PEPFAR BLUEPRINT:

CREATING AN AIDS-*free* GENERATION

“The goal of an AIDS-*free* generation may be ambitious, but it is possible with the knowledge and interventions we have right now. And that is something we’ve never been able to say without qualification before. Imagine what the world will look like when we succeed.”

- U.S. Secretary of State Hillary Rodham Clinton,
November 8, 2011

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November 29, 2012

As a nation, we are firmly committed to turning the tide on the 30-year-old fight against AIDS. That's why I proudly announced last year that creating an AIDS-free generation is a new policy imperative for the United States.

To be clear, we still face enormous challenges. Far too many people are dying from this disease. We need to reach more people with both prevention and treatment services. But today, thanks to remarkable scientific discoveries and the work of countless individuals, organizations and governments, an AIDS-free generation is not just a rallying cry—it is a goal that is within our reach.

At the International AIDS Conference this past July, I asked our Global AIDS Coordinator, Ambassador Eric Goosby, to prepare this blueprint outlining our path to helping create an AIDS-free generation. I want the next Congress, the next Secretary of State, and all of our partners here at home and around the world to understand everything we've learned and to have a road map for how the United States will contribute to an AIDS-free generation.

This blueprint should make one thing clear: the United States is and will continue doing our part. But creating an AIDS-free generation is too big a task for one government or one country. It requires the world to share in the responsibility. We call on partner countries, other donor nations, civil society, faith-based organizations, the private sector, foundations, multilateral institutions and people living with HIV to join us as we each do our part.

Together, we can deliver a better future to millions across the globe. A future where children are not born with HIV… where teenagers and adults are at far lower risk of contracting the virus… where those who do have the virus get lifesaving treatment. A future where every child has the chance to live up to his or her God-given potential.

That's a future worth fighting for, together.

Sincerely,

Hillary Rodham Clinton

Hillary Rodham Clinton
Secretary of State

VISION STATEMENT

Scientific advances and their successful implementation have brought the world to a tipping point in the fight against AIDS. The United States believes that by making smart investments based on sound science, and a shared global responsibility, we can save millions of lives and achieve an AIDS-*free* generation.

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INTRODUCTION

What a difference a decade makes. Ten years ago, AIDS was wiping out a generation of individuals and reversing important health and development gains being made in Africa. Hospitals were completely overwhelmed by the massive volume of dying people. Multiple people routinely shared a bed with others lying on the floor. And nothing was being done to save them. They were not getting the antiretroviral treatment (ART) that was available in the United States. For them, HIV infection was truly a death sentence.

AIDS threatened the very foundations of societies. It took people in the prime of their lives when they should have been caring for their families. It created millions of orphans, unable to attend school without the support provided by their parents. It disproportionately affected women and girls. And the disease stalled economic development, leaving countries stuck in a cycle of poverty. That, in turn, created instability—leading the UN Security Council to identify AIDS as a security issue in 2001.

Today, AIDS is no longer a certain death sentence in sub-Saharan Africa and other parts of the developing world. A decade ago, almost no one in Africa was receiving treatment. In 2011, over eight million men, women and children were on treatment in developing countries, with the vast majority of them in Africa. This is up from 6.6 million in 2010—an impressive increase of more than 20 percent.

Moreover, landmark scientific advancements have brought the world to a new era—a time when an AIDS-free generation is truly within our sights. In May 2011, a National Institutes of Health (NIH) randomized control trial documented for the first time that treatment also works as an extraordinarily effective tool for prevention. Initiation of ART by HIV-positive individuals substantially protected their HIV-negative sexual partners from acquiring HIV. Treatment lowered the viral load of HIV in a person with the virus, greatly reducing the risk of sexual transmission to a partner. ART produced an astonishing 96 percent reduction in risk of HIV transmission, on par with a vaccine.

America's contribution to the global AIDS fight on both the scientific and programmatic fronts has been immense. It was NIH that co-discovered the disease, and it has been our country's ongoing commitment to research that has helped produce breakthroughs that are driving a more aggressive response.

During the Clinton Administration, we began to make HIV treatment drugs more affordable, stepped up the fight against AIDS in Africa and India and expanded investments in scientific research. Under the leadership of President George W. Bush, the President's Emergency Plan for AIDS Relief (PEPFAR) was created in 2003 with bipartisan support from Congress, becoming the largest commitment by any nation to combat a single disease internationally.

Under the Obama Administration, the United States has strengthened this leadership and commitment. Through PEPFAR, as of September 30, 2012, the U.S. directly supported nearly 5.1 million people on antiretroviral treatment. That number is up from 1.7 million in 2008—a three-fold increase in only four years.

In Fiscal Year (FY) 2012 PEPFAR programs supported antiretroviral drugs to prevent mother-to-child transmission for nearly 750,000 pregnant women living with HIV. Thanks to this effort, an estimated 230,000 infant HIV infections were averted in 2012 alone. PEPFAR also supported HIV testing and counseling for more than 49 million in 2012. We are delivering these results despite the difficult budget environment.

These results are not just numbers, they represent lives saved and infections averted—and that is the true test of success. For PEPFAR, it is all about results. By adopting a targeted approach to address one of the most complex global health issues in modern history, and by then taking it to scale with urgency and commitment, the U.S. has helped demonstrate what is possible with focus, resources and science.

> "This is a global fight, and it's one that America must continue to lead…Looking back at the history of HIV/AIDS, you'll see that no other country has done more than this country, and that's testament to our leadership as a country. But we can't be complacent."
>
> -President Barack Obama

Our response to the global AIDS crisis has also strengthened the health sector in partner countries. While focusing on HIV, PEPFAR's investments have improved many elements of national systems resulting in more cost-effective delivery of essential health services. Clinics and hospitals once overwhelmed with AIDS patients now have the capacity to address many other health issues people in their communities face.

Beyond that, we have rebuilt hospitals and clinics, increased the quality and numbers of trained health care workers, and improved the efficiency of and cost-effectiveness of laboratory, supply chain and other fundamental health system components. Our focused investments have enabled access to basic health care where little or none existed. In countries with substantial PEPFAR investments, we have seen reductions in maternal, child and TB-related mortality, increased use of antenatal care and wider availability of a safe blood supply.

While our response has been tremendous, we have not acted alone. Partner governments, other donors and stakeholders, multilateral organizations, civil society—including faith-based and women's organizations—and people living with HIV have been vital collaborators. Our shared effort is helping to strengthen and support country ownership and to make national AIDS responses more successful and sustainable.

So there is great reason for hope. But we must also recognize the challenges we still face. According to UNAIDS, an estimated 1.7 million people are dying annually from AIDS-related causes. Global health and development resources are being squeezed due to difficult economic times. And issues of stigma and discrimination exist across the globe—including here in the United States—that continue to limit access to those in need.

While we cannot gloss over these challenges, we have also seen over the last decade that we can make great progress when we join together to tackle tough issues, underpinning our decision making with groundbreaking scientific advances that have brought the world to this point in the fight against AIDS.

As evidenced by this blueprint, PEPFAR is doing, and will continue to do, its part. This blueprint provides a strategic road map for saving even more lives and putting an AIDS-free generation within reach. The blueprint is PEPFAR's contribution to the fight against AIDS. We call upon the world to continue this journey with us. Through a truly global effort, we can achieve our shared goals.

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EXECUTIVE SUMMARY

On November 8, 2011, Secretary of State Hillary Rodham Clinton made the historic declaration that, thanks to new scientific evidence and success in implementing effective programs, the world is at the point where an AIDS-free generation is in sight. And on World AIDS Day 2011, President Barack Obama renewed the United States' commitment to end this pandemic "once and for all," announcing ambitious new prevention targets which include treating six million people with lifesaving medication by the end of 2013 and advancing other proven interventions to prevent the spread of HIV.

Secretary Clinton defined an AIDS-free generation as one where "virtually no children are born with the virus. As these children become teenagers and adults, they are at far lower risk of becoming infected than they would be today thanks to a wide range of prevention tools, and if they do acquire HIV, they have access to treatment that helps prevent them from developing AIDS and passing the virus on to others."

This is an ambitious, but reachable, goal—and now a policy imperative of the United States. That is why the Secretary called upon the President's Emergency Plan For AIDS Relief (PEPFAR) to produce this blueprint, providing a road map that clearly outlines PEPFAR's contribution to achieving an AIDS-free generation. This blueprint is therefore our promise—and our challenge—to the world. It reflects lessons learned from our almost ten years of experience with AIDS-related programs as well as our ongoing commitment to support countries in building sustainable health care systems that can deliver for the long term. Most of all, it sends an unequivocal message that the U.S. commitment to the global AIDS response will remain strong, comprehensive and driven by science.

When President George W. Bush created PEPFAR with the bipartisan support of Congress, its goal was to provide an emergency response to the global AIDS epidemic. During its first phase, PEPFAR was focused on addressing emergency health needs, establishing treatment sites, setting up supply chains, supporting testing and counseling and beginning to prevent mother-to-child transmission (PMTCT) of HIV. As the epidemic's tide was stemmed, and the foundations of a response were put in place primarily by PEPFAR, partner governments, civil society, and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), PEPFAR evolved to the natural next phase of helping countries build a long-term, sustainable response.

From PEPFAR's inception, the Office of Global AIDS Coordinator has played the unique role as a convener by assembling and drawing upon the expertise and experience of other U.S. government partners—The U.S. Agency for International Development; the Department of Health and Human Services, including the Centers for Disease Control and Prevention, and the Departments of Defense, Commerce and Labor, and the Peace Corps—to bring the full force of our government's capacity to the fight against global AIDS. Both within the United States and through our presence in many high-burden countries, PEPFAR broke the mold to tackle what was, and in many places remains, a devastating disease. We have also embarked upon an ambitious effort to integrate our HIV/AIDS and other global health programs where appropriate, and streamline our systems to avoid costly duplication.

As we enter the next phase of the program, the United States, through PEPFAR, remains firmly committed to doing its part to help make an AIDS-free generation a reality. Reaching this goal, however, is a shared responsibility, requiring the commitment and leadership of partner countries and reinforced with support from donor nations, civil society, people living with HIV, faith-based organizations, the private sector, foundations and multilateral institutions. It requires adapting to and adopting new science and evidence, both to reach more people and to capture cost-saving efficiencies. It means investing in the principle of country ownership—the end state in which partner countries lead, manage, coordinate and over time increasingly finance the efforts needed to

achieve an AIDS-free generation in order to ensure that the AIDS response is effective, efficient and durable.

The blueprint is intended to promote greater global investments and programmatic impact in the fight against AIDS. The U.S. leads the world in contributions in the fight against AIDS, having invested nearly $37 billion to date in bilateral funding and over $7 billion to the Global Fund since FY 2004. But even as we lead, other countries must step up, and in the end, we should all be measured not only by what we invest, but by the number of lives we help save.

PEPFAR's Principles for the Blueprint

The vision for this blueprint is simple: Scientific advances and their successful implementation have brought the world to a tipping point in the fight against AIDS. The United States believes that by making smart investments based on sound science, and a shared global responsibility, we can save millions of lives and achieve an AIDS-free generation.

To fulfill this vision, the blueprint is based on the following principles:

- Make strategic, scientifically sound investments to rapidly scale-up core HIV prevention, treatment and care interventions and maximize impact.
- Work with partner countries, donor nations, civil society, people living with HIV, faith-based organizations, the private sector, foundations and multilateral institutions to effectively mobilize, coordinate and efficiently utilize resources to expand high-impact strategies, saving more lives sooner.
- Focus on women and girls to increase gender equality in HIV services.
- End stigma and discrimination against people living with HIV and key populations, improving their access to, and uptake of, comprehensive HIV services.
- Set benchmarks for outcomes and programmatic efficiencies through regularly assessed planning and reporting processes to ensure goals are being met.

These principles drive PEPFAR's work and are the foundation for the road maps that comprise this blueprint. Each road map—the Road Map for Saving Lives; the Road Map for Smart Investments; the Road Map for Shared Responsibility; and the Road Map for Driving Results with Science—contains specific goals and comprehensive action and implementation steps on how PEPFAR will support partner countries' efforts to meet these goals.

Road Map for Saving Lives

This road map addresses the Secretary's call in her November 8, 2011 speech to scale up combination HIV prevention and treatment interventions to save more lives.

Specifically, the section outlines PEPFAR's plan to:

1. Work toward the elimination of new HIV infections among children by 2015 and keeping their mothers alive.
2. Increase coverage of HIV treatment both to reduce AIDS-related mortality and to enhance HIV prevention.
3. Increase the number of males who are circumcised for HIV prevention.
4. Increase access to, and uptake of, HIV testing and counseling, condoms and other evidence-based, appropriately-targeted prevention interventions.

Through its continued support for scale-up of combination prevention and treatment interventions in high-burden countries, PEPFAR will help countries reduce new HIV infections and decrease AIDS-related mortality, while simultaneously increasing the capacity of countries to sustain and support these efforts over time. This support will, in turn, move more countries past the programmatic tipping point in their HIV epidemics—the point at which the annual increase in new patients on ART exceeds annual new HIV infections—and put them on the path toward achieving an AIDS-free generation.

Road Map for Smart Investments

To achieve an AIDS-free generation, countries must target efforts where the virus is—reaching and supporting those populations at greatest risk and urgently needing services. Accordingly, PEPFAR will work with countries to scale-up activities that have a strong evidence base to produce a

population-level impact. We will not support interventions that fail to target the epidemic. Concurrently, we will work to realize efficiency gains to deliver greater results for our investment. We have vastly increased PEPFAR's value for money by reducing the cost of antiretroviral drugs (ARVs), streamlining supply chains, and working with partner countries to increase their investments, and this work will remain a PEPFAR priority. We will also continue to lead efforts to strengthen the Global Fund, which leverages U.S. contributions two times with contributions from other donors. This road map outlines how we will follow the epidemic, invest in evidence-based interventions, and continue to generate value for money in our fight against AIDS.

Specifically, this road map outlines PEPFAR's plan to:

1. Target HIV-associated tuberculosis (TB) and reduce co-morbidity and mortality.
2. Increase access to, and uptake of, HIV services by key populations.
3. Partner with people living with HIV to design, manage and implement HIV programs to ensure that they are responsive to, and respectful of, their needs.
4. Strengthen PEPFAR's continued focus on women, girls and gender equality.
5. Reach orphans and vulnerable children (OVC) affected by AIDS, and support programs that help them develop to their full potential.
6. Strengthen programmatic commitment to and emphasis on reaching and supporting young people with HIV services.
7. Strengthen PEPFAR supply chains and business processes to increase the efficiency of our investments.
8. Increase efficiencies through innovation and greater integration of services with other U.S., bilateral and multilateral global health investments.

Road Map for Shared Responsibility

As stated earlier, the goal of creating an AIDS-free generation is a shared responsibility with partner countries in a convening role. Neither the U.S. nor any other single entity can accomplish this goal alone. Rather, it requires a country to demonstrate political will and effective coordination of multiple partners that are providing financing and carrying out interventions both inside and outside of the health sector, and most importantly, meaningfully involve those living with and affected by HIV in all aspects of the response.

Specifically, this road map outlines PEPFAR's plan to:

1. Partner with countries in a joint move toward country-led, managed, and implemented responses.
2. Increase support for civil society as a partner in the global AIDS response.
3. Expand collaboration with multilateral and bilateral partners.
4. Increase private sector mobilization toward an AIDS-free generation.

Road Map for Driving Results with Science

Science has brought us to the point where we can actually call for an AIDS-free generation. And it is science that will underpin all our efforts to achieve this goal and save even more lives. To deliver the greatest response, PEPFAR will continue to support programs guided by scientific evidence—we will go where the science takes us, translating science into program impact.

Specifically, this road map outlines PEPFAR's plan to:

1. Leverage greatest impact by continuing to invest in implementation science.
2. Support implementation research.
3. Evaluate the efficacy of optimized combination prevention.
4. Support innovative research to develop new technologies for prevention (e.g., microbicides, vaccines) and care (e.g., new treatments or treatment regimens).
5. Develop evidence-based approaches to reaching people early enough in their disease progression to help maintain a strong immune system, stave

off opportunistic infections, particularly TB, and reduce new HIV infections.

6. Support the deployment of suitable technology for measurement of viral load, both through tiered laboratory networks and 'point-of-care' tests as they become available.
7. Assist countries in adopting breakthrough new technologies with proven impact, such as new, molecular-based TB tests that have dramatically reduced diagnosis and treatment time for people living with TB and HIV.

