
January 2010
Objectives

The independent Expert Panel issuing this report was established by Section 309 of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 ("the Act"), P.L. 110-293. The Panel was also established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, codified in 5 U.S.C. App.

According to the Act, the objectives and the scope of the activities of the Expert Panel are to “provide an objective review of activities to prevent mother-to-child transmission of HIV” (human immunodeficiency virus, the pathogen that causes Acquired Immune Deficiency Syndrome (AIDS)); and to “provide recommendations to the Global AIDS Coordinator and to the appropriate congressional committees for scale-up of prevention of mother-to-child transmission prevention services under this Act in order to achieve the target established” in the Act. The target is statutorily defined in Section 307 of the Act as “a target for the prevention and treatment of mother-to-child transmission of HIV that, by 2013, will reach at least 80 percent of pregnant women in those countries most affected by HIV/AIDS in which the United States has HIV/AIDS programs.” Recommendations are made based upon an extensive literature search reviewing the available evidence base on prevention of mother-to-child transmission (PMTCT) and through discussions with additional experts in the field of PMTCT research and service implementation. These recommendations are presented for the consideration of Members of Congress, the U.S. Global AIDS Coordinator, and U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) field programs and headquarters staff, and other interested parties.

Introduction

According to the recently released joint World Health Organization (WHO), Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Children’s Fund (UNICEF) Universal Access report, 33.4 million people are estimated to be living with HIV worldwide; 15.7 million of these are women and 2 million are children younger than 15 years of age (UNAIDS, WHO, UNICEF 2009). HIV is the leading cause of mortality among women of reproductive age worldwide and is a major contributor to maternal, infant and child morbidity and mortality (WHO 2009; UNAIDS 2009). Without treatment, one third of children living with HIV die before they reach one year of age and over 50% die by the second year of life (Newell 2004). In 2008, an estimated 1.4 million pregnant women living with HIV in low- and middle-income countries gave birth, 91% of whom reside in sub-Saharan Africa (UNAIDS, 2009).

Without intervention, 25-40% of infants born to HIV-positive mothers will become infected. With current interventions, this risk can be reduced to less than 5%. Therefore, transmission of HIV from a pregnant woman to her infant is preventable. Effective provision of Prevention of Mother-to-Child Transmission of HIV (PMTCT) interventions improves maternal health and infant HIV-free survival. PMTCT is a key component of overall HIV prevention efforts and represents a critical opportunity for stemming the tide of the HIV epidemic. Comprehensive PMTCT consists of a 4-pronged approach:

**Prong 1**
Prevention of HIV infection among women of childbearing age

**Prong 2**
Prevention of unintended pregnancies among women living with HIV

**Prong 3**
Prevention of transmission of HIV from mothers living with HIV to their infants

**Prong 4**
Treatment, care and support for mothers living with HIV and their children and families
When comprehensively implemented, PMTCT holds the potential to:

- substantially reduce new pediatric HIV infections, as has been accomplished in developed countries
- dramatically improve adult, maternal, infant and child health, particularly when well integrated into maternal, newborn and child health (MNCH) settings and in those countries where HIV contributes significantly to morbidity and mortality
- increase awareness of infection status for women and their partners and facilitate access to comprehensive care, support and treatment services
- identify children of HIV-positive women who also need to be tested and, if necessary, access HIV care, support and treatment services
- prevent new HIV infections in women and their male partners through prevention approaches targeted to the infection status of an individual woman and her partner
- prevent unintended pregnancies among HIV-positive women
- promote appropriate reproductive health services including family planning for those HIV-positive women who do not desire future pregnancies, and HIV transmission prevention interventions for those who wish to become pregnant
- contribute to reductions in HIV-related stigma and discrimination through partner, family and community education and awareness efforts
- help mitigate the disproportionate impact of HIV upon women and girls
- strengthen linkages between adult and pediatric treatment services available and PMTCT services
- build capacity for HIV, MNCH and reproductive health systems through education and training of health workers, improved laboratory and data systems, infrastructural improvements of antenatal clinics and labor and delivery wards, and strengthened systems for monitoring and evaluation

