: *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector, Progress Report, 2008.* WHO.

Coverage: ARV Prophylaxis among HIV+ Pregnant Women



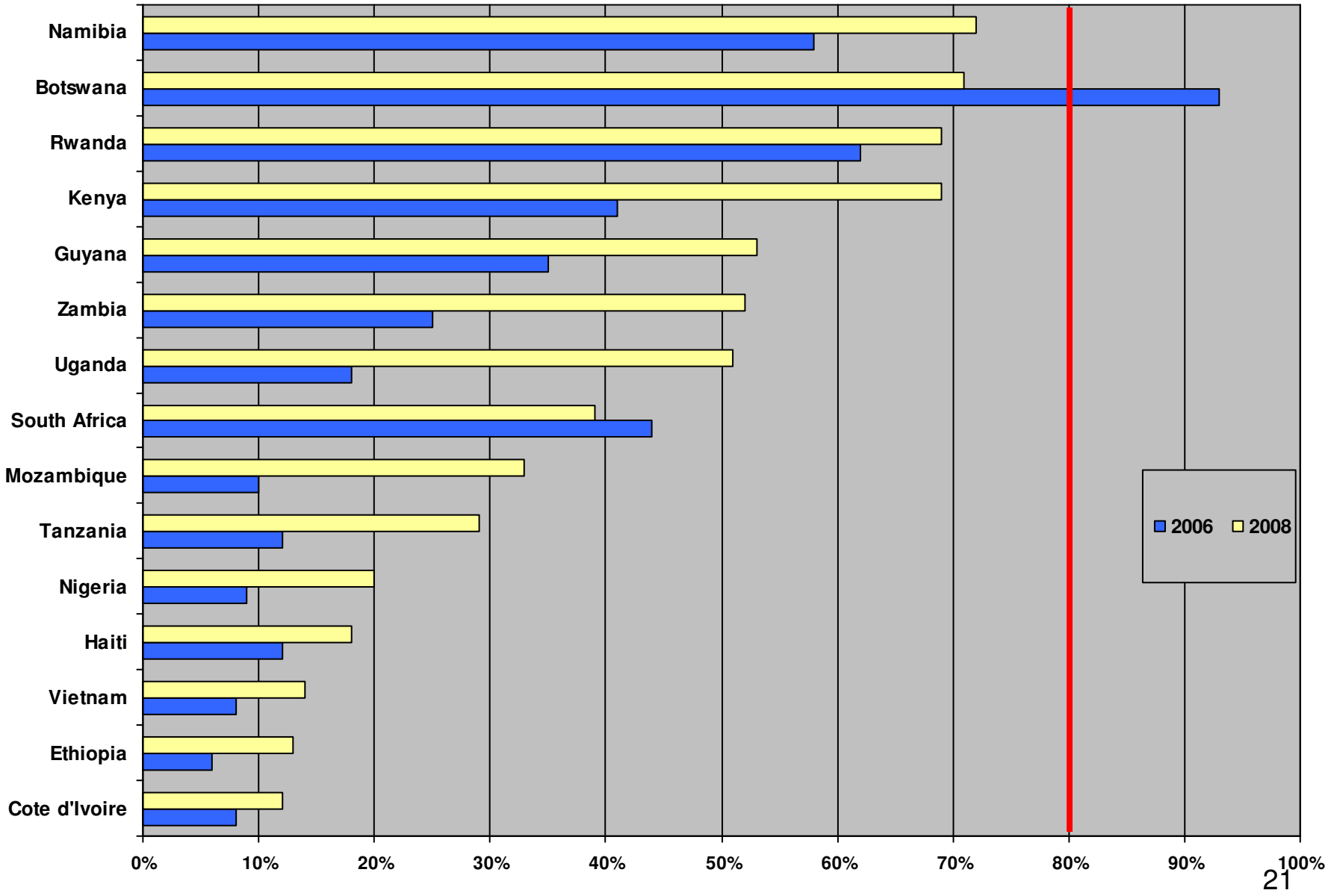
Numerator : PEPFAR 2007 and 2008 APR; Denominator: US Census Bureau, 2008.