The Opportunity Proposition: Illustrative Country Scenarios for Accelerated Progress toward Achieving an AIDS-free Generation

Globally, new HIV infections have declined nearly 19 percent over the past decade, and AIDS-related mortality has decreased by 26 percent since its peak in 2005.[1] In sub-Saharan Africa, progress has been even more marked, with new infections down by 22 percent over the past decade, and AIDS-related mortality declining by 31 percent since its peak in 2005.[2] These are encouraging trends, but more work remains to be done. In 2011 alone, an estimated 2.5 million people were newly infected with HIV, and 1.7 million people died of AIDS-related causes.[3]

Through rapid scale up of high-impact HIV combination prevention interventions, including antiretroviral treatment (ART), the global community can ultimately achieve an AIDS-free generation. One way of measuring progress toward this goal, in a country or globally, is to compare the number of new HIV infections with the increase in new patients on treatment over a given time period. By reducing infectivity while rapidly increasing coverage of ART, it is possible to bring the number of annual new HIV infections below the annual increase in new patients on ART—achieving what many have called a programmatic "tipping point" in the epidemic. This scale up will also have many broader social benefits. For example, in high HIV prevalence settings in sub-Saharan Africa, the U.S. Centers for Disease Control and Prevention (CDC) has estimated that for every 1,000 patients treated for one-year in the PEPFAR program, 449 children avert orphanhood due to the lifesaving effects of ART.[4] Table 1 illustrates country progress in moving toward—and in some cases beyond—this tipping point, as evidenced by this ratio.

Table 1: Country Progress in Reducing New HIV Infections and Scaling up of Antiretroviral Treatment

Country	2011 New HIV Infections	2011 Increase in New Patients on Treatment	Ratio of New HIV Infections to Increase in New Patients on Treatment
Botswana	8,500	17,811	0.5
Cote d'Ivoire	13,000	6,844	1.9
DRC	46,000*	9,375	4.9
Ethiopia	11,000	40,507	0.3
Kenya	91,000	93,912	1.0
Lesotho	22,000	5,845	3.8
Mozambique	100,000	48,912	2.0
Namibia	80,000	14,539	0.6
Nigeria	270,000	56,789	4.8
Rwanda	8,400	4,083	2.1
South Africa	350,000	276,017	1.3
Swaziland	12,000	11,751	1.0
Tanzania	120,000	31,700**	3.8
Uganda	120,000	60,014	2.0
Zambia	42,000	66,479	0.6
Zimbabwe	60,000	142,155	0.4

* Official data not available for new HIV infections; data generated through internal PEPFAR modeling.

**Due to concerns about data validity, the ratio shown for Tanzania was calculated using the increase in new patients on ART directly supported by PEPFAR in 2011.

Source: UNAIDS 2012 World AIDS Day Report

Bringing the ratio of new HIV infections to the increase in new patients on ART below 1.0, as several countries have achieved, is one measure that a country is getting ahead of its epidemic.[5] The global AIDS response will require continued commitment from many partners for years to come; yet, countries that achieve—and progress beyond—this tipping point lay the foundation for more successful, country-driven and economically-sustainable responses moving forward. PEPFAR is firmly committed to help countries in moving toward and beyond this tipping point—and in progressing toward achieving an AIDS-free generation.

[1] Together We Will End AIDS. UNAIDS. July 2012.
[2] Together We Will End AIDS. UNAIDS. July 2012.
[3] Together We Will End AIDS. UNAIDS. July 2012.
[4] Blandford, J, Presentation to PEPFAR Scientific Advisory Board, September 14, 2011.
[5] For countries that have already achieved high ART coverage, this ratio may less accurately reflect their progress toward achieving an AIDS-free generation. In such cases, earlier ART expansion has resulted in less unmet need for ART, and thereby relatively fewer patients to be newly initiated on ART.

The following illustrative country examples demonstrate the potential impact of bringing combination prevention interventions to scale by modeling the effect on the estimated adult HIV incidence rate[6] under three different scenarios in Zambia, Kenya, Uganda and Cambodia. These countries are used in this modeling because they are generally representative of four different stages toward achieving an AIDS-free generation. Thereby, they help to highlight the broader implications of selecting different policy and programmatic approaches as all countries move forward in their respective AIDS response. These scenarios, which are drawn from data on these four countries, suggest that through robust scale-up of high-impact combination prevention interventions, with support from all partners, these and other countries can get on the path toward achieving an AIDS-free generation in the next 3-5 years.

In each of the illustrative graphs below, the baseline scenario models out the expected impact on the adult HIV incidence rate of holding programmatic coverage steady at 2011 levels. The combination prevention with treatment scale-up (CD4 350 cells/mm^3 scenario) includes the expected impact of concurrently increasing coverage rates of a combination prevention package comprising prevention of mother-to-child transmission (PMTCT), voluntary medical male circumcision (VMMC), HIV testing and counseling (HTC), condoms and ART for individuals with CD4 counts below 350 cells/mm^3. Finally, the combination prevention with treatment scale-up (CD4 550 cells/mm^3 scenario) includes the expected impact of concurrently increasing coverage rates of this same combination prevention package but with ART for individuals with CD4 counts below 550 cells/mm^3.

This third scenario reflects the growing body of evidence, including from the groundbreaking HIV Prevention Trials Network (HPTN) 052 study[7], which suggests that early initiation of ART can result in reduced opportunistic infections, and fewer HIV-transmission events. The forthcoming 2013 WHO guidelines will consider this new evidence in providing guidance to countries on ART initiation. As countries approach saturation in treatment coverage for individuals with CD4 counts below 350 cells/mm^3, many may consider making ART available to individuals with CD4 counts above this treatment eligibility threshold.

Zambia

As Secretary Clinton noted at the 2012 International AIDS Conference, Zambia represents a country where the government has worked with PEPFAR and other partners to implement a shared response that is gaining momentum in the fight against HIV. National efforts to scale up PMTCT programs, with substantial support from PEPFAR, led to a steep drop in the number of new pediatric HIV infections between 2009 and 2011. Zambia has already brought the annual number of new HIV infections below the annual increase in new patients on ART—indicating that the country is beyond the programmatic tipping point and on the path toward achieving an AIDS-free generation.

PEPFAR has played a pivotal role in helping Zambia to realize this progress, including by directly supporting ART for 359,600 Zambians as of 2011. Zambia's simultaneous scale-up of VMMC and ART will further decrease new sexually transmitted infections (STIs) in the coming years. Zambia's declining adult HIV incidence rate and high ART coverage indicates that while Zambia is progressing toward achieving an AIDS-free generation continued work is needed to solidify and sustain the country's gains.

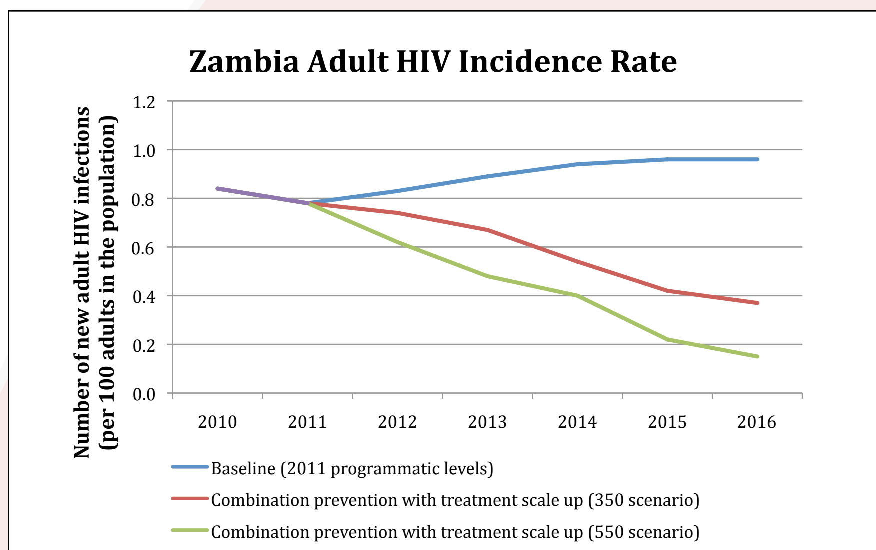
Due to Zambia's already high level of ART coverage, reaching 80 percent treatment coverage for individuals with CD4 counts below 350 cells/mm^3 would only require the addition of an estimated 145,300 patients between 2012 and 2016. By reducing its adult incidence rate under the combination prevention with treatment scale-up (CD4 350 cells/mm^3 scenario), as illustrated in Graph 1, Zambia would be able to avert a total of over 126,000 HIV infections between 2012 and 2016, as compared to the baseline scenario. As Zambia approaches the saturation point for treatment coverage for those with CD4 counts below 350 cells/mm^3, it has already begun to expand the treatment eligibility threshold through policies that provide lifelong treatment to people living with HIV in a serodiscordant partnership. As in many other countries, policy discussions surrounding the adoption of Option B+[8] are also currently under way in Zambia.

Given this national context, for Zambia to expand the universe of individuals eligible for treatment in the country, including all clients with CD4 counts below

[6] The adult HIV incidence rate represents the number of new HIV infections per 1,000 adults in the population over the period of a year.

[7] The HPTN 052 study found that early initiation of ART (providing treatment to individuals with CD4 counts between 350 cells/mm^3-550 cells/mm^3 cells/mm^3) led to a 96% reduction in HIV transmission. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2011; 365(6):493-505.

[8] Option B+ is a simplified test and treat approach for pregnant women where all HIV-positive pregnant women are initiated on lifelong ART regardless of how far their disease has progressed.



Graph 1: Zambia Adult HIV Incidence Rate declines under various scenarios.

550 cells/mm³ is a potentially impactful policy option, and analysis indicates that such an approach would steepen the estimated HIV incidence decline. Raising the treatment threshold to 550 cells/mm³ would require providing ART to an additional 197,600 individuals with CD4 counts above 350 cells/mm³ by 2016, but would be expected to result in a substantial drop in the number of new HIV infections in the country.

As illustrated in Graph 1, compared to the baseline scenario, the combination prevention with treatment scale-up (CD4 550 cells/mm³ scenario) would avert a total of 179,200 new HIV infections in Zambia—representing a 57 percent decline in infectivity—over a four-year period. This expansion of the treatment envelope would also result in approximately 118,000 fewer AIDS-related deaths relative to the baseline scenario. Such analysis suggests that in countries like Zambia, increasing the treatment threshold in accordance with national capacity offers a realistic, sustainable path toward helping achieve an AIDS-free generation.

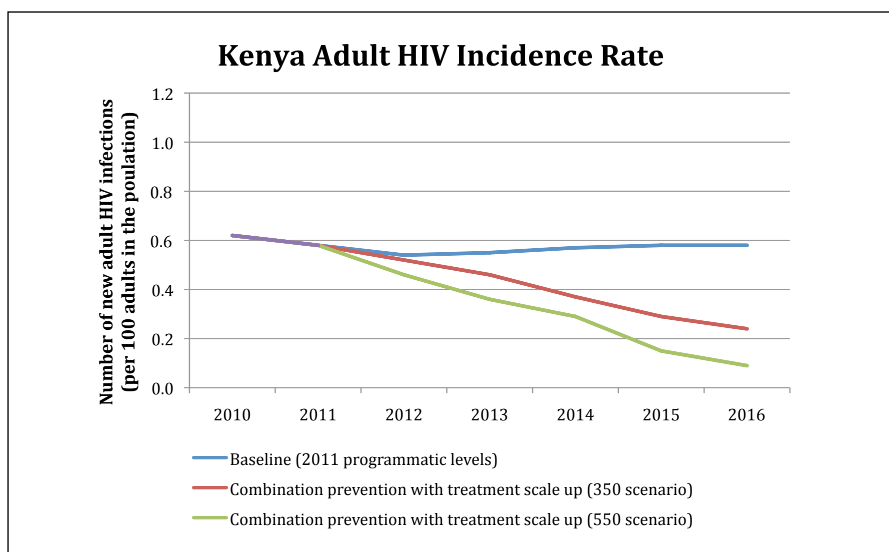
Kenya

With an estimated 1.3 to 1.6 million people living with HIV, Kenya continues to have one of the heaviest disease burdens in the world. In recent years, increased access to ART, effective prevention strategies and an ambitious VMMC program that aims to circumcise one million men by 2013 have helped to stabilize the epidemic. Kenya's progress has substantially reduced the number of new HIV infections in the country. Aggressive expansion of treatment targets and other high-impact prevention interventions has brought the ratio of new HIV infections to the annual increase in new patients on ART to 1.0.

PEPFAR has provided strong support to Kenya in driving down this ratio, including by directly supporting ART for 493,900 Kenyans as of 2011. Yet coverage rates of some core combination prevention interventions lag behind those of countries such as Zambia. Continued scale-up is needed to place the epidemic on a steeper downward trajectory and to further reduce this ratio. Rolling out lifelong ART for all pregnant women living with HIV will also be a key aspect of this scale-up, and Kenya has already begun a phased transition to Option B+ for pregnant women living with HIV.

As illustrated in the combination prevention with treatment scale-up (CD4 350 cells/mm³ scenario) in Graph 2, by achieving 94 percent VMMC coverage, 80 percent ART coverage for individuals with CD4 counts below 350 cells/mm³, and scaling up other combination prevention interventions, Kenya could avert a total of approximately 222,600 new HIV infections and 159,900 AIDS-related deaths between 2012 and 2016, as compared to the baseline scenario.

As Kenya approaches the saturation point in treatment coverage for individuals with CD4 counts below 350 cells/mm³, national policymakers will likely turn to new strategies in order to maintain momentum in combating the epidemic—as mentioned above, a trend that is already under way with Kenya's decision to implement Option B+. In Kenya, making ART available to all individuals with CD4 counts below 550 cells/mm³ would result in an additional 481,404 ART patients in 2016 compared to a CD4 350 cells/mm³ scenario.



Graph 2: Kenya Adult HIV Incidence Rate declines under various scenarios.

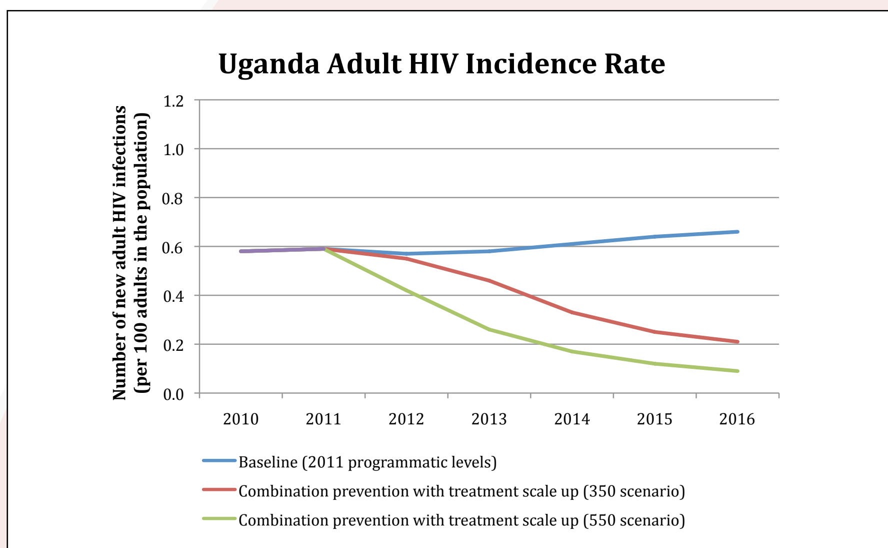
As is further illustrated in Graph 2, the impact of such a rapid and sizeable increase in the number of Kenyans receiving ART would be substantial. Under the combination prevention with treatment scale-up (CD4 550 cells/mm^3 scenario), Kenya could avert a total of approximately 333,300 new HIV infections and 258,000 AIDS-related deaths between 2012 and 2016, as compared to the baseline scenario. This suggests that a 550 cells/mm^3 threshold for treatment would dramatically accelerate Kenya's progress toward achieving an AIDS-free generation.

Uganda

Although Uganda was one of the first countries to launch a high-profile national response to the AIDS crisis, in recent years policy and programmatic issues have hampered attempts to accelerate VMMC, PMTCT and ART programs. Indications are that new HIV infections continue to far outpace the annual increase in new patients on ART in the country, as is evidenced by Uganda's ratio of 2.3 in Table 1. Despite these challenges, PEPFAR has made a significant contribution to Uganda's efforts to scale up treatment, including by directly supporting ART for 257,700 Ugandans as of 2011. However, according to the 2011 WHO Progress Report on the Global HIV/AIDS Response, Uganda's overall treatment coverage remains relatively low at 47 percent. At present, despite PEPFAR's substantial investment in the country, Uganda is one of the few countries with developed HIV programs where national incidence is increasing.

Despite this trend, analysis indicates that more rapid national scale-up of combination prevention interventions, including ART, can reverse the course of Uganda's epidemic. Under an accelerated combination prevention approach, Uganda could achieve 80 percent ART coverage for individuals with CD4 counts below 350 cells/mm^3, while continuing the current pace of scale-up for condoms and HTC. The acceleration scenario also assumes the pace of scale-up for VMMC will increase as improvements in health systems and program infrastructure allow VMMC programs to reach the national-level target of 80 percent VMMC coverage by 2015. Uganda is one of a number of countries that has begun implementing Option B+ by providing pregnant women living with HIV with treatment for life regardless of CD4 count. The national PMTCT program will further contribute to increasing the number of new patients on ART and of HIV infections averted.