To successfully reduce mother-to-child transmission of HIV, population-level efforts to prevent HIV infection among women of childbearing age must be realized. For the individual woman, a comprehensive, coordinated continuum of services must be provided beginning with increased access to counseling, testing, and primary prevention services, as well as reproductive health choices enabling either the prevention of unintended pregnancies or appropriate planning for intended future pregnancies for women living with HIV. For HIV-positive women who become pregnant, access to and follow through on effective interventions to prevent transmission to the infant and to provide treatment for the woman herself and her child if infected must be provided to maximize maternal health and infant HIV-free survival. This continuum of services is often referred to as the PMTCT cascade and includes:

1. Antenatal care attendance

2. HIV counseling and testing with same day return of results to the woman
3. Determination of eligibility for HIV treatment through CD4 count assessment (or less optimally, through clinical staging) with rapid return of results to the woman and her provider

4. Provision of antiretroviral therapy for women who require therapy for their own health and antiretroviral prophylaxis to prevent mother-to-child transmission to women who do not yet require therapy

5. Adherence to HIV treatment or prophylactic regimens as medically appropriate

6. Safe labor and delivery services

7. Timely provision of HIV prophylactic regimens and cotrimoxazole for the infant

8. Safe feeding practices for the infant

9. Early follow-up HIV testing for the infant with rapid initiation of antiretroviral treatment for those who are infected, and testing to determine final HIV status in breastfed infants.

10. Ongoing, clinical, psychological and social care, support and monitoring for the mother, infant and family

For optimal results, these services should be embedded within high-quality general maternal, newborn, infant and child health services and supported by national and local government commitment and funding, community sensitization and mobilization, male partner and other family involvement, strengthening of health systems to promote comprehensive care and treatment, accurate data collection, monitoring and evaluation, reliable supply of necessary equipment and supplies and well-trained, patient-friendly health care workers.

**Progress to Date**

PMTCT has been a high priority for the international HIV/AIDS response as evidenced in the Declaration of Commitment on HIV/AIDS adopted at the United Nations General Assembly Special Session on HIV/AIDS in 2001 (United Nations 2001), the Abuja Call to Action Towards an HIV-free and AIDS-free Generation in 2005 (High Level Global Partners, 2005), the Political Declaration of the United Nations General Assembly High-Level Meeting on AIDS to work towards universal access to HIV prevention, treatment, care and support in 2006 (UNGA 2006), and numerous other high-level statements by multilateral organizations.

The United States Government (USG) has played a sustained and critical role in worldwide PMTCT research and program efforts, including funding research that identified key PMTCT interventions followed by spearheading global program scale-up of these interventions under the 2002 U.S. Mother and Child HIV Prevention Initiative and during the first 5 years of PEPFAR. The PEPFAR reauthorization bill has brought a renewed emphasis to the urgent need for scale-up of PMTCT services. Specifically, the bill calls for the establishment of a comprehensive, integrated, 5-year strategy for PEPFAR, which must include a plan to help partner countries in the effort to achieve goals of at least 80% access to counseling, testing, and treatment to prevent the transmission of HIV from mother-to-child, emphasizing a continuum of care model, and increase support for prevention of mother-to-child transmission. The PEPFAR Five-Year Strategy, released in December 2009, outlines plans to ensure that every partner country with a generalized epidemic has both at least 80% coverage of testing for pregnant women at the national level, and 85% coverage of antiretroviral drug prophylaxis and treatment, as indicated, of women found to be HIV-infected (PEPFAR 2009). The policy also recognizes the work that PEPFAR is doing to expand access to PMTCT to at-risk populations in countries with concentrated epidemics. To help the children of these mothers, PEPFAR supports the expansion of early infant diagnosis to reach 65% coverage, along with comprehensive care and treatment of exposed infants.
Successful scale-up of PMTCT services is also well-aligned with the Obama administration’s strong support for the empowerment of women and improving the health of women, children and families through the Global Health Initiative (GHI), and contributes to Millennium Development Goals 4 (Reduce Child Mortality), 5 (Improve Maternal Health) and 6 (Combat HIV/AIDS, Malaria and Other Diseases).