Percentage of pregnant women attending ≥ 1 ANC visit who received HIV counseling and testing with USG support, 2006 and 2008

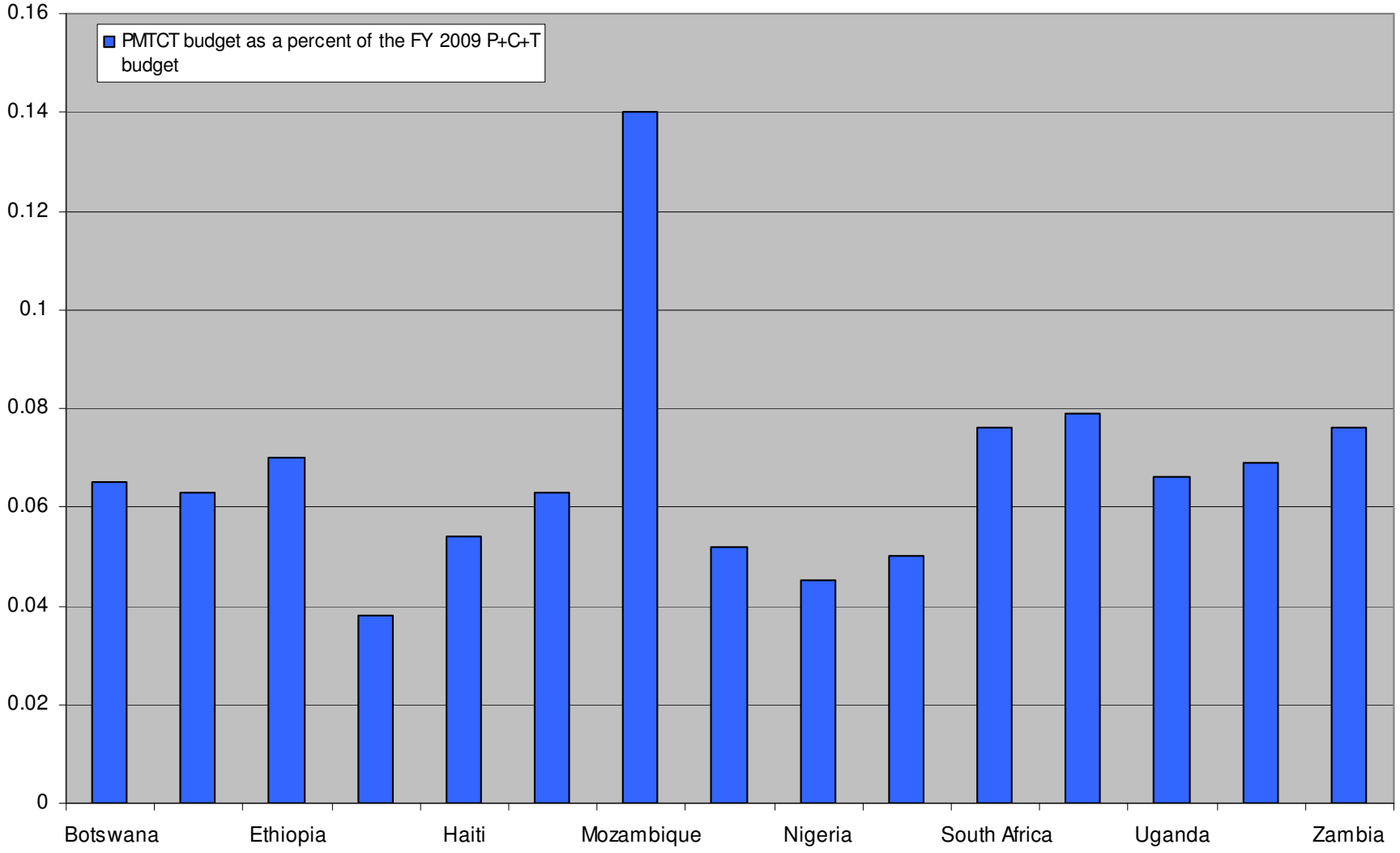


*The estimate for Guyana may not be