As illustrated in Graph 3, the combination prevention with treatment scale-up (CD4 350 cells/mm^3 scenario) could avert a total of approximately 226,829 HIV infections between 2012 and 2016 (a 43 percent decrease), as compared to the baseline scenario. This rapid decline in incidence could also result in an estimated 101,700 total fewer adult AIDS-related deaths in Uganda between 2012 and 2016. While Uganda still has substantial room to improve coverage under its current ART guidelines, a future move to a higher CD4 cell count treatment eligibility threshold could further reduce new HIV infections.



Graph 3: Uganda Adult HIV Incidence Rate declines under various scenarios.

Cambodia

Cambodia, unlike Zambia, Kenya and Uganda, represents a concentrated HIV epidemic. The country has received international recognition for scaling up HIV programs that are grounded in strong national leadership on AIDS, based on sound policy frameworks supported by adequate levels of resources and implementation capacity, and which maximize partner coordination and collaboration. These elements have proven successful in a national HIV epidemic that is primarily sexually-driven, with the greatest burden among key population groups (e.g., men who have sex with men (MSM), sex workers (SW), and people who inject drugs (PWID)). In 2010, adult HIV prevalence was estimated to be 0.7 percent[9], compared to 2.0 percent[10] in 1998—a reduction of 65 percent. In addition to introducing the 100 percent Condom Policy, Cambodia has successfully extended HIV treatment to over 80 percent[11] of eligible individuals.

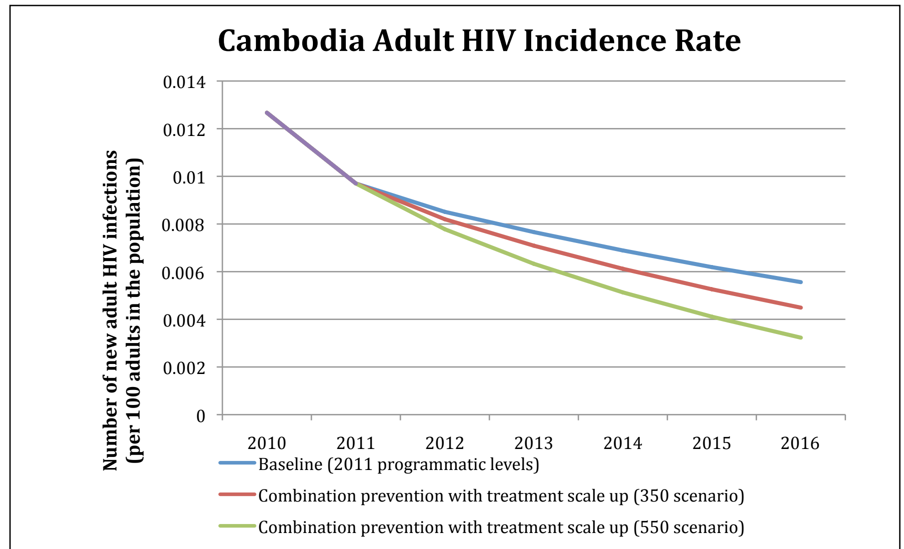
In September 2011, the United Nations recognized Cambodia with an international award for the early achievement of its Millennium Development Goals for HIV/AIDS. Cambodia's success is largely due to its commitments to use limited resources where they are most needed by collecting and applying data to identify priorities, delivering health services to address the greatest needs and developing policies and strategies to enhance access to and utilization of these services. The U.S. government has contributed substantially to Cambodia's achievements in fighting AIDS, having provided over $145 million[12] in support through PEPFAR since 2004, as well as through U.S. contributions to the Global Fund, which has approved over $188 million in HIV funding[13] for Cambodia to date. In collaboration with the Royal Government of Cambodia and other donors, PEPFAR helped to establish the surveillance, service delivery and quality assurance platforms needed to achieve this success.

Cambodia's current strategy focuses on delivering a combination prevention service package for key populations, including peer education; targeted behavioral interventions; access to condoms; HTC; ART; diagnosis and treatment of STIs; reproductive health and family planning services; and linkages to other health and social services. By placing limited resources where evidence shows they will have the greatest impact, Cambodia has established itself as a global leader in the fight against AIDS. To sustain this success and to move toward achieving an AIDS-free generation, it will be important for the Royal Government of Cambodia and its partners to continue investing in high-impact, cost-effective combination prevention interventions. Moreover, it will be critical to address stigma, discrimination and other legal barriers to ensure access to services by key populations, and keep Cambodia ahead of its epidemic.

As illustrated in Graph 4, by continuing investment in combination prevention interventions—under the

[9] Cambodia Country Progress Report: Monitoring the Progress towards the Implementation of the Declaration of Commitment on HIV and AIDS, Reporting Period January 2008 – December 2009.
[10] Report of a Consensus Workshop: HIV Estimates and Projections for Cambodia 2006 – 2012. Ministry of Health National Center for HIV/AIDS, Dermatology and STD.
[11] UNAIDS World AIDS Day Report, 2011.
[12] http://www.pepfar.gov/documents/organization/199572.pdf
[13] http://portfolio.theglobalfund.org/en/Country/Index/CAM

Graph 4: Cambodia Adult HIV Incidence Rate declines under various scenarios.



combination prevention with treatment scale-up (CD4 350 cells/mm3 scenario), or the combination prevention with treatment scale-up (CD4 550 cells/mm^3 scenario)—Cambodia could further reduce the number of new HIV infections compared to the baseline scenario by more than 25 or 50 percent respectively over the next five years.

Rapid Scale up of Combination Prevention Can Reduce Resource Needs and Support Sustainability

The challenge ahead is to scale up effective combination prevention quickly enough to have a transformative impact on the epidemic and make national AIDS responses sustainable over time. This requires strategic reallocation of existing resources toward high-impact interventions, and increased and sustained investments through shared responsibility, led by countries, with support from donors and other partners.

While the upfront costs associated with scaling up combination prevention toward realizing the potential adult HIV incidence rate declines depicted in the country scenarios above are substantial, these investments do not result in ever-increasing costs. In fact, as is illustrated by the Uganda estimates[14] in Graph 5, the impact of these upfront investments lead to a decline and then flattening of out-year costs, as fewer new services are required and the number of newly infected individuals falls substantially.

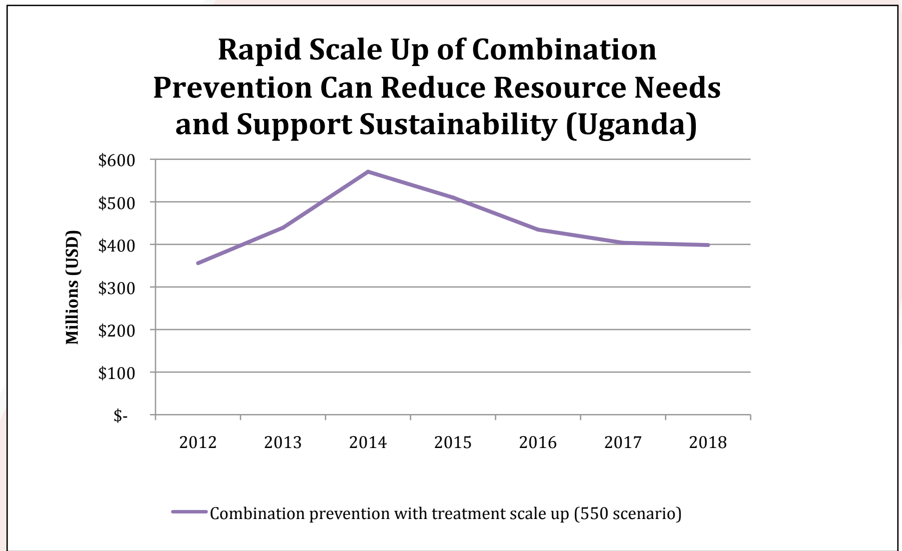
Strong country ownership and optimized investments can put countries on the path toward an AIDS-free generation, and support efforts to make AIDS responses more economically-sustainable over time.

Estimated Proportional Contributions of Core Combination Prevention Interventions to HIV Infections Averted

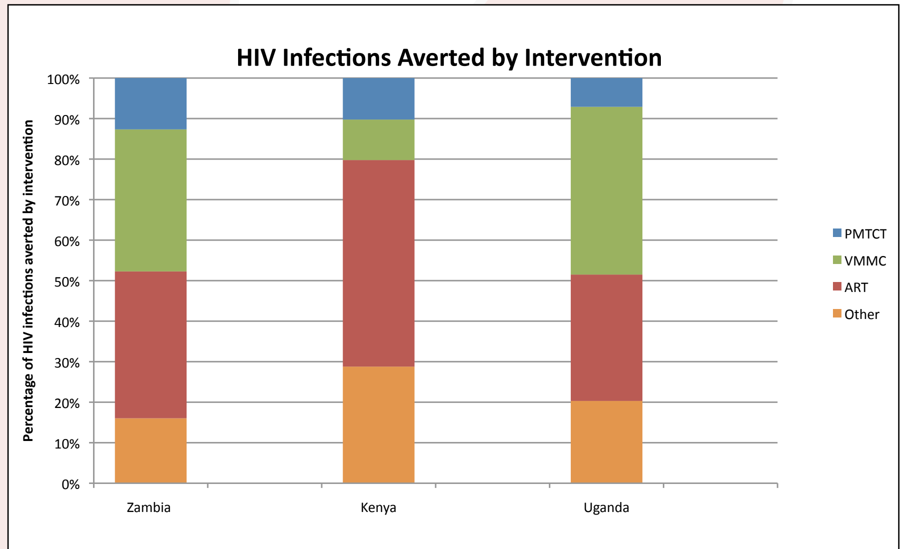
While the impact of individual interventions with the core combination prevention package are not easily compartmentalized—particularly given that these interventions work best when implemented in concert—it is possible to roughly compare interventions and their relative impact on averting new HIV infections. Graph 6 highlights the estimated proportional contribution of each core combination prevention intervention—PMTCT, VMMC, ART; as well as HTC, condoms and other evidence-based and appropriately targeted prevention activities (collectively represented below as "Other")—through 2016. ART and VMMC clearly make major contributions in averting new HIV infections in each epidemic; however, there are complex interrelationships that make each core intervention important in helping each country progress toward achieving an AIDS-free generation. In particular, ongoing expansion of HTC remains vital as a gateway to successful scale up of all interventions within the core combination prevention package.

[14] Data are U.S. government estimates based on global data.

Graph 5: Rapid Scale Up of Combination Prevention Can Reduce Resource Needs and Support Sustainability (Uganda).



Graph 6: HIV Infections Averted by Intervention.



ROAD MAP FOR SAVING LIVES

PEPFAR GOAL: Scale Up Combination Prevention and Treatment

ACTION STEPS

- Work toward the elimination of new HIV infections among children by 2015 and keeping their mothers alive.
- Increase coverage of HIV treatment both to reduce AIDS-related mortality and to enhance HIV prevention.
- Increase the number of males who are circumcised for HIV prevention.
- Increase access to and uptake of HIV testing and counseling, condoms, and other evidence-based and appropriately targeted prevention interventions.

Scientific innovation, research advances and implementation success, combined with increasing efficiencies in delivery and effectiveness of services, have put the promise of an AIDS-free generation within sight. To help achieve this goal, PEPFAR is committed to making strategic, scientifically-sound investments to rapidly scale up HIV prevention, treatment and care interventions, particularly in high-burden countries. PEPFAR's combination HIV prevention strategy comprises a core set of interventions that, particularly when pursued in concert, provide us with the potential to end the epidemic: prevention of mother-to-child transmission (PMTCT) of HIV; antiretroviral treatment (ART) for people living with HIV; voluntary medical male circumcision (VMMC) for HIV prevention; and HIV testing and counseling (HTC), condoms, and other evidence-based and appropriately-targeted prevention activities. These are not only the most effective interventions; they are also the most cost-effective interventions that we have at our disposal.

> "And there's no greater priority – and this is something our American citizens must understand and our government must understand – there is no greater priority than living out the admonition: To whom much is given, much is required. We're a blessed nation in the United States of America. And I believe we are required to support effective programs that save lives."
>
> -President George W. Bush

Scientific advances and implementation experience have shown that these core interventions work best not only when they are used in combination, but also when the specific mixture of interventions is tailored to country conditions, including by taking into account epidemiology, the social and cultural context and treatment cost-effectiveness. Success in saving lives also depends on promoting and supporting institutional and social changes, such as ending stigma and discrimination against key populations (e.g., men who have sex with men (MSM), sex workers (SW), and people who inject drugs (PWID)), as well as people living

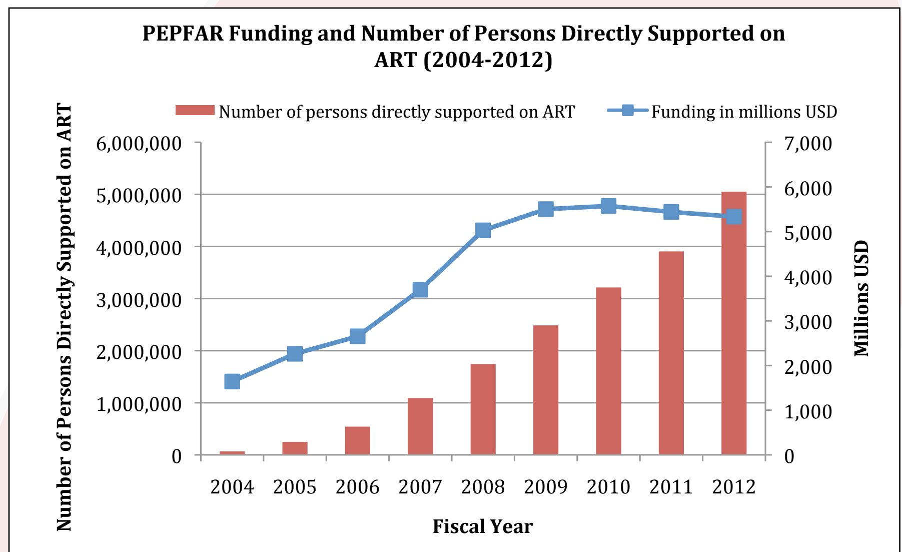


Figure 1. PEPFAR funding and number of persons directly supported on ART (2004–2012). Source: Office of the US Global AIDS Coordinator.

with HIV (PLHIV); promoting gender equality, including education for girls along with economic opportunities and assets for women; preventing and addressing gender-based violence (GBV) and exploitation which continue to put women and girls at higher risk for HIV infection; and repealing laws that penalize people simply because of their sexual orientation.

Through its continued support for scale-up of this core combination prevention package, particularly in high-burden countries, PEPFAR will assist in reducing new HIV infections and decreasing AIDS-related mortality, while simultaneously increasing countries' capacity to sustain these efforts over time. This will, in turn, move more countries past the tipping point in their HIV epidemics—the point at which the annual increase in new patients on ART outpaces annual new HIV infections—and put them on the path toward achieving an AIDS-free generation.

PEPFAR Goal: Scale-Up Combination Prevention and Treatment

Action Step: Work toward the elimination of new HIV infections among children by 2015 and keeping their mothers alive.

Prevention of mother-to-child transmission (PMTCT) of HIV is a critical component of PEPFAR's work to save lives and to help create an AIDS-free generation. The good news is that we know that virtual elimination of mother-to-child transmission of HIV is possible because it has been achieved in most high- and many middle-income countries, including several countries in sub-Saharan Africa. The extraordinary efficacy of high quality PMTCT interventions is long-established, and no significant scientific or technical barriers stand in the way of achieving this same goal in low- and middle-income countries where babies are still being born with HIV.

Preventing new HIV infections among children and keeping their mothers alive is not only a moral imperative, it is also one of the best investments the world can make to address AIDS. Through comprehensive PMTCT programs, we not only keep mothers and babies alive and healthy, we also support healthier and more productive families and communities. Moreover, when a pregnant woman living with HIV enters the health care system, it provides an opportunity to link the rest of her family with highly effective interventions, such as HTC, VMMC, family planning services and other health services.

In Fiscal Year (FY) 2012, PEPFAR PMTCT programs had their highest results ever. The U.S. government supported antiretroviral medications to prevent mother-to-child transmission of HIV for nearly 750,000 women living with HIV. This allowed approximately 230,000 infants who would otherwise have been infected to be born HIV-free. By the end of FY 2013, PEPFAR is on track to reach more than 1.5 million additional pregnant women living with HIV with antiretroviral medicines to protect children from infection.