Countries have realized significant achievements in PMTCT. According to the 2009 Universal Access Report, 70 of 123 reporting low- and middle-income countries have established a national PMTCT scale-up plan that includes population-based targets, up from 34 in 2005 (UNAIDS, WHO, UNICEF 2009). Due in part to increased implementation of provider-initiated (‘opt out’) HIV testing in antenatal care (ANC) settings, rates of HIV counseling and testing for pregnant women have improved. In six of the ten countries estimated to have the largest numbers of pregnant women living with HIV (Kenya, Malawi, Mozambique, South Africa, Tanzania and Zambia), rates of counseling and testing for pregnant women have risen to 60–80%. Progress has also been made in providing antiretroviral medications for PMTCT to those women who test positive. In 2008, 45% of pregnant women living with HIV in low- and middle-income countries received antiretroviral drugs to prevent HIV transmission to their infants, including antiretroviral therapy for their own health, an increase from 35% in 2006. However, half of countries with a generalized HIV epidemic have an unmet need for family planning among married women age 15-49 years of over 25%.

In a supportive role for country-level leadership, PEPFAR has contributed significantly to many of these achievements. Specifically, three of the fifteen original PEPFAR focus countries (Botswana, Guyana, and South Africa) have achieved 80% coverage of HIV counseling and testing among pregnant women with PEPFAR support, with several others close behind (Figure 1). Nigeria, in contrast, is behind and requires special intervention given its size, poverty and gaps in health system capacity.

In 2008, three countries (Botswana, Guyana and Rwanda) achieved at least 80% antiretroviral drug (ARV) provision among known HIV-positive pregnant women with PEPFAR support (Figure 2). Sustaining these achievements and assisting the remaining countries to increase coverage to at least 80% (regardless of antenatal care attendance), is essential for successfully meeting the PMTCT goals outlined in the next phase of PEPFAR. It should also be noted that PMTCT programs can contribute significantly to each of the PEPFAR goals of directly supporting more than 4 million people on treatment, preventing 12 million new infections and enrolling 12 million HIV-infected persons in care and support.
As pregnancy is only for a limited time, urgent intervention to provide treatment or prophylaxis as quickly as possible is essential, or the window of opportunity to prevent HIV infection in the infant may close. However, clinics providing antiretroviral therapy and ongoing management for HIV-positive patients are not always located in the same place where the woman receives her ANC and labor and delivery care. This is due to multiple factors including limited numbers of health care workers trained in provision of such services, lack of appropriate infrastructure and facilities and potentially long distances between health care sites and the individual woman’s home. Thus, following up with these services may be extremely difficult. PMTCT services must also be provided during labor and delivery. As many women deliver at home rather than in a health facility, ensuring women and their babies have access to and take the needed antiretroviral at the time of labor and delivery is very difficult. After delivery, the woman and infant need ongoing monitoring, care and support and potentially treatment which poses yet another challenge for reasons similar to those described above.