accurate and likely reflects double-counting

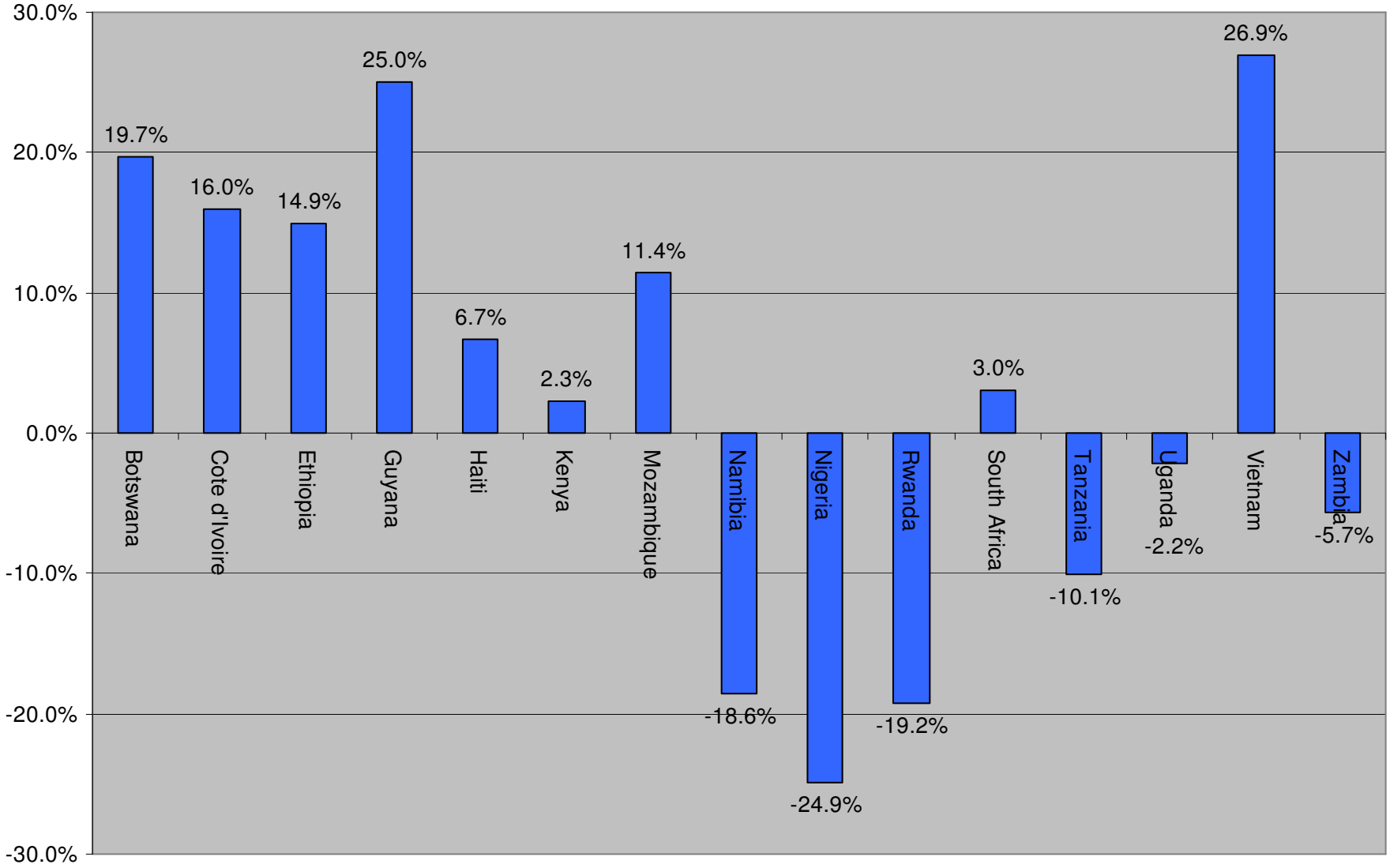
Percentage of HIV-positive pregnant women attending ≥ 1 ANC visit who received PMTCT ARV in with USG support, 2006 and 2008