Since its launch in 2004, PEPFAR has supported countries to substantially reduce mother-to-child transmission

Photo Credit: Peace Corps

(MTCT) of HIV. Globally, the number of annual new pediatric infections has been nearly cut in half, from a peak of 570,000 in 2003 to 330,000 new HIV infections in children in 2011[15]. This extraordinary progress is due in large part to consistently increasing PEPFAR investments in PMTCT and a global effort to scale-up PMTCT services. Equally important, the science around PMTCT has evolved tremendously. In the past, one dose of a single antiretroviral drug—Nevirapine—was our only tool to prevent MTCT of HIV. It reduced the likelihood that a mother living with HIV would pass the virus to her infant to approximately 12-15%. Today, we have highly efficacious triple antiretroviral drug (ARV) combinations—the same medicines used for adult treatment—that can reduce MTCT of HIV to less than 5%. PEPFAR has been instrumental in encouraging countries to adopt World Health Organization (WHO) guidelines and transition from single-dose Nevirapine to the most efficacious ARV regimens, better protecting infants from HIV while improving the health of mothers living with HIV. PEPFAR continues to work with WHO to encourage consideration of adoption of rapidly evolving PMTCT guidance related to options such as B+ that can broaden PMTCT benefits and simplify operational delivery.

PEPFAR is committed to finding more effective ways to retain mothers living with HIV in care and on ART, not only through delivery and breast-feeding but also throughout their lives. This will ensure that their own health is optimally protected while simultaneously preventing MTCT throughout their reproductive years. It is better for the medical delivery system and women to make it unnecessary to re-identify mothers living with HIV—sometimes very late in pregnancy—and re-initiate them on ARVs with each successive pregnancy, particularly in countries with high fertility rates.

PEPFAR has long made PMTCT a priority, and it continues to scale up this work across its program portfolio. In June 2011, PEPFAR and UNAIDS, along with other partners, launched the *Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping their Mothers Alive* (Global Plan) at the United Nations General Assembly High Level Meeting on AIDS. The Global Plan's central goals are to reduce the number of new HIV infections among children by 90 percent by 2015, and reduce AIDS-related maternal mortality by 50 percent by supporting accelerated action in 22 priority countries that account for nearly 90 percent of new pediatric HIV infections globally. Through the Global Plan, high-burden countries are already achieving real results. From 2009 to 2011, the number of children being newly infected with HIV globally declined by 24 percent[16]. Botswana saw a 29 percent reduction in new pediatric infections between 2009 and 2011; in Namibia there was a 58 percent reduction; and Zimbabwe achieved a 45 percent reduction during the same time period[17].

To implement this action step, PEPFAR is and will:

1. Support country-led implementation of the WHO's comprehensive four-pronged approach

[15] Together We Will End AIDS. UNAIDS. July 2012.
[16] Together We Will End AIDS. UNAIDS. July 2012.
[17] Together We Will End AIDS. UNAIDS. July 2012.

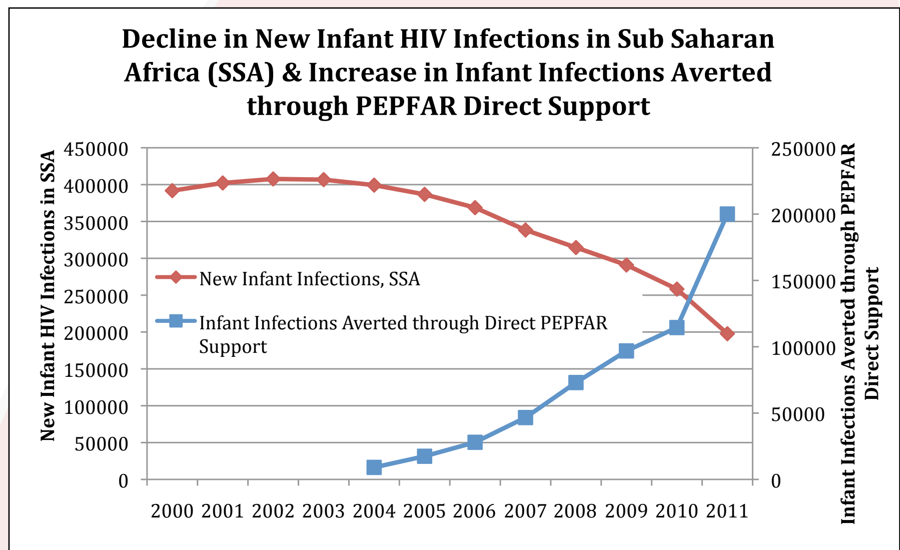


Figure 2. Source: Office of the US Global AIDS Coordinator.

to PMTCT, working toward the goals of the Global Plan—the elimination of new HIV infections among children and keeping their mothers alive.

Prong 1: Invest in high-impact, evidence-based interventions to prevent HIV infection among women of childbearing age, including interventions targeting male partners of these women. Specifically, PEPFAR will support:

a) HIV testing and counseling (HTC) as a gateway to other effective interventions, both in the community and through providers, supported by strong linkages to care and treatment for those testing positive, and to other prevention programs for those testing negative.

b) Interventions targeting male partners:

  i. ART for discordant couples, including ART for HIV-positive partners regardless of CD4 count, where supported by national guidelines.

  ii. Voluntary medical male circumcision (VMMC).

c) Condom provision and promotion, including female condoms, supported by risk reduction counseling and coaching on condom negotiation.

d) HIV services for women in key populations, as well as populations with high prevalence.

e) Economic strengthening and other structural interventions to help women avoid high-risk behaviors and situations, where appropriate; gender-based violence reduction activities.

Prong 2: Support women living with HIV to make informed decisions about their future reproductive life, with special attention to preventing unintended pregnancies. Specifically, PEPFAR will:

a) Continue to leverage support for family-planning commodities (including long-acting reversible contraceptives) purchased by USAID and other partners to ensure that facilities offering PMTCT also offer voluntary comprehensive family planning services to all women, regardless of their HIV status. Referral to facilities offering voluntary family planning will be established wherever direct integration of PEPFAR-supported PMTCT services and family planning services that are supported by other partners is not possible.

Prong 3: Provide the most efficacious antiretroviral medication to prevent mother-to-child transmission of HIV during pregnancy and breastfeeding. Specifically, PEPFAR will:

a) In accordance with current WHO guidelines and national policies, support the provision of the most efficacious regimens to all women and infants, working to ensure that all eligible women receive lifelong ART.

b) Support countries that choose to transition to Option B or Option B+[18] in implementing this policy and programmatic shift.

c) Support critical cross-cutting systems strengthening interventions to enhance PMTCT outcomes, including:

   i. Laboratory capacity strengthening and quality assurance.

   ii. Support for task-shifting where appropriate and for strengthened human resources for health, including support for development and codification of standards of practice, pre-service and in-service training.

   iii. Community-based activities, including demand generation; ensuring better community-facility linkages to improve retention and adherence; and innovative community-based service delivery models.

   iv. Strategic information, including enhanced monitoring and evaluation to identify programmatic bottlenecks and to track retention and adherence.

   v. Effectiveness evaluation to measure the population-level impact of PMTCT programs.

   vi. Expenditure and costing analyses.

d) Enhance efforts to improve linkages and strengthen referrals where they occur. Wherever feasible, cost-effective and appropriate within national context, PEPFAR will support countries to move toward more integrated service delivery models, including decentralization of ART and other key services to lower level facilities, such as models allowing family-based care to be provided at a single "one-stop" location. As PMTCT and ART programs become increasingly integrated, ensuring that the full package of maternal health services and ART services are offered together is a key priority.

e) Work to improve retention in the PMTCT cascade, wherever feasible, by providing point-of-care diagnostic machines or transferring samples, rather than patients, for diagnostic testing (e.g., CD4) for rapid test result turn-around. Other priority approaches to improving retention and adherence include engaging civil society to ensure that service delivery models are developed to meet the needs of women and children, and involving mentor mothers and other lay counselors in providing comprehensive quality services.

Prong 4: Provide ongoing care, support, and treatment for women living with HIV and their families. Specifically, PEPFAR will:

a) Support PMTCT programs toward the primary goals of preventing new HIV infections among children and keeping their mothers alive.

b) Work to ensure that regardless of a country's guideline choice, scale-up of PMTCT services includes a concomitant expansion of treatment for eligible pregnant women, and early infant diagnosis (EID) for all HIV-exposed infants as well as pediatric treatment for all infants identified as HIV-positive.

   i. EID is critical not only to identify HIV-positive infants and early initiation of ART to preserve cognitive and growth development, but also as a tool to demonstrate the effectiveness of our PMTCT interventions. Ensuring high coverage of high quality EID services is a priority and PEPFAR is committed to supporting active case finding to ensure early initiation of treatment for all HIV-positive infants.

c) Explore public-private partnership opportunities to support the development of age-appropriate pediatric formulations, including fixed dose combinations of ARVs (first-, second- and third-line) and TB drugs (first- and second-line) particularly for infants and young children at the highest risk of dying without treatment.

d) Provide all mothers with appropriate counseling and support on infant and young child feeding and linkage with a minimum standard package of infant care including immunizations, bed nets etc.

[18] WHO Guidance for PMTCT outlines several approaches (Option A, Option B) for PMTCT. Both options include lifelong ART for eligible women (with a CD4 count of 350 or less) and ARV prophylaxis for women who do not yet qualify for treatment for their own health (CD4 count of over 350). The ARV drug regimen, diagnostic algorithm and duration of prophylaxis differs between Options A and B. Option B+ is a simplified test and treat approach for pregnant women where all pregnant women living with HIV are initiated on lifelong ART regardless of how far their disease has progressed. The recent WHO Technical Update recognizes that "substantial clinical and programmatic advantages can come from adopting a single, universal regimen both to treat HIV-infected pregnant women and to prevent mother-to-child transmission of HIV," which is inherent in both Options B and B+.

e) Antenatal care (ANC) clinics represent a critical entry point for women to healthcare systems, and are the primary means by which to scale up PMTCT programs. Leverage this approach to extend HIV prevention services to women testing negative for HIV, and prevention, treatment and care to women and infants testing positive for HIV.

f) Strengthen linkages between PMTCT programs and broader maternal, neonatal, and child health (MNCH) services and voluntary family planning programs in order to optimize the range of support provided to mothers and their infants. Leverage existing PMTCT, MNCH, and family planning platforms to help extend HTC, prevention and ART services to male partners and families.

g) Closely link PEPFAR-supported PMTCT programs with orphans and vulnerable children (OVC) programming to ensure that women and adolescents living with HIV, HIV-exposed infants and their families are linked with appropriate social services.

> "Millions of human beings are alive today because the United States, and others in the global community, are paying for their anti[retro]viral medication. This investment allows us to say, without any hint of exaggeration, that by 2015, the world could see the beginning of the end of AIDS, something that was unthinkable just a few years ago. We need to continue this kind of foreign aid investment, not just in PEPFAR, but in malaria control and vaccine programs and in agriculture initiatives so that we can make similar strides in preventing hunger and establishing a healthy global community."
>
> - U.S. Senator Marco Rubio

Action Step: Increase coverage of HIV treatment both to reduce AIDS-related mortality and to enhance HIV prevention

Scientific advances and implementation experience have enabled us to better recognize, diagnose and treat HIV infection. Working closely with partner governments and other partners, PEPFAR has played a leading role in the global effort to bring ART, once thought to be only possible to deliver in high-income settings, to large-scale deployment in developing countries. Supporting national treatment programs and building country capacity for sustaining such access over time remain central PEFPAR priorities.

Science has recently demonstrated that treatment is also highly effective in preventing HIV transmission to others. In 2011, the groundbreaking HIV Prevention Trials Network (HPTN) 052 study definitively demonstrated that provision of antiretroviral therapy reduced HIV transmission to HIV-uninfected partners in serodiscordant couples by 96 percent—an efficacy on par with a vaccine[19]. Now, in addition to having a direct impact in reducing AIDS-related mortality, which has declined by 26 percent since its peak in 2005[20], it is also clear that treatment has also been a major contributor to the global decline in new HIV infections over the past decade.

By the end of Fiscal Year 2012, PEPFAR directly supported life-saving treatment for nearly 5.1 million men, women and children worldwide, putting PEPFAR on pace to meet President Obama's goal of treating six million people by the end of FY 2013. Further treatment expansion must be driven by local priorities and context, strategically adopted with prioritization of coverage for those most in need. Supporting national treatment programs to increase access to those in need of treatment for their own health, as a first priority, remains a central tenet of the PEPFAR program. PEPFAR also endorses and will assist national programs in the implementation of recent WHO Guidelines on treatment for serodiscordant couples regardless of immune status[21]. In addition, PEPFAR will support national programs interested in adoption of the Option B+ approach for pregnant women described in the recent WHO Programmatic Update[22].

[19] Cohen M et al. Prevention of HIV-1 infection with early ART. New England Journal of Medicine, 2011 Aug 11; 365(6):493-505.
[20] July 2012 UNAIDS Global Report
[21] WHO Guidance on couples HIV testing and counseling, including antiretroviral therapy for treatment and prevention in serodiscordant couples; http://whqlibdoc.who.int/publications/2012/9789241501972_eng.pdf
[22] WHO Programmatic Update: Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants; http://www.who.int/hiv/pub/mtct/programmatic_update2012/en/

In moving forward, PEPFAR will continue to support countries in rapid scale-up of treatment, with attention to maximizing both its life-saving and preventive impacts. As programs mature and healthier populations are considered for treatment, PEPFAR will support countries in systematically ensuring adherence and retention on ART and the quality of ART programs. This will maximize the beneficial effects for individuals receiving treatment as well as the broad and important contributions of ART to supporting PMTCT of HIV.

PEPFAR will collaborate with countries and other donors to ensure support for recurring costs associated with the delivery of core interventions defined by the country as their continuum of services, including salaries, drugs and lab supplies. PEPFAR will also work with other partners to support countries as they work to increase access to viral load testing and other technologies to better monitor people on ART and support patient adherence and, through better viral suppression, reduce HIV transmission to uninfected partners.

PEPFAR will continue to support country efforts to strengthen a continuum of care that is appropriately linked to community-based care, and to foster an environment conducive to service uptake, adherence and retention. PEPFAR will enhance its efforts to identify eligible people living with HIV through various testing and counseling activities across our programmatic portfolio and link those individuals to ART services.

To implement this action step, PEPFAR is and will:

1. Prioritize continued scale-up of ART, given its significant impact in saving lives, building healthier communities and preventing sexual transmission of HIV.
2. Reaffirm that increasing access to those in need of ART for their own health is a central tenet of its support for country treatment programs, and work with countries to ensure that these individuals receive priority implementation.
3. Support countries to follow, and implement in accordance with, evolving WHO treatment guidelines as they are revised to recommend earlier treatment initiation and safer, more tolerable ART regimens.
4. Ensure our treatment scale-up strategy continues to be closely informed by the epidemic profile of each country, and work with countries to ensure that treatment programs are adapted to, and aligned with, their respective needs, the relative pace of progress and other resources available for ART in the country, as follows:
    a) High prevalence countries with high service coverage where rapid progress could get them quickly to, or beyond, the programmatic tipping point.
    b) Generalized epidemics with lower service coverage.
    c) Concentrated epidemics.
5. Work with countries to maximize the health and prevention benefits of ART by ensuring that programs implement rigorous measures of adherence and retention, striving to optimize outcomes using evidence-based and innovative methodologies.
6. Build capacity to ensure HIV diagnostics and ART for children are scaled-up, including EID and age-appropriate pediatric formulations of ARVs, particularly for infants and young children at highest risk of dying without treatment.
7. Ensure support for implementation of treatment primarily for prevention is driven by country priorities and the availability of resources, including by:
    a) Supporting national programs in the implementation of recent WHO Guidelines on treatment for serodiscordant couples regardless of immune status.
    b) Supporting national programs that have chosen to transition to PMTCT Option B or Option B+ for pregnant women in implementing this policy and programmatic shift.
    c) In accordance with each national epidemiological context, working with countries to prioritize key populations (e.g., MSM, SW, PWID) for ART, ensuring ART programs support a non-stigmatizing clinical environment that affords all individuals meaningful access to treatment services, including both facility and community-based care and support.

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8. Support HIV drug resistance (HIVDR) surveillance activities, stepping up pharmacovigilance efforts to ensure optimized long-term outcomes, particularly as the treatment programs mature and patients are initiated on ART earlier and on therapy for longer periods of time.

Action Step: Increase the number of males who are circumcised for the prevention of HIV.

Scale-up of voluntary medical male circumcision (VMMC) for HIV prevention is another critical component of the combination prevention strategy for saving lives and achieving an AIDS-free generation. Three large, randomized control trials (RCTs) demonstrated that adult VMMC reduces men's risk of HIV acquisition by approximately 60 percent, making it one of the most effective, available interventions to prevent sexual transmission of HIV. Extended follow-up of participants in two of these RCTs for up to five or six years post-trial indicated that this protective effect was durable and even increased over time. Of particular value is the fact that, unlike with many other interventions, VMMC is a one-time, short procedure that confers a lifetime of reduced HIV infection risk for heterosexual men. VMMC also reduces the risk for human papillomavirus (HPV), cervical cancer and STIs among female sexual partners of circumcised males[23,24].