Moreover, risk of mother-to-child transmission of HIV does not end at birth but continues for as long as the infant is breastfeeding. Women may not be able to reliably access appropriate infant formula or the clean water needed to prepare it. Even if this can be accomplished, breastfeeding is often the cultural norm, and formula feeding may draw

Challenge:

Despite the successes realized thus far, significant challenges remain to achieving at least 80% coverage of counseling and testing for pregnant women and 80% coverage of ARV provision for HIV-positive pregnant women. Comprehensive provision of PMTCT is a complex intervention that involves multiple services delivered to different individuals at different points in time and in a variety of different settings. For example, for any intervention to be provided, a woman’s HIV status must first be determined. This would ideally happen in an ANC setting; however, many women do not attend ANC services and those who do are unlikely to complete the WHO recommended 4 visits throughout a pregnancy. Thus, expansion of testing to other settings where women access services (eg. maternity wards, family planning clinics, immunization clinics and other pediatric services, community health centers, etc.) will help to achieve this goal and contribute to broader strengthening of women’s health. Women who test negative remain at risk for acquiring HIV during pregnancy or lactation; thus engagement of their sexual partner in preventive services is an important target. Transmission of HIV to the infant is very high when a woman acquires a new HIV infection during these time periods. Thus, women who test negative who are in high HIV prevalence and/or high-risk settings need ongoing prevention interventions and repeat testing during pregnancy. Women who test positive must be assessed for treatment eligibility by CD4 test and clinical exam. Increased availability of CD4 tests in antenatal settings is critically needed. The majority of pregnant women are clinically well, but as many as 50% are likely to be eligible for treatment for their own health based on low CD4 count. Women who receive a CD4 test typically wait 2 weeks or more for the results to return, necessitating a return visit which can result in losing the woman to follow-up.

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of HIV+ pregnant women receiving ARV prophylaxis in FY 2008</th>
<th>Estimated number of pregnant women living with HIV needing antiretrovirals for PMTCT based on UNAIDS/WHO methods 2008</th>
<th>Estimated coverage of HIV+ pregnant women receiving ARV prophylaxis FY2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>10,900</td>
<td>12,000</td>
<td>91%</td>
</tr>
<tr>
<td>Côte d’Ivoire</td>
<td>5,800</td>
<td>22,000</td>
<td>26%</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>5,300</td>
<td>36,000</td>
<td>15%</td>
</tr>
<tr>
<td>Guyana</td>
<td>200</td>
<td>&lt;200</td>
<td>100%</td>
</tr>
<tr>
<td>Haiti</td>
<td>1,400</td>
<td>5,500</td>
<td>25%</td>
</tr>
<tr>
<td>Kenya</td>
<td>61,100</td>
<td>110,000</td>
<td>56%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>39,900</td>
<td>110,000</td>
<td>36%</td>
</tr>
<tr>
<td>Namibia</td>
<td>6,500</td>
<td>8,200</td>
<td>79%</td>
</tr>
<tr>
<td>Nigeria</td>
<td>29,800</td>
<td>210,000</td>
<td>14%</td>
</tr>
<tr>
<td>Rwanda</td>
<td>9,800</td>
<td>10,000</td>
<td>98%</td>
</tr>
<tr>
<td>South Africa</td>
<td>129,600</td>
<td>200,000</td>
<td>65%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>37,100</td>
<td>86,000*</td>
<td>43%</td>
</tr>
<tr>
<td>Uganda</td>
<td>41,600</td>
<td>82,000</td>
<td>51%</td>
</tr>
<tr>
<td>Vietnam</td>
<td>900</td>
<td>3,300</td>
<td>27%</td>
</tr>
<tr>
<td>Zambia</td>
<td>42,900</td>
<td>70,000</td>
<td>61%</td>
</tr>
<tr>
<td>Total</td>
<td>422,800</td>
<td>879,000</td>
<td>48%</td>
</tr>
</tbody>
</table>