USG PMTCT budget for FY 2009 as a percent of the P+C+T budget



The percent change in USG PMTCT budget between FY08 and FY09



Key Program Elements for Comprehensive PMTCT Program

PMTCT Core Interventions

- Routine ANC and L&D T&C
  - Simplified pre-test, rapid same-day results
- ARV prophylaxis (NVP, combination AZT, HAART)
  - Minimum of short prophylaxis to all
  - Longer ARV combinations and HAART where feasible, and when woman eligible
- Infant feeding counseling
  - Program support for safe, feasible alternatives
  - Early exclusive BF, early weaning
- "PMTCT-Plus" / Entry to care and treatment
  - Follow up of infants/ early infant diagnosis
  - Care and treatment for mother, child, family

PMTCT ARV Prophylaxis / Treatment

WHO, 2006 guidelines: “tiered” approach

- HAART for eligible women
- Combination prophylaxis (eg. AZT+SD NVP)
- SD NVP where other interventions not feasible/ available
- *NVP resistance is continuing concern*

Reality: Combination ARVs and HAART are just in the process of being implemented or scaled up in many country programs

PMTCT / HAART: Current Status

- Very few pregnant women now receiving HAART in PEPFAR programs
  - Currently not being reported
  - Standard reporting is critical
- With CD4 < 200:~ 20-30% of pregnant women will be eligible
- With CD4 <350: ~30-40% of pregnant women will be eligible

- Most effective intervention to decrease transmission (including postpartum breastfeeding transmission), decrease resistance, increase links with ART program.

PMTCT/Peds TWG: Priorities

- Routine, opt-out testing (PITC) – key success
- Linking PMTCT with ART (more effective ART)
- HIV status on mother and infant health cards
- M&E *(critical need for harmonization and systems)*
- PMTCT and Peds targets and national scale-up
- Early Infant Diagnosis and early treatment
- Training and capacity-building
- Operations Research/Public Health Evaluations
  - Program quality, effectiveness and impact
- Integration (EPI, malaria, MCH, family planning)
- Funding (increase funding and increase efficiency)

Comprehensive Approach with PEPFAR ART Partners

- Support regional / provincial / district health systems
- Mapping of clinical sites in region
  - PMTCT sites? ART sites?
  - Levels of care and network referrals
- PMTCT as HIV care site (pre-ART)
- Support PMTCT and care and tx linkages
  - Active support for ART screening (CD4), HAART and combination prophylaxis
  - Active links for mother and child follow up
  - Supply chain
- Monitoring and reporting

Best Practices to Improve Cascade

- Routine offer of counseling and testing - “opt-out
  - When implemented consistently increases uptake to >90%.
  - Also dramatically reduces staff time and thereby cost.
- Rapid testing with same day results. CD4 testing at same visit if positive.
- Lay counselors
- Sending nevirapine home with mothers at the first antenatal visit
- Providing access to HAART for treatment-eligible pregnant women and combination regimens as an entry point into care
- Quality assurance/team problem solving approaches.
- Observed dosing of infant with NVP prior to discharge from L&D
- Psychosocial support groups, male involvement, community mobilization.

Comprehensive Approach with PMTCT and Care and Treatment

- *PMTCT at all ART sites and ART site networks*
- *ART access at all PMTCT sites*
- *Integrated approach as programs expand to district and primary health care (PHC) levels*

PMTCT / ART Operational Issues

- Systems for CD4 screening of pregnant women
  - Need to move towards point of service testing if intervention is based on CD4 results
- Coordination of PMTCT and ART programs
- ART forecasting and supply chain for pregnant women
- ART availability and initiation in MCH
- Tracking of women and infants
- Program monitoring and reporting

Emerging Evidence / New Recommendations

- Important new evidence for safety and efficacy of:
  - extended infant prophylaxis regimens
  - extended maternal HAART prophylaxis for all women
- Breastfeeding transmission remains major problem in resource-poor settings
- Resistance is a concern for both infant infections (breakthrough infections) and for later maternal treatment
- Field programs are still at the early stages of implementing the 2006 WHO PMTCT guidelines (moving from SD NVP to combination prophylaxis + HAART for eligible women)
- WHO has started process to review PMTCT (and adult treatment) guidelines: emerging evidence and field experience
  - *Role for extended infant and/or HAART prophylaxis for all HIV-infected pregnant women?*
  - *Evidence, impact, simplicity, links w care and treatment*