The benefits of VMMC are greater in populations with a high prevalence of primarily heterosexually-driven HIV infections and low rates of male circumcision, as is the case in many areas of sub-Saharan Africa. Mathematical modeling studies suggest that if eight of 10 adult men become circumcised within five years in 14 priority countries[25] in eastern and southern Africa, approximately 3.5 million new HIV infections may be prevented within 15 years, averting as much as $16.5 billion in HIV care and treatment costs. Almost half of these are among women, because women's probabilities of encountering HIV-infected sex partners decrease as HIV-prevalence in men decreases due to circumcision.

This indirect protective effect against HIV extends beyond women to women's uncircumcised male sexual partners, and ultimately the whole population, and this indirect protection increases in relation to breadth of coverage and the speed at which coverage is achieved[26]. In 10 of these 14 priority countries, one HIV infection may be prevented for every 10 or fewer men who become circumcised according to the modeled scenario described. In addition to the lives saved and substantial health system cost savings, economic productivity will be maintained as the workforce remains HIV-free, VMMC programs also offer unprecedented opportunities to engage men in health education and counseling, notably HTC services. Moreover, men who are identified as living with HIV by VMMC programs are referred for HIV care and treatment, benefiting their

[23] Wawer MJ, Tobian AA, Kigozi G, et al. Effects of circumcision of HIV-negative men on transmission of human papillomavirus to HIV-negative women: a randomized trial in Rakai, Uganda. Lancet, 2011; 377: 209-218.
[24] Casteluega X, Bosch FX, Munoz N, et al. Male circumcision, penile human papillomavirus infection, and cervical cancer in female partners. N Engl J Med. 2002; 346:1105-1112.
[25] Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Uganda, the United Republic of Tanzania, Zambia and Zimbabwe.
[26] UNAIDS/WHO/SACEMA Expert Group on Modeling the Impact and Cost of Male Circumcision for HIV Prevention (2009). "Male Circumcision for HIV Prevention in High HIV Prevalence Settings: What can mathematical modeling contribute to informed decision making? PLoS Medicine. 6(9):e1000109, September 2009.

> “So everyone knows that ending AIDS [is] not going to be easy, not going to be quick, not going to be cheap. But we know now that it may be a huge effort or investment, but just like the eradication of smallpox, it's an investment that is absolutely guaranteed to show enormous returns.”
>
> - U.S. Senator John Kerry

health and broadening the potential community-level HIV prevention benefits of the program by ensuring their access to the continuum of care, including ART, and decreasing their HIV transmission risk.

Since 2007, PEPFAR has supported VMMC for an estimated two million men in sub-Saharan Africa. In Kenya and Tanzania alone, during special campaigns, clinicians now perform more than 35,000 circumcisions a month. Given the potential for high-impact of VMMC on HIV prevention, PEPFAR collaborated closely with WHO, UNAIDS and others in developing an *Action Framework* for VMMC scale-up in the 14 priority countries referenced above. The *Action Framework* calls for achieving 80 percent male circumcision coverage in these 14 countries, or in priority areas within the countries, by 2016.

As VMMC is scaled-up, challenges faced have differed from country to country, but in many populations, PEPFAR programs have encountered high acceptability of, and demand for, VMMC. There is a need for continued innovation both in how VMMC is expanded and in the products and tools that support such expansion. For example, a number of new devices, proposed as potential alternatives to surgical methods for VMMC, are still being evaluated by the WHO, and should be considered for use based on final WHO recommendations and guidelines.

In moving forward, PEPFAR will continue to support the 14 priority countries to develop and implement multi-year VMMC scale-up strategies, as part of a comprehensive package of prevention activities, and in accordance with the Action Framework. By the end of FY 2013, PEPFAR will support VMMC for 4.7 million men in eastern and southern Africa, and it will continue to leverage VMMC as a high-impact, and potentially cost-saving, intervention that saves lives.

To implement this action step PEPFAR is and will:

1. Support the 14 priority countries referenced above in developing and implementing multi-year VMMC scale-up strategies with the primary goal of maximally reducing HIV incidence. These strategies should be designed and deployed in accordance with the *Action Framework* for scale-up.
2. Provide technical support to these countries in establishing aggressive national annual and multi-year targets that promote national strategies for VMMC, and work with other partners to ensure coordinated support for countries in meeting those targets.
3. Work closely with partner governments and other relevant partners to promote the most ambitious possible VMMC scale-up in support of the strategies of these countries, or in priority areas within countries.
4. Encourage visible political advocacy and engagement by partner governments and civil society, recognizing that VMMC scale-up is a national endeavor.
5. Support innovation in VMMC programs and products in order for countries to reach more people, more effectively and efficiently with VMMC services.
6. Strongly encourage programs to incorporate as many service efficiency recommendations as possible, outlined in WHO's *Considerations for Implementing Models for Optimizing the Volume*

and Efficiency of Male Circumcision Services (MOVE) *document*.

7. Support governments and other partners in evaluating devices (e.g., medical devices that do not require the injection of local anesthetic, or sutures that can be delivered by nurses and/or in non-clinical settings) that may help to address challenges experienced in VMMC scale-up to date, so that devices proven effective may be incorporated as a service delivery option as quickly as possible.
8. Support improved uptake of VMMC in men over 25 years old with continued expansion of communications to include motivating factors related to VMMC, such as improved hygiene, health benefits for women, women's preferences concerning men's circumcision status and other attributes men may appreciate and sometimes associate with circumcision.
9. Build the capacity of partner countries to assure quality in VMMC programs, given that in many countries VMMC for HIV prevention is a new procedure, by helping to ensure that external quality assurance (EQA) activities are conducted to verify that administrative and clinical quality standards are being met and that the program is safe.
10. Build the capacity of partner governments to begin planning for and financing an integrated, long-term early infant male circumcision (EIMC) program as the adult VMMC program is being scaled-up. PEPFAR's financial support is prioritized to the adult VMMC program. However, once the adult program has progressed sufficiently, PEPFAR funds may be used to support EIMC activities.

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Action Step: Increase access to and uptake of HIV testing and counseling, condoms and other evidence-based and appropriately-targeted prevention interventions.

HIV testing and counseling (HTC), condoms and other evidence-based and appropriately targeted prevention interventions are also all key components of achieving an AIDS-free generation. PEPFAR will continue to support a multi-pronged approach to combating new HIV infections, working with partner governments and civil society to address the sources of new infections and create enabling environments for HIV prevention.

Knowledge of HIV serostatus is fundamental to the prevention, treatment and care of HIV. It is the gateway to a range of core interventions including VMMC, PMTCT, HIV care and treatment, blood safety and TB screening and services. Despite the central importance of HTC, globally fewer than 40 percent of PLHIV know they are positive. Increasing knowledge of serostatus, especially among PLHIV, is a critical focus of PEPFAR-funded HTC programs.

Since its inception, PEPFAR has provided nearly 190 million HIV testing and counseling encounters and this number continues to grow. In 2012 alone, PEPFAR directly supported HTC for more than 49 million people. Moving forward, PEPFAR will support countries in expanding their capacity to continue this work while increasing a focus on reaching individuals living with HIV and linking them to services. These linkages include referrals from HTC to clinical and community services, as well as referrals to HIV prevention, treatment and care services. PEPFAR will also work to expand the use of rapid HIV test kits and new models of service in order to enable more widespread use of testing outside of health facilities and promote more effective linkages of people testing positive to HIV care and treatment services. The strength of linkages between HTC points of diagnosis and other HIV services (both clinic- and community-based) will fundamentally impact the effectiveness of any HTC programming.

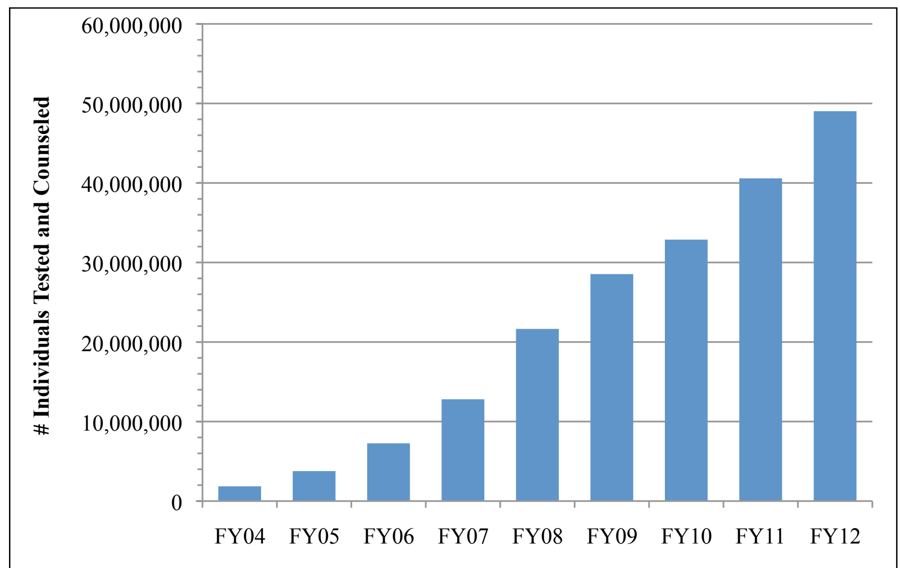


Figure 3: The number of individuals who received testing and counseling services for HIV supported by PEPFAR during US Government Fiscal Years 2004-2012. Source: Office of the U.S. Global AIDS Coordinator.

Rapid scale-up of other high-impact combination prevention interventions depends on expansion of the availability of HTC, and more effectively reaching populations that are at elevated risk for HIV infection. Therefore, scale-up of HTC programs should be strategic, with an emphasis on reaching these populations , and all programs should strive for early enrollment in care and treatment for those found to be living with HIV—both for the health of the individual and to achieve maximum prevention impact.

Providing HTC services for couples remains an essential component of PEPFAR's support for country prevention portfolios. Couples HTC can help ease disclosure between partners and identify serodiscordant couples eligible for early treatment services. For maximum impact, both individual and couples HTC should be provided in a range of settings and approaches. These include provider-initiated HIV testing and counseling (PITC) in both out-patient and in-patient settings, as well as outreach and community-based HTC. Each of these approaches has the potential to reach different population segments depending upon how and where they are implemented and will be used strategically to most effectively reach PLHIV.

Ensuring a consistent supply and availability of quality male and female condoms is also critical toward achieving an AIDS-free generation. PEPFAR will work with partner governments to develop national condom strategies that increase condom use, identify the relevant target populations for condom outreach and articulate appropriate approaches for meeting these needs. This includes ensuring that male condoms, which continue to play a key role in HIV prevention, are widely available and accessible to both men and women. Female condoms are unique in providing a female-controlled HIV prevention option, and PEPFAR will work with partner governments and other donors to promote them wherever effective programs can build sustainable demand.

Comprehensive condom programming will utilize various condom promotion and distribution channels—as well as the appropriate mixture and targeting of free, subsidized and private-sector supplied condoms—in line with a total market approach. Evidence-based behavior change communication (BCC) and social marketing campaigns relevant to specific settings and target populations will be employed to support increased condom uptake and utilization.

As outlined in PEPFAR Prevention Guidance[27], interventions to minimize risky behaviors and promote healthy ones, as well as those to optimize biomedical interventions by creating demand for services or improving adherence and aftercare, are also integral to advancing HIV prevention, treatment and care efforts. Explicitly addressing relevant behavioral factors is part of all PEPFAR prevention interventions, including biomedical ones. To be effective, these behavior change components must be strategically designed, implemented and evaluated.

Many social and cultural factors shape risk and risky behavior, including GBV. PEPFAR remains committed to addressing GBV in all our programs, including its

[27] Available at www.pepfar.gov.

prevention platform. We will continue our work with countries and other partners to include GBV screening in our HTC programs, to mobilize communities against GBV and to create prevention interventions for vulnerable women and girls, providing the support and information they need to reduce their risk of both violence and HIV. PEPFAR will additionally continue to support platforms that work to address and document sexual violence against children, especially girls. PEPFAR will also support efforts to create enabling environments for key populations and address the stigma, discrimination and violence that increase their risk for HIV infection and often prevent them from entering, or being retained in, health services.

To implement this action step, PEPFAR is and will:

1. Address structural, social and economic barriers to effective HIV prevention, including GBV, stigma and discrimination and gender inequality, with a focus on advocacy, policy and evidence-based interventions.
2. Strategically target HTC services to, and normalize HTC among, those populations at elevated risk for HIV infection, using new incidence measurement technology and placing particular emphasis on reaching PLHIV and HIV serodiscordant couples.
3. Provide quality services for individuals, couples/partners and families to learn their HIV status with appropriate pre-test information and post-test counseling based on serostatus, enhancing the benefits of this service and reinforcing linkages.
4. Implement innovative strategies for supporting and facilitating the linkage of individuals, couples and families to appropriate HIV treatment, care and support, suggesting HIV prevention services based on their serostatus.
5. Ensure that HTC is implemented within a rights-based approach.
6. Achieve HTC coverage rates that allow ART, VMMC and PMTCT scale-up targets to be met.
7. Support countries in articulating a strategy for condom programming that addresses key supply and demand issues related to increasing condom use, assessing the relevant target populations that need to be reached with condom programming and delineating how different market actors (e.g., public, social marketing and private sectors) can contribute to provision of condoms for these target populations.
8. Promote the female condom as an essential part of an overall condom strategy, with programs that account for each country's broader condom market and that consider the unique attributes and benefits of the female condom for various populations.
9. Employ evidence-based strategies to create demand for, and utilization of, male and female condoms, such as ensuring that high-quality condoms are available, that offered condoms correspond to consumer preferences, and that a variety of price points for different distribution channels are used.
10. Provide subsidized commodities to poor and vulnerable populations frequently not reached by private sector supply chains. Distribute free public sector male and female condoms primarily to populations lacking disposable income and/or those at elevated risk of HIV transmission or acquisition.
11. Support technical assistance to improve national commodity forecasting and procurement planning, including for male and female condoms and HIV test kits. Where condom stock-outs or shortages occur, use established emergency mechanisms to fill these gaps while working with national counterparts to identify the root cause(s) and devise solutions to prevent their future occurrence.
12. Promote risk reduction and healthy behaviors through BCC and social marketing programs directly linked to core combination HIV prevention interventions, including those designed to reach specific setting and key populations.
13. Work with Ministries of Education and Ministries of Health to provide age- and gender-appropriate, evidence-based HIV-prevention curricula to all school-aged children.

ROAD MAP FOR SMART INVESTMENTS

PEPFAR GOAL:
Going Where the Virus Is: Targeting Evidence-Based Interventions for Populations at Greatest Risk

ACTION STEPS

- Target HIV-associated tuberculosis and reduce co-morbidity and mortality.
- Increase access to and uptake of HIV services by key populations.
- Partner with people living with HIV to design, manage and implement HIV programs responsive to and respectful of their needs.
- Strengthen PEPFAR's Continued Focus on Women, Girls, and Gender Equality.
- Reach orphans and vulnerable children (OVC) affected by AIDS, and support programs that help them develop to their full potential.
- Strengthen programmatic commitment to and emphasis on reaching and supporting young people with HIV services.

As the world pursues the goal of an AIDS-free generation, all are mindful of the current economic climate. This means maximizing the impact of each dollar entrusted to HIV/AIDS programs. PEPFAR is therefore prioritizing smart investments by making our programming more effective and efficient and leveraging our investments with partner governments, the Global Fund, the private sector and other vital stakeholders.

What does the term smart investments mean for PEPFAR? First, it means prioritizing interventions that science indicates will save the most lives as outlined in the previous chapter: Road Map to Saving Lives. Second, it means going where the virus is—targeting those key populations at most risk and in most need of HIV services. Third, it means maximizing the impact of each dollar invested.

Working with partner nations, PEPFAR will continue to scale up interventions with a strong evidence base that will have population-level impact. Recognizing that environments are dynamic and constantly evolving, PEPFAR will be flexible and strategic in our response—expanding what works and curtailing what does not. PEPFAR will also fully participate in national planning processes to ensure that annual Country Operational Plans (COP) program resources have maximal impact.

> "I know that creating an AIDS-*free* generation takes more than the right tools, as important as they are. Ultimately, it's about the people...."
>
> -U.S. Secretary of State
> Hillary Rodham Clinton

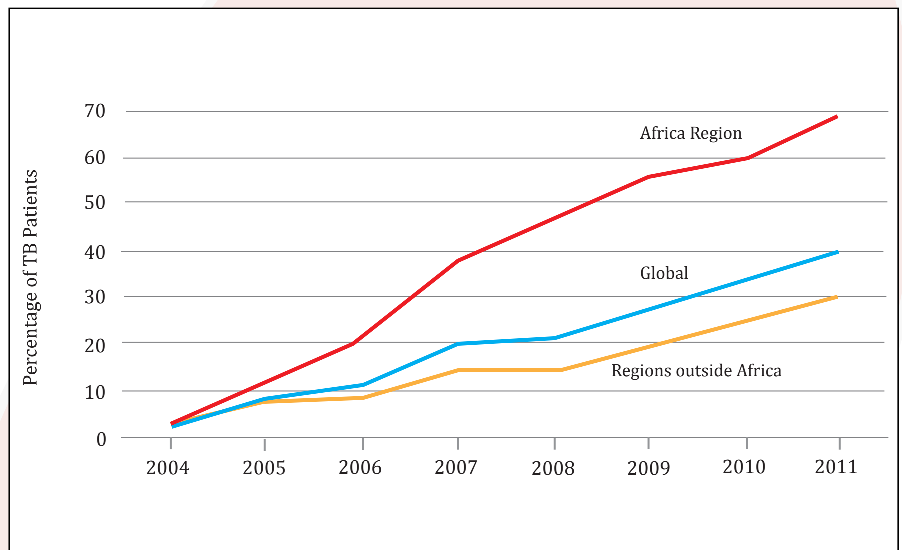


Figure 4: Percentage of TB patients who knew their HIV status, 2004-2011. Source: WHO Global TB Report, 2012.