Footnotes:
2 Coverage rates were calculated by dividing PEPFAR program (upstream and downstream) results by the estimated number of HIV+ pregnant women needing antiretrovirals for PMTCT based on WHO/UNAIDS methods.
3 This is a preliminary estimate, currently being reviewed and will be adjusted, as appropriate, based on ongoing data collection and analysis.
scrutiny from friends and family, potentially exposing the woman to stigma and discrimination, and leading to formula feeding in private and breastfeeding in public. This ‘mixed’ feeding of part breast milk and part formula has been shown to present the greatest risk for HIV transmission. Additionally, if formula feeding is interrupted due to inadequate supply of formula or compromised by use of unsafe water for preparation, infants are at extremely high risk for morbidity and mortality from other causes, such as diarrhea and malnutrition, thus defeating the ultimate goal of HIV-free infant survival. For these reasons, WHO infant feeding guidelines for HIV-positive women have recommended exclusive breastfeeding for all women unless specific criteria for formula feeding can be met - specifically formula feeding must be ‘AFASS’ (affordable, feasible, acceptable, safe and sustainable). This conditional approach has been extremely difficult to implement and has resulted in tremendous confusion among health care workers and mothers and likely contributed to ongoing transmission during breastfeeding. Given recent clinical trial results demonstrating that provision of antiretroviral drugs to the breastfeeding infant or lactating mother can significantly decrease breast milk transmission, WHO now recommends that countries develop a national plan for feeding guidance for all infants of HIV-positive women that should include a comprehensive approach to health care access. If breastfeeding is chosen for national guidelines, exclusive breastfeeding for 6 months followed by continued breastfeeding with appropriate complementary feeding through age 12 months accompanied by antiretroviral prophylaxis of the infant or mother to prevent breast milk HIV transmission is recommended.

Even if all of the programmatic challenges of making services available are met, agreeing to testing, accepting a positive diagnosis and following through on the recommended interventions places a tremendous burden on the individual woman especially given the weakness of health systems and the impact of social barriers for women’s health, including stigma. Disclosure of HIV infection to a partner, family or community member can be extremely daunting, and in some cases even dangerous, for a woman who culturally may have very little decision-making power and limited ability to provide for the needs of herself and her children. Stigma and discrimination combined with very little male involvement in issues related to pregnancy and childbirth and underlying cultural systems that disempower women create a situation that makes it extremely challenging to follow through on essential PMTCT interventions.

An additional challenge has been ambiguity around the definition of PEPFAR targets and whether the goals are PEPFAR program specific or whether they reflect national population level coverage. Finally, provision of adequate PMTCT services is dependent upon sufficient funding. As the USG, country governments and other donors face the reality of the current economic crisis, availability of resources to support PMTCT programs is limited. Although PEPFAR has recently allocated an additional one-time $100 million for strategic acceleration of PMTCT scale-up in 6 countries in FY2010 (Malawi, Mozambique, Nigeria, Tanzania, South Africa, and Zambia), PEPFAR resources overall have not increased as substantially in 2009 or 2010 as in the program’s earliest years. As these additional funds are currently provided on a one-time basis, it is difficult to strategize and plan for the scale-up of coverage on a long-term basis. While scale-up of PMTCT services requires additional initial investments, and a broadened strategic framework, the long-term savings, both in terms of improving maternal health, thus helping to ensure a stable caregiver for children and a potential contributor to economic development, political stabilization and in prevention of infections in infants who would otherwise go on to require a lifetime of treatment, must be considered.

**PEPFAR Expert PMTCT Panel Recommendations**

The following recommendations of the PEPFAR Expert PMTCT Panel are directed to Members of the U.S. Congress, the U.S. Global AIDS Coordinator and PEPFAR field programs and headquarters staff. The Panel has summarized their recommendations below and organized them by the following categories: 1) Service Delivery; 2) Health Workforce; 3) Health Information Systems, Targets, and Monitoring and Evaluation; 4) Research and Innovation; 5) Financing; 6) Leadership and Governance; and 7) Collaboration and Coordination, in order to demonstrate the multisectoral approach needed to develop successful PMTCT programs, and to highlight the ways in which PMTCT has wider impacts on country health systems.
A. Service Delivery:

1. The first two prongs of PMTCT (prevention of HIV infection and unintended pregnancies) are often neglected but are crucial to the success of PMTCT and overall HIV and global health efforts. PEPFAR should support and fund comprehensive programs that include prevention of adult HIV infection, particularly for those women found to be HIV-negative in PMTCT settings, provision of accurate family planning advice and safe contraception for all women of childbearing age living with HIV, and access to advanced health services if HIV-infected to prevent death of the mother and child.