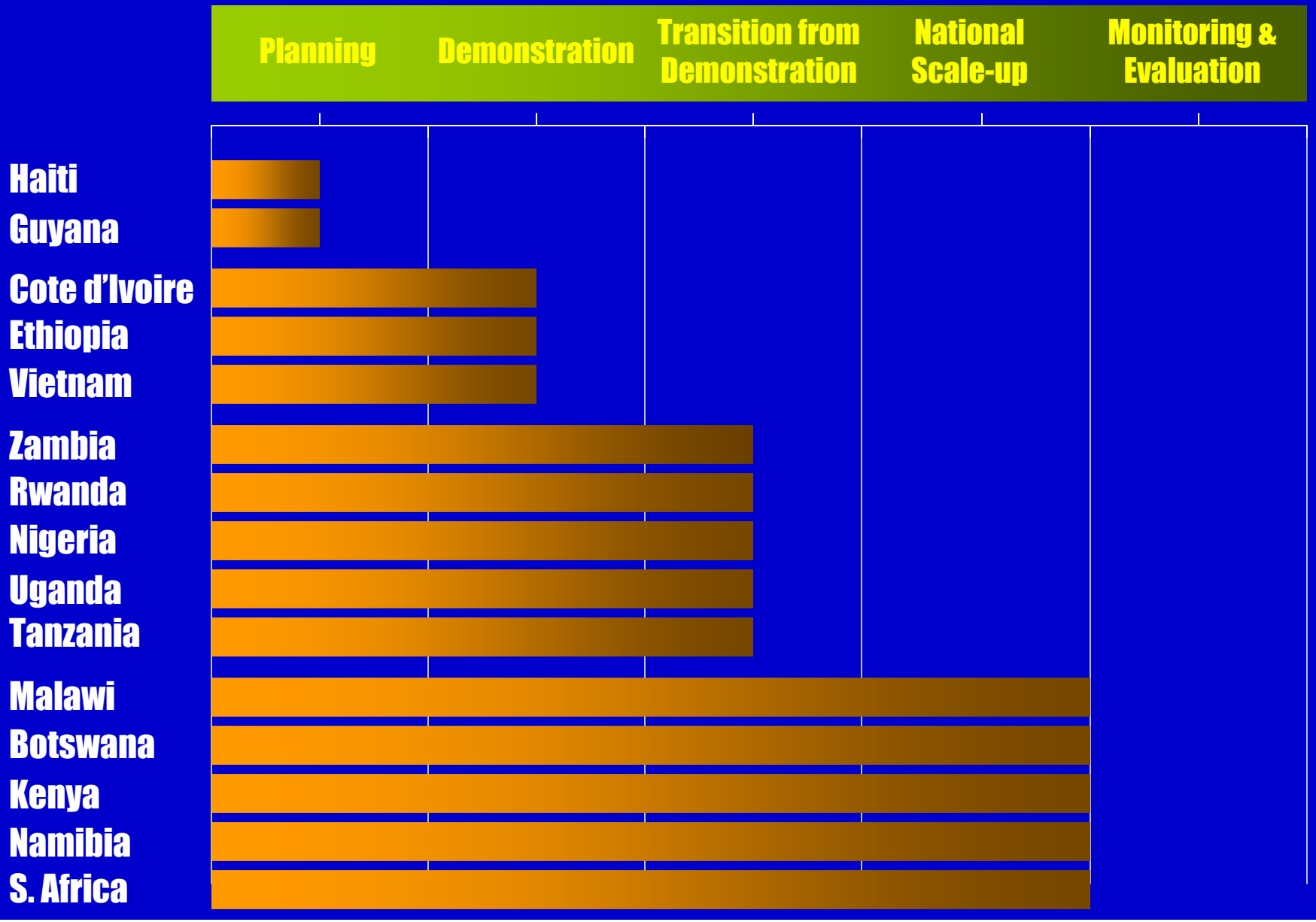
Early Infant Diagnosis (EID)

- Tremendous progress: Within past 3 years, PEPFAR has supported DBS PCR lab programs in all 15 focus countries
  - *Important opportunity to monitor program impact (evaluate early transmission rates) and link infected infants to early treatment*
  - *Becoming "standard of care" – new WHO guidelines being finalized*
- Standard protocols, testing and evaluation