PEPFAR Goal: Going Where the Virus Is: Targeting Evidence-Based Interventions for Populations at Greatest Risk

Action Step: Target HIV-associated tuberculosis and reduce co-morbidity and mortality.

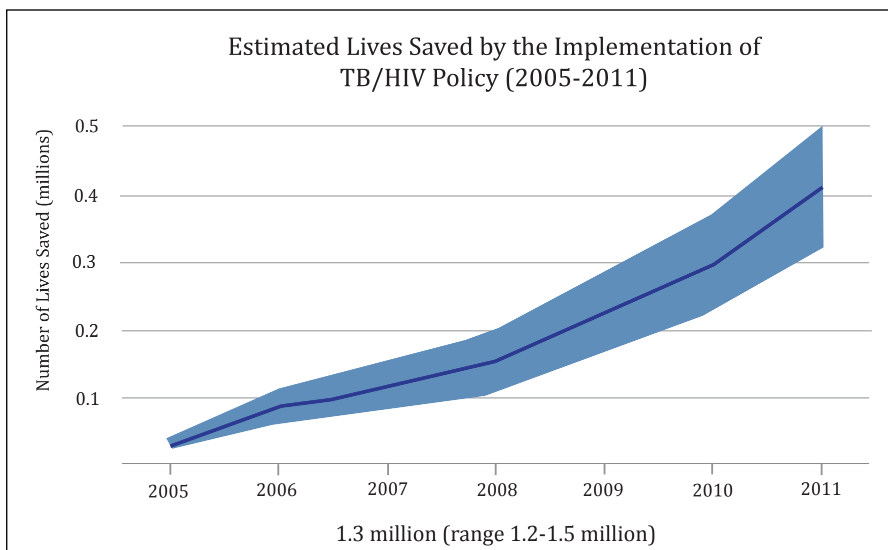
Tuberculosis (TB) remains the most common cause of death among people living with HIV in sub-Saharan Africa. According to the Stop TB Partnership, more than 1,000 people infected with HIV die every day from tuberculosis. Tuberculosis and HIV/AIDS constitute a deadly combination that speeds the progression of illness and death. Nothing makes a person more vulnerable to developing TB disease than the presence of HIV. TB is the most common opportunistic infection among people with HIV, and HIV makes a person highly vulnerable to moving from a state of latent TB infection to the development of TB disease. Conversely, having TB disease accelerates HIV disease progression and HIV-infected TB patients are at high risk for death and often die early.

Ending HIV-associated TB among PLHIV is possible through a combination of widespread ART coverage, early identification and treatment of TB, isoniazid preventive therapy (IPT), and infection control activities. These high-impact interventions will be critical to achieving an AIDS-free generation and are integral to PEPFAR planning and program implementation.

PEPFAR funding for TB/HIV collaborative activities increased more than 800% over the past five years. High rates of HIV testing among TB patients are being reported in many of the countries where PEPFAR works. In 2011, 69 percent of reported TB patients in the African region had a reported HIV test.

PEPFAR provides critical infrastructure to support countries in addressing TB/HIV, including more than 13,500 HIV care and treatment sites, including 5,200 providing ART. These activities have contributed substantially to the cumulative

Figure 5: Source: WHO Global TB Report, 2012



1.3 million lives that were saved from 2005-2011 through collaborative TB/HIV interventions.

To implement this action step, PEPFAR is and will:

1. Promote immediate access to ART, regardless of CD4 count, to all persons living with HIV who are diagnosed with TB and on appropriate treatment.
2. Track and report on progress toward all relevant TB-HIV indicators, including universal access to ART for people living with HIV who are diagnosed with TB, and access to TB screening and Isonaizid Preventive Therapy (IPT).
3. Support the expansion of interventions to improve the early diagnosis and treatment of TB among PLHIV. Expand access to new technologies, such as the Gene XPert MTB/RIF rapid diagnostic.
4. Strengthen services and tools for co-management of TB and HIV care.
    a) Plans for scale-up and decentralization of ART services should include existing networks of TB clinics as potential ART sites.
    b) Encourage countries to adopt task-shifting to allow nurses and other cadres to initiate both ART and TB treatment.
    c) Support countries in high-burden settings to routinely screen pregnant and postpartum women and children for TB, and to provide access to IPT or timely TB treatment as appropriate.
    d) Support coordination between TB and HIV programs at all levels to ensure linkages and retention along the continuum of care for individuals with both TB and HIV infection, and strengthen the capacity of partner countries to manage and sustain these programs over time.
    e) Promote use of community-based platforms to improve timely TB case finding and ensure successful treatment outcomes for TB and HIV. Enhance the engagement of country civil society organizations to scale up the delivery of community-based integrated health services including TB, HIV and MCH services.
5. Support measures to prevent transmission of TB in health care settings, particularly those that serve vulnerable, most-at-risk PLHIV.

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> "The fight against AIDS has raised a lot of boats – to fight tuberculosis and malaria, to improve health systems, to challenge and motivate governments and NGOs alike, to deliver more and better health care…"
>
> -President Bill Clinton

Action Step: Increase access to and uptake of HIV services by key populations.

Key populations (men who have sex with men (MSM), sex workers (SW), people who inject drugs (PWID)) typically have HIV prevalence rates that exceed those of the general population. However, stigma, discrimination and fear of violence or legal sanctions often undermine their access to health care, including HIV services. Breaking down these barriers is essential to achieving an AIDS-free generation. PEPFAR seeks to promote an enabling environment of supportive laws, regulations, policies and social norms in order to facilitate meaningful access to HIV services by key populations at both the facility- and community-level. PEPFAR believes that, where epidemiological data dictates (by incidence and prevalence), key populations should be prioritized for HIV services, including ART. Moreover, PEPFAR supports investing in further epidemiologic studies to ensure that needed data is available to policy and program decision-makers.

In low- and middle-income countries in all regions of the world, recent studies reveal that HIV disproportionately impacts key populations. Even as epidemic profiles show significant regional variation, data from country-specific surveillance surveys have demonstrated the existence of concentrated epidemics among key populations, even within larger generalized epidemics. In a review of low- and middle-income countries, MSM were found to be 19 times more likely to be living with HIV than people in the general population. In a similar global review, female SW were 13.5 times more likely to be living with HIV when compared to other females of reproductive age in the general population. Globally among PWID, 16 million individuals report injection drug use, and an estimated three million PWID are living with HIV.

Along with a disproportionately high HIV disease burden, only 9% of MSM and 22% of female SW in sub-Saharan Africa have access to HIV prevention services. Of the 3.2 million opioid injectors living in 13 PEPFAR-supported countries, only 3.4% are receiving methadone treatment from government clinics[28]. In certain studies, HIV prevalence among MSM has been found to be as high as 25% in Ghana, 30% in Jamaica, 43% in coastal Kenya

[28] PLOS Medicine 2007; CSIS, 2010; Lancet 2009; J Sex Tran Infect 2008; Lancet ID 2012.

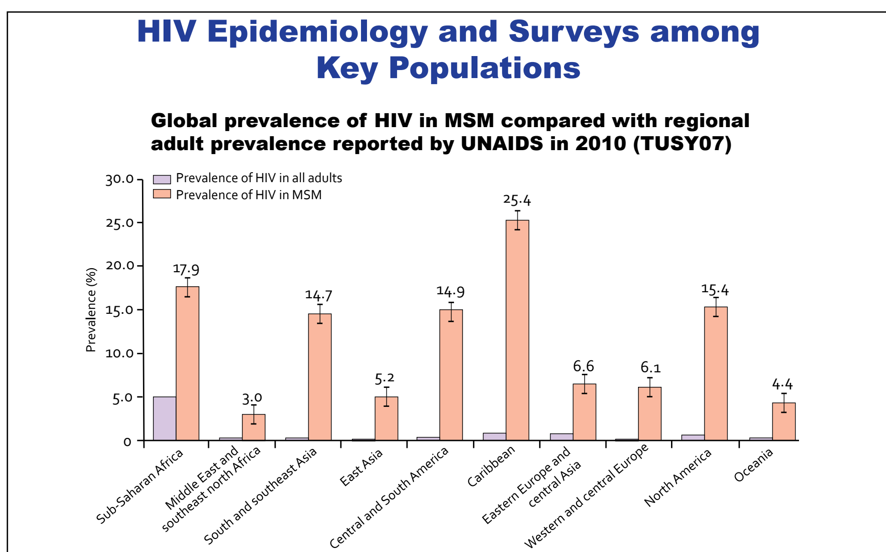

Figure 6: Source: Beyrer, Baral, van Griensven, Goodreau, Chariyalertsak, Wirtz, Brookmeyer, *The Lancet*, 2012.

and 25% in Thailand[29]. Among transgender people, HIV prevalence is thought to be even higher. Data presented at the 2008 International AIDS Conference in Mexico showed HIV prevalence of over 25% among transgender people in three Latin American countries and prevalence ranging from 10% to 42% in five Asian countries[30].

During the International AIDS Conference in July 2012, Secretary Clinton announced three new PEPFAR initiatives for key populations including: 1) support for the Robert Carr Civil Society Network Fund; 2) a challenge fund; and 3) implementation science grants. To date, PEPFAR has pledged two million dollars to the Robert Carr Civil Society Networks Fund to support the activities of global and regional civil society and community networks. These funds have already helped to leverage significant contributions from other donors. PEPFAR has also allocated $20 million to its Key Populations Challenge Fund (KPCF). The KPCF will support a number of projects that contribute to an evidence-based, sustainable HIV response for key populations. Through it, PEPFAR will fund proposals advancing an enabling environment for key populations, as well as those improving implementation and scale-up of a high impact comprehensive package of services. Finally, PEPFAR has committed $15 million to its Key Populations Implementation Science Fund. These funds will support research projects focused on providing knowledge necessary to implement the most effective HIV services for key populations. Each project will be linked with country programs so that findings have maximum impact on the scale-up of prevention, treatment and care for key populations.

Working with partner countries, PEPFAR is supporting scale-up of services for MSM, PWID and SW, and building and strengthening national capacity to prioritize and serve these populations. Key contributions from PEPFAR include the provision of technical support for scaling-up evidence-based interventions, and dissemination of specific PEPFAR guidance documents. (These documents can be found here: PEPFAR prevention Guidance http://www.pepfar.gov/guidance/171094.htm; Prevention for People Who Inject Drugs http://www.pepfar.gov/guidance/combinationprevention/combprevidu/index.htm; and Prevention for Men Who Have Sex with Men http://www.pepfar.gov/guidance/combinationprevention/combprevmsm/index.htm.).

To implement this action step, PEPFAR is and will:

1. Ensure that PEPFAR country portfolios are closely informed by the epidemic profile of the country, including the role of key populations.
2. Invest in epidemiologic studies to determine burden of disease among key populations, avoiding delaying the pilot and scale-up of known effective interventions.

[29] amfAR 2008, *MSM, HIV, and the Road to Universal Access—How Far Have We Come?* Special Report, amfAR, USA.
[30] Data presented by the International HIV/AIDS Alliance at "The hidden HIV epidemic: a new response to the HIV crisis among transgender people" press conference, August 4, 2008, Mexico City, Mexico.

3. Collect, analyze and share epidemiological data on program investment to inform plans, making course corrections when appropriate and monitoring progress.
4. Increase our commitment to "go where the virus is" by addressing key populations in countries with generalized, concentrated and mixed epidemics.
5. Stimulate greater country and regional programming for key populations through challenge grants to PEPFAR country teams, including in countries with concentrated epidemics that may not have a COP process.
6. Expand the evidence-base for effective interventions for key populations through implementation science awards linked to country programs to facilitate rapid scale-up of high-impact innovations.
7. Support civil society and faith-based work best able to address the epidemic in key populations through mechanisms such as country small grants.
8. Use diplomatic channels to help create an enabling environment allowing key populations to access health services.
9. Prioritize engagement in health diplomacy to promote the health and human rights of women, girls, and LGBT populations, and advance gender equality.
10. Ensure that the evolution of HIV-related programs toward country ownership supports the human rights of, and continuation of services for, key populations, including through partnerships with civil society.
11. Through the Local Capacity Initiative (LCI) Fund support country civil society organizations that advocate for key populations, from both a policy and program perspective, to do the following:
    a) Reduce legal and policy structural barriers to an effective HIV response.
    b) Reduce stigma and discrimination, creating greater access to HIV services.
    c) Ensure that key populations are involved in the planning and implementation of programs that affect their lives.

Action Step: Partner with people living with HIV to design, manage and implement HIV programs responsive to and respectful of their needs.

People living with HIV (PLHIV) are essential partners in achieving an AIDS-free generation. As service recipients, they must be empowered to play a meaningful role in the design, management and implementation of HIV prevention, treatment and care services for greatest impact. In many countries where PEPFAR operates, PLHIV are often significant providers of important services in the continuum of response. Embracing their roles as both service providers and recipients has the two-fold benefit of ensuring that HIV programs are responsive to the changing needs of PLHIV, and that PLHIV's knowledge and experience is included in ongoing strategies for achieving an AIDS-free generation.

For all of these reasons, services for PLHIV must be informed by strong partnerships with those best positioned to identify from their experience the most effective methods for HIV service outreach and delivery. PLHIV are also particularly important in sensitizing health care workers so that clinics provide quality services and do not discriminate. PEPFAR is communicating to partner countries the reality that involvement of PLHIV in the design and implementation of HIV programming is critical.

Implementation of comprehensive positive health, dignity and prevention (PHDP) interventions for PLHIV is also an important HIV prevention approach. Under PEPFAR, this includes provision of consistent and reinforcing messages and services across various settings. PEPFAR's August 2011 Sexual Prevention Guidance stresses integrating HIV prevention for PLHIV into routine care as a core component of a comprehensive HIV prevention, care and treatment strategy. Prevention interventions with PLHIV should include both behavioral and biomedical interventions aimed at reducing their own HIV-related morbidity and mortality, and reducing the risk of transmission to HIV-negative partners and infants.

> “More awareness is needed so that no one with HIV/AIDS is stigmatized or discriminated against.”
>
> \- President Barack Obama

Ensuring that people receive HIV testing and counseling is critical to identifying PLHIV early and making the link to needed prevention, care and treatment services. HTC also provides opportunities to encourage partner testing and support to enroll and remain in care. PEPFAR facilitates this by promoting co-location of services, peer escort/educator services, ongoing case management, follow-up counseling by community health workers, community support and psychosocial support groups and expanding use of technology (e.g., mobile phone calls/text messaging).

To implement this action step, PEPFAR is and will:

1. Foster international and country-specific benchmarks for inclusion of PLHIV in design, management and implementation of HIV programs by:
    a) Stressing meaningful involvement and leadership of PLHIV and their civil society partners to ensure sustainability and continuity.
    b) Adding PLHIV consultation as part of the broader civil society engagement that is an explicit component of the COP process.
2. Work with Ministries of Health and National AIDS Programs to ensure PLHIV involvement in development of national guidelines and policies (e.g., care and treatment, the national prevention strategy) and addressing implementation and monitoring issues.
3. Support through the Local Capacity Initiative (LCI) and other mechanisms, civil society organizations that advocate for key populations including PLHIV to pursue policy and programmatic interventions that:
    a) Reduce legal, policy and structural barriers to an effective HIV response.
    b) Reduce stigma and discrimination, creating greater access to HIV services.
    c) Ensure that key populations are involved in the planning and implementation of programs that affect their lives.
4. Provide ongoing, comprehensive HIV prevention services for PLHIV and their partners by integrating HIV prevention messages and services into all clinical and community settings serving individuals, couples and families living with HIV, including:
    a) HTC for partners and family members.
    b) Support for safe disclosure to sexual partners and family members.
    c) Safer sex counseling.
5. Provide voluntary family planning and safer pregnancy counseling for HIV-positive or discordant couples who desire pregnancy.
6. Provide the comprehensive package of services defined by WHO through consultation with PLHIV, including the above plus:
    a) Alcohol use assessment and counseling.
    b) Assessment and treatment of other sexually transmitted infections (STIs).
    c) Male and female condom and lubricant distribution and promotion.
    d) Adherence counseling and support.
    e) Development and support of client-driven prevention goals.
    f) Peer support groups and activities.