2. Routine, provider-initiated, opt-out HIV screening during pregnancy, delivery and the postpartum period is essential to reduce the stigma of accessing the test, enabling women to know their infection status and access treatment and care and PEPFAR should support country efforts to make this standard policy and practice.

3. Given the dual benefits of improving maternal health and preventing new pediatric HIV infections and in light of USG efforts to provide woman- and family-centered services, PEPFAR should support policies that prioritize pregnant and lactating women for HIV care and treatment services and work with governments to improve their longitudinal care systems for PMTCT and linkages with care and treatment programs that aim to maximize the health and survival of mothers and infants.

4. PEPFAR should support policies and practices that ensure that:
   a. Pregnant women found to be HIV-positive are urgently assessed, preferably with a CD4 cell count drawn on the day of diagnosis, to determine their need for antiretroviral therapy for their own health, with the added benefit of dramatically reducing transmission to the baby, and CD4 count assays need to be readily available in the antenatal setting.
   b. All HIV-positive pregnant women should be integrated into ongoing care and those who are medically eligible for antiretroviral treatment for their own health initiated on ART as soon as possible and continued on this therapy for life, along with ongoing management of clinical, psychological and social issues.
   c. Pregnant women not yet medically eligible for antiretroviral treatment for their own health are integrated into ongoing medical monitoring and care and, urgently started on a highly efficacious prophylactic ARV regimen to prevent in utero, peripartum, and postpartum breast milk transmission to the baby, and are linked to long-term follow up care to evaluate need for antiretroviral treatment and other interventions in the future. This also facilitates monitoring of their exposed infant for treatment services if infected and strengthens linkages for childhood vaccination and other child health initiatives.

5. PEPFAR must contribute to putting programs in place that ensure all infants born to mothers living with HIV are enrolled in ongoing care and support services and actively followed to ensure clinical HIV-related and general pediatric management, early and repeat HIV testing, developmentally appropriate psychological and social support, provision of cotrimoxazole, appropriate infant feeding and, if indicated, ongoing antiretroviral prophylaxis to further reduce the likelihood of transmission. These programs should ensure that infants who are determined to be HIV-infected are initiated on antiretroviral treatment given the high morbidity in untreated HIV-infected infants and children.

6. PEPFAR and the broader GHI should strongly promote country-level integration and coordination of PMTCT, HIV care and treatment programs, MNCH and family planning programs to maximize the benefits of these investments.
7. PEPFAR should promote nutrition counseling and support with linkages to food security programs as an integral component of PMTCT programs as pregnant women are under increased nutritional and metabolic demands, and often suffer from preventable nutritional deficits, which are worsened by the additional burden of HIV infection.

8. PEPFAR programs and the wider GHI must focus additional resources to increase demand for antenatal care services and outreach services for women who deliver at home to increase the reach of PMTCT programs and potentially reduce stigma and loss to follow-up.

9. PEPFAR should promote policies and programs that prioritize the inclusion of male partners and other family members in PMTCT service delivery, as this has been shown to improve test acceptance by women and reduce the stigma of positive test results. Increased community and male partner knowledge, understanding, and participation in PMTCT services as well as the provision of psychosocial support services to women are critical in helping HIV-infected women successfully complete the PMTCT cascade, and can lead to improvements in men’s health.

B. Health Workforce:

1. Improved and ongoing training, mentoring, supervision and appropriate compensation of both professional and lay health care workers are needed to ensure quality services are provided. Strengthening of local academic and technical educational institutions including new curriculum and certification programs in the area of maternal and child health and HIV are needed to achieve long-term sustainability. Training of health care workers to provide PMTCT and related pediatric HIV treatment services should be included in PEPFAR’s goal of training 140,000 new health care workers.