  - Botswana, Namibia, Kenya, S. Africa >15,000 DBS PCR/year

  - Nigeria, Rwanda, Cote d'Ivoire, et al. multi-partner programs rapidly moving from demonstration phase to scale-up
- Regional training site established in S. Africa
- Key opportunity for international collaboration
  - PPP lab subgroup and IATT lab subgroup supporting EID expansion
- CDC lab and program support groups working closely with partner and host countries to establish national systems

Early Infant Diagnosis in PEPFAR Countries



Early Infant Diagnosis (EID)

- Key Success - Botswana:

  Based on a nation-wide testing program of DBS PCR, the national MTCT transmission rate is estimated at <5%

  Still very challenging to assure that PCR results are returned to family and that the relatively few infected infants are started on early treatment

- Goal this year

  Assist other countries to evaluate PCR results to estimate early transmission rates across multiple sites

  - Need standardized collections to reduce bias
  - Need standardized information on PMTCT regimens, to assess impact of the different regimens
  - Late postnatal transmission through BF not addressed

Infant Feeding

- Most challenging part of PMTCT in resource-constrained settings
- Where breastfeeding is the safest option:
  - HAART for eligible women
  - Exclusive breastfeeding and weaning, with support, after 6 months
- New and emerging evidence for efficacy of prophylaxis to mother or child during BF to reduce risk of postpartum transmission
  - PEPFAR relies on WHO (and IATT) leadership in updating international guidance in response to new evidence, and defining international standards and best practices

Integration: Within PEPFAR, with other partners, and with MCH

- Need to overcome vertical, silo approach
- PEPFAR is moving towards comprehensive programming by partners, but more can be done to strengthen integrated approach within PEPFAR
- PEPFAR needs to better integrate PMTCT support within national programs and with other partners
- Active work ongoing to define an “integration strategy” with MCH systems, family planning, STI prevention, immunizations, malaria, safe water, etc.

Program quality, evaluation and impact

- Need for program evaluation, standardization and assessments of quality and special studies and innovative surveillance methods to assess program impact
- What is the infection rate and HIV-free survival rate?

Public Health Evaluation (PHE)

- Not initially part of PEPFAR
- Introduced to respond to need for better program monitoring, evaluation of program impact, and to assess new program approaches

Public Health Evaluation (PHE)

- PMTCT is a PEPFAR focus area for PHE
- 14 single-country evaluations on PMTCT
- 3 multi-country studies:
  - PEARL (PMTCT Effectiveness in Africa: Research and Linkages to Care)
  - Antiretroviral Pregnancy Registry
  - HOPE (How to Optimize PMTCT Effectiveness)

How to Optimize PMTCT Effectiveness (HOPE)

- Planning just starting
- 5 countries: CI, Kenya, Nigeria, Tanzania, Uganda
- Objectives:
  - To describe, characterize, and compare PMTCT program sites (e.g., models, characteristics, populations served), service delivery indicators, and early infant diagnosis data from participating countries and sites.
  - To identify characteristics associated with PMTCT program models that increase the uptake and/or retention of HIV infected pregnant women in antenatal care, PMTCT, and HIV care/treatment programs and that have the most impact on MTCT reduction and other maternal and child health outcomes.

Indicators and SI Issues

PMTCT SI Issues and Opportunities

- National vs. PEPFAR targets; Direct vs. Indirect
  - Current reporting is inconsistent
  - In many countries, focus is more on PEPFAR program and less on national program and "3 ones"
  - Recommendation: PEPFAR should provide clear support for national targets and national reporting
- Need updated and expanded PMTCT program indicators
  - Current PEPFAR indicators helpful for general coverage but limited
  - In conjunction with the IATT, the TWG has proposed an expanded group of core indicators and national program indicators
  - Current status and decision about new indicators and support unclear
  - Recommendation: Need review and support of expanded list of PMTCT indicators, with active SI support for meaningful reporting
- Creative and active use of SI activities to support PMTCT
  - Recommendation: active use of ANC surveillance; AIS; malaria and other related program surveys; active use of EPP and mapping to reenforce program