Action Step: Strengthen PEPFAR's Continued Focus on Women, Girls, and Gender Equality.

In low- and middle-income countries worldwide, HIV remains the leading cause of death and disease in women of reproductive age. In sub-Saharan Africa, 60 percent of those living with HIV are women and in some of these countries prevalence among young women aged 15-24 years is on average three times higher than among men of the same age. This disparity arises from systematic disadvantages faced by adolescent girls and young women's increasing early exposure to HIV at a time of particular biological and often social vulnerability. Many girls are forced into sexual activity and marriage at very young ages and are extraordinarily vulnerable to unintended pregnancy, HIV, sexual violence and exploitation. Lacking a full range of opportunities and devalued because of gender bias, many girls are seen as unworthy of investment or protection by their families, communities and governments. Moreover, because males are less likely to access medical services, men living with HIV are less likely to know their status and be on antiretroviral treatment, putting themselves and the women and girls they expose to their disease at greater risk.

PEPFAR programs are focused on supporting countries to implement evidence-based, multisectoral activities that improve the health and well-being of women and girls and promote gender equality through:

1. Increasing gender equity in HIV/AIDS programs and services, including access to reproductive health services.
2. Reducing violence and coercion.
3. Engaging men and boys to address norms and behaviors.
4. Increasing women and girls' legal protection.
5. Increasing women and girls' access to income and productive resources, including education.

Programs include empowering adolescent and pre-adolescent girls by fostering and strengthening their social networks, educational opportunities and economic assets. PEPFAR programs also target the men with whom girls and young women engage in sexual activity—whether voluntarily or not—with programs that address harmful gender norms, provide HIV prevention (e.g., voluntary medical male circumcision) and link men living with HIV to services. At the same time, PEPFAR works with clinical partners to develop and strengthen innovative platforms that incorporate results from gender analyses to make HIV care and treatment services accessible and acceptable to both men and women living with HIV.

This work is guided by the Global Health Initiative's Guidance on Women, Girls and Gender Equality. PEPFAR has also invested significant resources in developing evidence-based tools and guidance focused on improving the health of women and girls and on improving gender equality. In particular, PEPFAR now supports *What Works for Women and Girls*—an open website dedicated entirely

to reviewing existing research on HIV prevention, treatment and care so that programs on the ground can be based on the latest evidence of what works. In addition, PEPFAR's 2011 Guide for Integrating Gender-Based Violence (GBV) Prevention and Response in PEPFAR Programs reinforces the importance of putting GBV at the center of an effective HIV response.

These efforts are also reflected in terms of results on the ground. In FY11, PEPFAR supported post-exposure prophylaxis to prevent HIV infection for survivors of violence to over 47,000 people, nearly 34 percent more than the year before. Moreover, PEPFAR will continue to work with partners to align its efforts focused on women, girls and gender equality with other U.S. government-supported efforts, and with key policies and frameworks across PEPFAR implementing agencies. In order to ensure that these various policies and frameworks are implemented on the ground, PEPFAR will continue to invest in building the capacity of partner countries, as well as its own field teams.

Table 2: Women and girls served through PEPFAR-supported programs and services. Source: Fiscal Year 2012 PEPFAR Annual Program Results.

PEPFAR Indicator	Total Receiving Program or Service	Total Women and Girls	Percent Women and Girls
HIV Testing & Counseling (including PMTCT)	49 million	29.1 million	59%
Antiretroviral Treatment	5.1 million	3.1 million	61%

To implement this action step, PEPFAR is and will:

1. Increase gender equity in HIV/AIDS programs and services.
   a) Support countries in identifying the social, legal, economic and cultural barriers that prevent women and girls, as well as men and boys, from accessing essential health services, and tailor HIV prevention, treatment and care programs to address these barriers and meet their needs.
   b) Strengthen surveillance efforts both to ensure that adolescent girls and young women are being adequately represented in samples and that the reasons behind their higher risk are well understood in the country context.
   c) To the extent feasible, disaggregate data by sex and age in all health service programs, including those serving adolescent girls and young women, to track service uptake and provision.
   d) Encourage countries to integrate a range of health services to increase their efficiency and convenience, meeting the multiple needs of women and girls.
2. Prevent and respond to GBV through integration across prevention, care and treatment programs. Provide continued support through PEPFAR Gender Central Initiatives, including support for integration and evaluation of GBV-related programming, completion of the

GBV Response Initiative and continued implementation of the Gender Challenge Fund.

3. Encourage implementing partners providing pediatric and adult treatment and care, as well as PMTCT, to adopt evidence-based best practices in youth-friendly health care and services.
   a) Support positive youth development through peer networks and mentorship programs in elementary and secondary schools and for out-of-school youth—with a particular focus on girls.
   b) Develop specific programming for out-of-school adolescent and pre-adolescents, including males and married adolescent girls.
   c) Link health activities to education and viable livelihoods programs.
   d) Work with communities to change behavior and attitudes towards child marriage and support community programs that implement specific interventions to increase age at marriage, such as keeping girls in school.
   e) Support interventions to prevent and respond to sexual abuse and coercion of minors, working with male teachers and other male authority figures in girls' lives with whom they may engage in sexual activity.
4. Focus on increasing women and girls' access to income and productive resources—including education—to reduce their risk of HIV acquisition and increase their access to HIV prevention, treatment and care services. Collaborate across prevention and OVC technical areas to improve programming in economic strengthening and access to education, particularly for adolescent and pre-adolescent girls.
5. Optimize PEPFAR as a platform to incorporate and integrate other essential health services for women, including the integration of HIV and voluntary family planning (FP) services, aimed at safeguarding the rights of individuals living with HIV in reproductive decisions.
   a) PEPFAR supports teams to pursue the following activities, as appropriate:
      i. Provide counseling or referrals to voluntary family planning programs for women and men in HIV prevention, treatment and care programs—ideally at the same site.
      ii. Provide HIV prevention messaging and support, as well as HIV testing and counseling, within antenatal care, maternal and child health, and family planning programs for both men and women.
      iii. Ensure access to contraceptive commodities for HIV-positive clients who wish to delay or prevent pregnancy.
      iv. Monitor enrollment and receipt of services when referrals are made to capture linkages and ensure uptake of high-quality services including FP, maternal, neonatal and child health (MNCH) and primary care.
      v. Develop and disseminate technical guidance materials related to HIV/FP and HIV/MNCH integration.
      vi. Strengthen the policy environment for appropriate integration of HIV with other health platforms, including FP and primary care.
      vii. Evaluate the efficiency and effectiveness of integrated service delivery, including HIV/FP and HIV/MNCH integrated services.
      viii. Support quality assurance efforts to improve integrated health services for women.
      ix. Conduct operations or implementation science research on effective integration approaches.
      x. Strengthen public health and primary health care systems, including commodity procurement, information systems, and logistics and distribution systems designed to improve the availability of HIV and FP commodities and to improve essential primary care and health maintenance services.
      xi. Ensure that HIV and FP integrated program activities respect a client's right to make informed decisions about his or her reproductive life and that a range of contraceptive options are available for those clients who wish to avoid pregnancy. The principles of voluntarism and informed choice are prerequisites for good quality of care and must form the basis of integrated programs.

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Action Step: Reach orphans and vulnerable children (OVC) affected by AIDS, and support programs that help them develop to their full potential.

OVC programs are central to achieving an AIDS-free generation, not only because they respond to socio-economic issues in the lives of children, but also because their work with community platforms creates the enabling environment for children and their parents to access other services, including HIV treatment and prevention services.

As we move towards an AIDS-free generation, the number of children living without one or both parents because of AIDS will decrease. However, there continue to be many children in need of support. Today, over 16 million children worldwide are living without one or both parents due to AIDS. Millions more children are vulnerable because of chronically ill parents or suffer the social and economic effects of living in high HIV-prevalence communities. PEPFAR is committed to strengthening the capacity of partner governments, civil society, communities and households to provide long-term physical, emotional and social support—so that children living with and affected by HIV/AIDS are protected, grow up healthy, and transition into adulthood with the knowledge and opportunities they need to eventually raise AIDS-free generations to come.

The PEPFAR OVC program will continue its leadership role by working with countries to mobilize and strengthen the community platform. Strong communities responsive to the needs of people infected and affected by HIV/AIDS play a critical role within PEPFAR's vision of sustainable and country-owned HIV programs. True country ownership must also include community groups at the grassroots level. This is an important element of country ownership at the local level that profoundly contributes to broader outcomes and is crucial for sustainability in both the short and long term. With strong community ownership, government initiatives can be more effective at the community level, where people work and live.

PEPFAR programs have promoted resilience in children and broader society by reducing adversity and building services and systems that reach people directly in their households and communities. The evidence shows that these interventions are working. They have kept children in school and improved both education and psychosocial outcomes for individuals. They have developed household economic strengthening (HES) initiatives, established parent/caregiver education and support groups, and increased health care access and nutrition outcomes for families and households.

OVC programs also support the medical goals of the response in critical and mutually beneficial ways. For example, efforts to keep children in school positively impact HIV prevention. Economic strengthening activities help remove barriers to accessing facility-based services, and child-focused health interventions are important platforms to target mothers for PMTCT. In addition, OVC community-based programming helps reduce stigma and discrimination while promoting an environment for people living with and affected by HIV to access services.

In 2011, PEPFAR's efforts served over four million

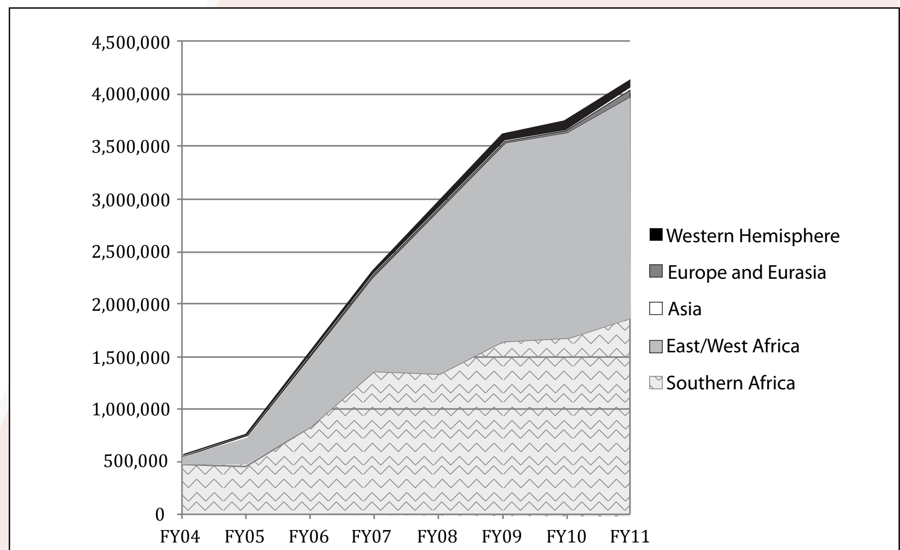

Figure 7: Number of children served by PEPFAR supported programs. Source: PEPFAR Annual Program Reports (APR) direct results data 2004–2011.

children by offering vast benefits for children and adults of PEPFAR's broader HIV prevention, treatment and care programs. Looking forward, PEPFAR is committed to building sustainable responses at both the community and national levels so that HIV services are available and accessible until the day when they are no longer needed.

To implement this action step, PEPFAR is and will:

1. Implement interventions that address children's socio-economic needs as a result of the HIV epidemic:

   a) Education: Support efforts to reduce educational disparities and barriers to access among school-age children through sustainable "systemic" interventions (e.g., school block grants).

   b) Psychosocial care and support: Prioritize psychosocial interventions that build on existing resources and place and maintain children in stable, supportive and affectionate environments.

   c) Household Economic Strengthening (HES): Support HES activities to reduce the economic vulnerability of families, empowering them to provide for the essential needs of their children through money management interventions and by integrating HES activities with complementary interventions, such as parenting skills and income promotion.

   d) Social Protection: Reduce vulnerability and risks, foster human capital development, and interrupt the transmission of poverty from one generation to the next by supporting governments to initiate, expand, or be innovative in their social protection initiatives at both the policy and operational levels.

   e) Health and Nutrition: Improve children's and families' access to health and nutritional services through effective integration with existing child-focused community- and home-based activities, including PMTCT, treatment, the President's Malaria Initiative (PMI), and child survival programs along with reducing access barriers to health services.

   f) Child Protection: Develop appropriate strategies for preventing and responding to child abuse, exploitation, violence and family separation by supporting communities to prevent and respond to child protection issues, and by building government capacity to carry out and improve child protection responses.

   g) Capacity Building: Within their country context, PEPFAR programs will prioritize capacity-building and systems-strengthening interventions that build strong leadership and governance, particularly those that strengthen the social service workforce and system.

   h) Legal Protection: Work to develop and implement strategies that ensure basic legal rights, birth registration, and inheritance to improve access to essential services and opportunities.

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2. Continue its leadership role in expanding the community platform to increase access to all services along the continuum of care by:
    a) Responding to socio-economic needs of children created by the epidemic to ensure their most critical needs are met, whenever possible by working to strengthen families that can then address those needs.
    b) Continuing to inform and enhance facility services by ensuring those services are appropriate for communities and households, and by identifying and addressing barriers to access for clinical and other services.
3. Ensure prioritized, focused interventions to address children's most critical care needs as outlined in the National Action Plan for Children in Adversity.
4. Allocate funding to monitoring, evaluation and more rigorous intervention-level research in order to improve the quality of monitoring and evaluation activities, providing the evidence and essential information for strategic planning, documenting long term impact, program improvement, accountability of funds and effort and advocacy.

Action Step: Strengthen programmatic commitment to and emphasis on reaching and supporting young people with HIV services.

To achieve an AIDS-free generation, we must forthrightly address young people, particularly girls and young women, and tackle harmful norms ingrained at an early age that increase female risk of HIV acquisition. Due to social, cultural, economic and biological reasons, young people are particularly vulnerable to HIV infection. Early sexual debut puts young people at increased risk of HIV acquisition and lengthens the potential period of exposure to HIV, typically resulting in a higher number of lifetime sexual partners as well as increased risk of unintended pregnancy.

Achieving effective HIV prevention with young people requires meeting them where they live, play, learn and work with interventions tailored to their needs, risks and interests. PEPFAR's 2011 Guidance on the Prevention of Heterosexual Transmission of HIV highlights best practices for doing so.

All young people need broad education about sex, sexuality and reproductive health, including HIV. Where and how they get this education will vary. PEPFAR will work with partner governments to develop age-appropriate, evidence-based curricula for use in schools and throughout the education sector. For those young people who are not in school, PEPFAR will work with parents, community and faith-based organizations, other implementing partners and other donors to ensure that their prevention educations needs are met.

Some populations of especially vulnerable youth need HIV prevention beyond education. These young people may need comprehensive packages of HIV prevention, care and treatment similar to those for key populations. In sub-Saharan Africa, most countries with large HIV epidemics also have large young populations, and many youth are therefore very vulnerable to HIV, in particular girls. In these countries, it is especially critical that PEPFAR work with partner governments and other stakeholders to provide strong HIV prevention programs for at-risk young people to help them stay HIV-free.

In many PEPFAR-supported countries, large numbers of young people are already living with HIV. Due to the availability of ART, HIV-positive infants are living into adolescence. These young people need special support to successfully transition to adulthood, including transitioning from pediatric to adult HIV care and treatment programs. Other young people have acquired HIV through sexual transmission or injecting drug use. To reach these populations, HTC programs must be strengthened to effectively link HIV-positive adolescents to youth-friendly HIV care and treatment programs. An AIDS-free generation requires us to reach and treat young PLHIV before they develop AIDS.

Finally, further research is needed to identify new HIV prevention interventions that reduce risk for the most vulnerable young populations. In particular, interventions are urgently needed that protect adolescent girls and young women who often cannot negotiate condom use and experience high levels of GBV and are therefore at increased risk of acquiring HIV. If we can help girls and young women remain HIV-free into adulthood, we can greatly reduce the chance that they or their children will ever have to live with HIV.