2. PEPFAR should use Partnership Frameworks to encourage country governments to allow task-shifting, including non-physician health care worker initiation of antiretroviral treatment for pregnant women, infants and children and the use of trained counselors to provide HIV counseling and testing. Efforts should be made to utilize and compensate HIV-positive women who have been through PMTCT services as counselors and educators for new patients as their services have been successfully utilized in numerous PEPFAR-funded programs. PEPFAR should allow for “topping-up” of salaries for public health sector employees and incentivize productivity through performance-based financing.

3. Fear of stigmatizing behaviors from health care workers is a barrier to service uptake. PEPFAR should promote programs that focus on improving the counselor-patient interaction and including formal training for staff on the reduction of stigmatizing behaviors. They should address imbalances in quality of services offered at hospitals, health centers and maternities by improving training of staff and infrastructure at all venues.

C. Health Information Systems, Targets, and Monitoring and Evaluation:

1. The PEPFAR goals established in the Reauthorization and PEPFAR Five-Year Strategy as related to target set for PMTCT counseling and testing, provision of prophylaxis, early infant diagnosis, infants born HIV-free and pediatric testing and treatment must be better defined to enable a clear strategy toward achieving them. PEPFAR leadership should:

   a. Convene an interagency USG group to rapidly assess methodologies and gain consensus on the definition of these targets for the next phase of PEPFAR.

   b. Use national figures for all denominators used in PEPFAR reporting, and include all women, regardless of antenatal care attendance.
c. Work with national monitoring and evaluation staff to promote disaggregation of data provided to
OGAC on the ARV regimens provided in their programs, as a means of encouraging utilization of more efficacious
regimens.

d. Define and measure targets that focus on providing HIV treatment to pregnant women who need it
for their own health, including documentation of clinical and/or laboratory staging of HIV disease and engagement in
care and/or treatment services for all women identified as HIV-positive.

e. Strongly encourage establishment of reporting systems that provide an indicator of linkage of HIV-
infected women to treatment and care programs.

f. Establish indicators for and define program success in terms of PMTCT impact, such as infant HIV-
free survival.

2. Promote ownership of the PMTCT program through feedback of program results to clinical sites and support
of quality assurance (QA) and quality improvement (QI) activities that allow for local identification of problems and
generation of potential solutions to improve program quality.

3. Conduct public health evaluation studies to identify the barriers to treatment and care and the degree to which
these barriers also negatively impact the completion of the PMTCT cascade.

4. PEPFAR must support country-led efforts to move toward one monitoring and evaluation system and inter-
national efforts to harmonize targets and indicators.

D. Research and Innovation:

1. Operational research is urgently needed to determine optimal strategies for implementation of the PMTCT
cascade. Research is particularly needed to ascertain program models that facilitate integration of MNCH, PMTCT,
and comprehensive care and treatment services in a comprehensive, longitudinal, synergistic way to optimize mater-
nal, infant and child health and survival. A recent meeting convened by UNICEF and the Elizabeth Glaser Pediatric
AIDS Foundation, and attended by PMTCT and pediatric HIV experts from the USG, international agencies and
implementing partners produced a list of 20 priority Operational Research questions reached by consensus among all
attendees. PEPFAR is in a position to rapidly facilitate answering these questions and should fund, prioritize and fast
track research in these areas through Public Health Evaluations and other research and evaluation mechanisms.

2. As increasing numbers of HIV-infected pregnant women receive antiretroviral drugs during pregnancy, sur-
veillance for the effect of such treatments on maternal health, pregnancy outcome, including birth defects, and the
short- and long-term effects of in utero antiretroviral drug exposure on their infants (including HIV-exposed but unin-
fected infants) is critical. PEPFAR support of pharmacovigilance programs to monitor for such effects is important.

3. PEPFAR should take a proactive approach to new interventions and development of new technologies, includ-
ing funding pilot projects to evaluate innovative and cost-effective methodologies, such as point-of-care CD4 instru-
ments and comprehensive provision of PMTCT to promote women’s health and empower women to access services.