Health Systems and Sustainability

- PMTCT relies upon well-functioning MCH, laboratory and ARV systems
- Chronic issues of weak and overburdened health systems, human resource and capacity shortages
- Need effective program management at national, provincial and district levels
- Need national monitoring systems
- PEPFAR is at an early but critical phase of addressing health systems and sustainability issues

Key Issues

FY 09 COP Review

Key issues emerging from COP PMTCT Technical Review

- Need to develop / update and implement country-level strategies for scaling up PMTCT services, especially in settings with little existing health infrastructure, low ANC coverage and/or a high percentage of home deliveries
- As scale up and expansion of services occurs, quality must also be assured
- Ongoing need for accurate data to strategically guide target setting and program implementation
- Assure strong government support and program management, national program scale-up, rapid update and implementation of WHO and PEPFAR guidelines and best practices

Key issues emerging from COP PMTCT Technical Review

- Achieving the end result of PMTCT cascade (getting antiretrovirals to pregnant women and newborns) remains a significant challenge.

  Contributing factors:

  - Services often remain centralized
  - Difficulties in providing lab services, particularly CD4 testing, to identify HAART eligible women and monitor those on therapy
  - Inadequate systems for early infant diagnosis and tracking of mother/baby pairs post delivery
  - Existing drug formulations and packaging are not convenient for distribution (eg: Large stock bottles of liquid pharmaceuticals necessary for infants must be hand aliquotted by health care workers into smaller 'take-home' bottles leading to potential for wastage, stockouts, and inaccurate dosing.)

Key issues emerging from COP PMTCT Technical Review

- Postnatal PMTCT services, particularly AFASS screening and support, are often neglected. Very difficult to assess in current program reports and implementer plans
- Integration of PMTCT services with other MNCH interventions essential for HIV-free infant/child survival and optimal maternal health is insufficient
- Need for expanded focus on community and family-centered approaches to delivering PMTCT interventions, not only facility-based programming

General Recommendations from PEPFAR PMTCT/Peds TWG

- Medically eligible pregnant women should explicitly be prioritized for access to HAART
- Women identified as HIV-positive through PMTCT programs should be used as index cases to identify partners and family members in need of counseling, testing, care and treatment services
- ARV forecasting and costing exercises must include PMTCT-related drug needs, particularly as the possibility of recommending continuation of ART throughout the breastfeeding period, and expanding ART in pregnanchy, is under consideration

General Recommendations from PEPFAR PMTCT/Peds TWG

- Emphasize importance of continuation of PMTCT into postnatal and breastfeeding periods
- Work toward integration of PMTCT, family planning and MNCH programming and service delivery to achieve optimal maternal, neonatal and child survival and health outcomes
- Strengthen role of community-based service provision
- Focus on resolving obstacles impeding improvement of end of cascade results

PEPFAR II: Targets and national scale-up

- The strength of PEPFAR is that it is a target-driven program
  - Eg. Adult ART program
- PEPFAR II provides an opportunity to develop clear national scale-up targets for PMTCT and to prioritize achievement of these targets
- Recommendation: Task force (panel, TWG, PEPFAR leadership, SI, IATT) to develop target framework and then implement in all PEPFAR countries
  - Need clear support and accountability from PEPFAR leadership
  - Need clear country buy-in (Compacts)

Issues and Recommendations for Panel

PEPFAR PMTCT/Peds TWG Recommendations for the Panel

- Establish
  - clear panel leadership and goals
  - rapid timeline to complete recommendations in time for COP ’10 (June)
  - mechanism for ongoing interaction within panel and with key stakeholders, including TWG
- Review
  - key PMTCT PEPFAR strategies and documents
  - OGAC management and support for PMTCT
  - Funding and cost/efficiency implications
  - key country successes and best practices

How can we be bolder in addressing barriers to scale-up?

Biggest barriers: confusion between USG PEPFAR and national program, lack of clear targets and limited PEPFAR focus on PMTCT/Peds, policy issues, less than optimal coordination

- Support national program scale up and national SI
- Support clear targets and mapping for scale up
- Identify and address policy and program barriers
- Assure adequate funding and funding efficiencies
- Assure enhanced stakeholder / partner coordination

Funding, Targets and Accountability

Thank you for your support!