E. Financing:

1. Within PEPFAR, PMTCT should be prioritized for funding because it is one of the most effective and cost-
effective forms of HIV prevention and contributes to multiple PEPFAR goals related to prevention, treatment, care
and support, health care workforce and health system strengthening and embodies a woman- and family-centered
approach to programming and foreign assistance funding.
2. PEPFAR should lead efforts to identify and implement cost-effective practices and reduce inefficiencies at multiple levels, including within USG agencies, implementing partners, country governments, and PEPFAR coordination with other donors.

F. Leadership and Governance:

1. PEPFAR should use the Partnership Framework as a means of improving country government engagement and should take a proactive role in working effectively with all stakeholders through effective national and international coordinating bodies. Strong country government leadership that translates throughout the leadership to the local level, prioritization of and commitment to PMTCT in the national HIV/AIDS plan and other critical national HIV/AIDS activities and strategies such as Global Fund applications and general health sector plans are required for rapid and comprehensive scale-up and ongoing sustainability of PMTCT services. National coordination among relevant country ministries (Health, Finance, Social Welfare, etc), USG agencies, implementing partners, international agencies and faith-based organizations is required for the most effective and efficient service provision.

2. Given staffing and capacity challenges often faced by national-level Ministries of Health, PEPFAR programs should also emphasize staffing up and supporting Provincial and District Health Offices as an effective method of promoting decentralization of country leadership around PMTCT activities.

3. PEPFAR programs should work with host country governments to focus on concrete efforts to reduce stigma and increase population-level understanding and acceptance of PMTCT interventions.

4. PEPFAR policies should protect people living with HIV/AIDS (PLWHA) and engage PLWHA in the development of country operational plans, Partnership Frameworks and other key documents and planning.

G. Collaboration and Coordination:

1. PEPFAR leadership and technical experts should work closely with those responsible for developing GHI strategy. There are tremendous opportunities for synergies and joint efforts toward achieving common health and development goals related to PMTCT and maternal, newborn, infant and child health. However, the approach must be developed and implemented in harmony so as to reduce redundancy, achieve common goals, capitalize on existing achievements and platforms and maximize sustainability. Comprehensive implementation of PMTCT achieves the woman- and family-centered approach articulated as a priority for USG initiatives.

2. In order to facilitate achievement of PMTCT goals, PEPFAR must:

   a. Continue and expand coordination with international/multilateral organizations within the framework of the “three ones” (one national HIV/AIDS action framework, one national HIV/AIDS coordinating authority, one national monitoring and evaluation system) based on the core competencies of the different stakeholders to ensure clear and unified information is provided to Ministries of Health and Finance.

   b. Actively engage international/multilateral organizations in the PEPFAR Partnership Framework process and coordinate where possible with the Global Fund National Strategy Application process.

   c. Provide support to improve capacity of international/multilateral organizations.

   d. Continue to fully engage with the UNICEF/WHO co-convened Interagency Task Team on PMTCT as the primary forum for coordination at headquarters level and emphasize strong coordination at country level to avoid duplication and gaps.
Strengthen local governments and non-governmental organizations directly involved in implementing best practices in order to translate PEPFAR’s successes into long-term sustainable programs that are part of the fabric of health care provided to women and children.

Conclusions

The members of the Expert Panel emphasize the importance of maximizing the extent to which PMTCT, one of the most effective and cost-effective tools for the prevention of HIV, is funded and scaled-up. If PEPFAR is able to reach its stated goals over the next 5 years, it will have the effect of dramatically reducing new HIV infections and reducing the long-term costs of care and treatment costs for infected children, and improving the health of women. These investments and efforts should also be leveraged through the Administration’s GHI to achieve broader MNCH and reproductive health goals through a woman-centered approach. Thank you for this opportunity to share our insights and recommendations.

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