To implement this action step, PEPFAR is and will:

1. Target and tailor programming for sexually active and most-at-risk youth based on patterns of behavior and their needs.
2. Provide necessary information and skills building to help youth prepare to make their eventual transition to sexual activity safer and healthier, including delay of sexual debut.
3. Work with parents and guardians to help improve communication to youth about their values and expectations regarding adolescent behavior, as well as stressing the importance of monitoring and supervision of their adolescents.
4. Engage influential adults within the community to create an enabling environment conducive to the adoption of safer sex behaviors among youth.
5. Expand access to community-level prevention programs, including peer outreach, and curriculum-based programs for out-of-school youth.
6. Provide or refer sexually active youth to confidential youth HTC, and ensure linkages to care for HIV positive youth.
7. Encourage sexually-active youth to learn their HIV status, practice safer sex and reduce their number of sexual partners. Provide sexually active young people with risk reduction information and skills building, including access to male and female condoms and information on correct and consistent condom use.
8. Prioritize interventions targeting evidence-based prevention, care and treatment for adolescents living with HIV/AIDS in the following areas:
   a) Measurement: Work with the UN and partner governments to better track the numbers of adolescents living with HIV (ALHIV) and the coverage of critical HIV services for these populations.
   b) Prevention: Work with global experts to identify the most effective interventions for preventing new HIV infections in vulnerable adolescent populations and support partner governments to bring them to scale.

c) Treatment: Work with partner governments and implementing partners to scale programs that increase access to treatment for ALHIV, and help those currently in pediatric care to effectively transition to adult care.

d) Advocacy: Work with UNICEF and other global partners to raise awareness of the needs of ALHIV and vulnerable adolescents, and build commitments to bringing effective programs and interventions to scale.

9. Provide comprehensive packages of interventions for highly vulnerable youth and young members of key populations tailored to be accessible and acceptable to younger people.
10. Where feasible, support structural interventions to reduce young people's exposure to risk and increase protection.
11. Strengthen and expand gender-sensitive programs to respond to the unique needs of male and female youth, including addressing harmful gender norms that foster the spread of HIV.
12. Evaluate the impact of PEPFAR-funded youth programs to build a stronger evidence base for these interventions.

PEPFAR GOAL: Promoting Sustainability, Efficiency and Effectiveness

ACTION STEPS

- Strengthen PEPFAR supply chains and business processes to increase the efficiency of our investments.
- Increase efficiencies through innovation and greater integration of services with other U.S., bilateral and multilateral global health investments.

PEPFAR Goal: Promoting Sustainability, Efficiency and Effectiveness

In its first eight years, PEPFAR, working closely with countries and other partners, demonstrated that resources combined with substantial technical assistance and program support could overcome barriers and resource limitations in many health systems and deliver lifesaving services in challenging conditions[31]. PEPFAR's implementation of biomedical, behavioral and other HIV interventions, adapted to local environments, has saved many lives, prevented new HIV infections, and produced broader societal benefits[32]. Moving forward, it will be critical to make this program sustainable.

Looking forward, PEPFAR will continue to accelerate gains in efficiency. We are committed to being better able to measure and report on these gains—for example, through annual percentage changes in commodities costs and local and global unit costs of providing services. Finally, PEPFAR is committed to increasing the efficiency of its own business processes.

While PEPFAR must do what it can to increase the efficiency and effectiveness of the programs it funds, country leadership in these areas is the most critical priority. To ensure sustainability, effective collaboration among donors will be essential in supporting country-owned national responses that are able to withstand current and future financial constraints[33]. Innovative country financial approaches can also contribute to progress in sustainability. Given the need for continued improvement of systems of care in AIDS-affected countries, PEPFAR will continue to play a role in strengthening key elements of country health systems, such as supporting health workforce, laboratories, blood safety, and regulatory systems; and partnering with civil society, country academic medical centers and the private sector so they can bring their strengths to bear.

Finally, the countries must play the critical role of the convener. They must define and run a process that allows for their unmet needs to be defined and prioritized. This will directly inform the allocation process no matter what

[31] Fu, Gavaghan, Millett, and Walsh. "Replicating PEPFAR's Success: How Interventions Shown to be Effective Abroad Can be Applied to the AIDS epidemic in the U.S." *Health Affairs*. Vol. 31. No. 7. July 2012.
[32] Fu, Gavaghan, Millett, and Walsh. "Replicating PEPFAR's Success: How Interventions Shown to be Effective Abroad Can be Applied to the AIDS epidemic in the U.S." *Health Affairs*. Vol. 31. No. 7. July 2012.
[33] Holmes, Blandford, Sangrujee, Stewart, DuBois, Smith, Margin, Gavaghan, Ryan, and Goosby. "PEPFAR's Past and Future Efforts to Cut Costs, Improve Efficiency, and Increase the Impact of Global HIV Programs." *Health Affairs*. Vol. 31. No. 7. July 2012.

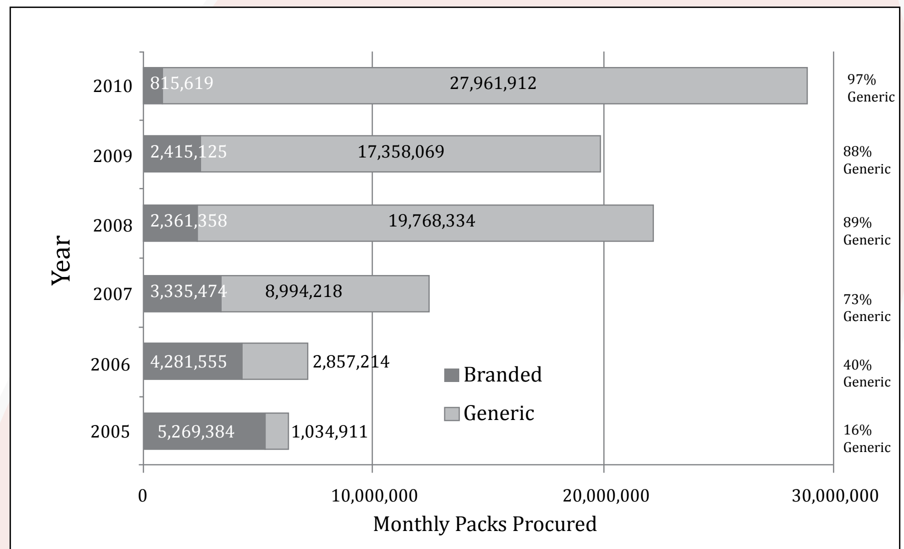


Figure 8: Number of generic versus branded drugs procured (monthly packs, 2005–2010). PEPFAR increased its use of generic drugs from 16% in 2005 to 97% in 2010.

the source of funding. This puts the partner country leadership, both government and civil society, in an accountable position to those who use the services.

Action Step: Strengthen PEPFAR supply chains and business processes to increase the efficiency of our investments.

To implement this goal, PEPFAR is and will:

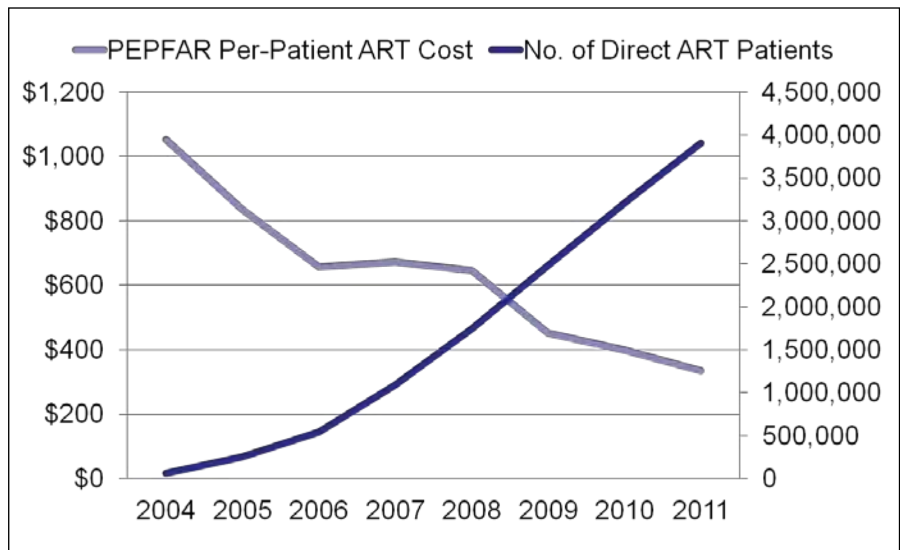
1. Improve PEPFAR's managerial efficiency by continued strengthening of coordination across the U.S. government:
   a) Support the U.S. Ambassador in country as the 'CEO' of a unified, interagency effort on AIDS and principal point of contact for partner government counterparts.
   b) Pursue systematic analysis of USG costs and structures to ensure efficient allocation of human and other resources to program oversight.
   c) Be an active partner in the Global Health Initiative's efforts to improve integration, coordination, and efficiency.
   d) Embrace innovations to improve efficiency of country programs, including:
      i. Improve understanding of program costs through expansion of expenditure analysis to additional countries, and share results with countries.
      ii. Integrate services when integration will enhance efficiency.
2. Expand use of electronic health information systems that promote more efficient use of clinician time.
3. Expand surveys of partners' drug purchases to assess price heterogeneity and clinical effectiveness, and feed information back to partners.
4. Redouble efforts to strengthen country supply chains, including promoting the lowest possible cost methods for shipping drugs.
5. Expand use of pooled procurement to achieve best available costs.

Action Step: Increase efficiencies through innovation and greater integration of services with other U.S., bilateral and multilateral global health investments.

To implement this action step, PEPFAR is and will:

1. Support policy reform to optimize use of available health workforce, including expansion of task-shifting.
2. Support countries in building well-functioning regulatory structures to eliminate regulatory bottlenecks.

Figure 9: PEPFAR per-patient treatment costs have declined substantial as the number of patients receiving direct PEPFAR support has increased markedly.[34]



3. Support country efforts to use creative mechanisms for financing health care:
   a) Expand performance-based financing approaches, refocusing accountability from inputs to outcomes.
   b) Support country experimentation with cost-recovery schemes for providers.
   c) Partner with countries to explore health insurance models.
   d) Accelerate use of private sector approaches to expand access to country health systems.
4. Strengthen country leadership in overseeing the national response to maximize program impact by:
   a) Intensifying coordination at the country level with other partners, including the Global Fund.
   b) Working with multilateral organizations to harmonize expenditure categories to enable countries to better understand the totality of investments in country.
5. Strengthen country health systems needed for an effective, sustainable response:
   a) Maintain the Medical and Nursing Educational Partnership Initiatives, evaluate their impact, and consider expansion.
   b) Support the African Society for Laboratory Medicine, and assess whether other country or regional health systems strengthening initiatives are needed to strengthen technical capacity.
   c) Seek to more aggressively engage the private sector, especially indigenous businesses, in contributing to the response from their core competencies and knowledge of how to reach their countries' populations.
   d) Support countries in strengthening systems for procurement and distribution, health management information, blood safety and regulation, to expand and enhance HIV service delivery.

[34] Per-patient PEPFAR budget allocation is estimated as treatment budget allocation divided by lagged number of current patients directly supported on ART by PEPFAR at the end of the annual reporting period. Budget per result estimates may vary from site-level costing estimates.

ROAD MAP FOR SHARED RESPONSIBILITY

PEPFAR GOAL: Creating an AIDS-Free Generation Requires a Global Effort

ACTION STEPS

- Partner with countries in a joint move to country-led, managed, and implemented responses.
- Increase support for civil society as a partner in the global AIDS response.
- Expand collaboration with multilateral and bilateral partners.
- Increase private sector mobilization toward an AIDS-free generation.

The goal of creating an AIDS-free generation cannot be accomplished by any single actor alone. Rather, it requires multiple organizations working to provide financing, demonstrate political will, carry out interventions both in and out of the health sector and, most importantly, involve those infected and affected by the virus. The concept of shared responsibility encompasses the tasks, duties, and accountability that these various actors must take on to achieve the joint, and truly global objective, of an AIDS-free generation.

The multisectoral, multidisciplinary approach that PEPFAR and its partners have taken to curb the AIDS epidemic has not only saved lives, but resulted in important lessons that are being applied to other infections and chronic diseases, health systems challenges and barriers to care. Shared responsibility is one such important lesson, enabling us to develop lasting solutions to meet the current unmet need. In addition to gaining resource efficiencies, PEPFAR's collaboration at the national level and below helps partner governments to mobilize their health sectors to achieve a broad range of health goals.

> "We know we can't create an AIDS-free generation by dictating solutions from Washington. Our in-country partners – including governments, NGOs, and faith-based organizations – need to own and lead their nation's response. So we are working with ministries of health and local organizations to strengthen their health systems so they can take on an even broader range of health problems."
>
> -U.S. Secretary of State
> Hillary Rodham Clinton

While this blueprint focuses on the specific actions PEPFAR will take to contribute to shared responsibility, achieving shared responsibility will also require action from our partners. Country governments must play the role as orchestrators of a country response and conveners of all partners. Civil society, including faith-based organizations, should be active in working to make sure that programs meet the needs of communities affected by HIV. Putting country leadership—both government and civil society—

> "For us in Tanzania, whenever we talk about the successes we have made in the fight against HIV/AIDS, we cannot fail to recognize and acknowledge the invaluable support we have received and continue to receive from the people and the government of the United States of America."
>
> \- Tanzanian President Jakaya Kikwete

in an accountable position to meet the needs of their populations will further the goal of a sustainable HIV response. Other national and multilateral partners are critical for resource mobilization and technical support. And all partners need to be accountable to each other for contributions to an AIDS-free generation.

PEPFAR's core mission will continue to focus on saving lives. That will never change. But PEPFAR is changing the way it does business to support a broader combined impact in the global fight against AIDS. In order to create an environment where multiple partners, from the community level upwards, are able to join the fight, PEPFAR will continue to focus on expanding its activities around country ownership with civil society, multilateral and bilateral donors, and the private sector. By taking the following action steps, PEPFAR will serve to galvanize shared responsibility among partners toward achieving an AIDS-free generation.

PEPFAR Goal: Creating an AIDS-Free Generation Requires a Global Effort

Action Step: Partner with countries in a joint move to country-led and implemented response.

The concept of country ownership has been endorsed by the global community in agreements around aid effectiveness such as the Paris Declaration, Accra Agenda for Action, and Busan Partnership Document. In June 2012, Secretary Clinton defined country ownership as "the end state where a nation's efforts are led, implemented, and eventually paid for by its government, communities, civil society and private sector…. it is principally about building the capacity to set priorities, manage resources, develop plans, and carry them out."

PEPFAR has worked to increasingly incorporate country ownership into its programs. We have been working to support countries in building management and operational capacity. We have signed over 20 Partnership Framework agreements with governments that outline clear and accountable activities and targets for both PEPFAR and the partner country. Since 2011, PEPFAR has been working with select countries on a country ownership tool that allows for definition of goals in four specific areas; this tool is being adapted as

Photo Credit: State Department

a foundation for the pilot country ownership scorecard announced by the State Department in September 2012.

To implement this action step, PEPFAR is and will:

1. Create sustainability strategies: PEPFAR will work with countries to build upon the promise of Partnership Frameworks by supporting multi-year sustainability plans. These will focus on advancing capacity and national management of programming and support technical oversight and financing. In developing these strategies, PEPFAR will work with a variety of stakeholders from partner countries, including both country governments and local civil society representatives.
2. Change business practices to support country leadership: As PEPFAR engages in country ownership activities, we will work with organizational experts to evaluate the changes needed to undertake at the country level to support country ownership, such as changes in PEPFAR's country team staffing and portfolios. Doing so will help the program further move from emergency mode to one configured to support sustainability at the country level.
3. Engage in the U.S. government's country ownership scorecard process: In September 2012, Secretary Clinton announced the start of a dialogue with partner countries around country ownership, in which both the U.S. and its counterpart government will be objectively measured on progress each has made toward country ownership. PEPFAR will work with its counterparts in the USG to support this process in countries.

Action Step: Increase support for civil society, with particular concern for the voice and role of people living with HIV, as a partner in the global AIDS response.

Our progress to date in the fight against AIDS is due to the active involvement of the communities affected and infected by HIV. Whether serving as peer educators, helping to plan clinic outreach activities or asking political leaders for increased support, PLHIV, their families and their friends are critical to creating an AIDS-free generation. Yet too often, individuals face stigma and discrimination when they try to get involved. Many times, their own experiences in living with HIV are ignored by governments and the medical profession as they design programs and activities. And too often, programs are not transparently run to allow those whom they serve to identify whether they are efficient and effective.

PEPFAR has worked through various channels to support civil society groups, ranging from groups of PLHIV to key populations to women's groups to faith-based organizations. We have established funding for local partners, both to help them provide more effective HIV services and to expand advocacy capacity. Working with other parts of the State Department, PEPFAR has also worked to promote inclusion of civil society groups, especially key populations, within the civic framework.

To implement this action step, PEPFAR is and will:

1. Increase financial support for civil society groups: The fight against AIDS has, as its foundation, a response from individuals and communities impacted by AIDS. Throughout the past thirty years, civil society has organized and mobilized against the virus, often with the support of governments and foundations. However, civil society groups in developing countries often need additional support to set up and maintain organizations that provide care, support and advocacy. Without this support, many groups may find that administrative functions distract from their advocacy focus. Through the Local Capacity Initiative (LCI), which is a follow-on to the New Partners Initiative, PEPFAR is providing advocacy support to civil society organizations. LCI funding targets civil society organizations at national, district and local levels to build their capacity and support advocacy for transparent and evidence-based policies and reduction of legal and structural barriers to the HIV response. PEPFAR is also a major supporter of the Robert Carr Civil Society Networks Fund, a collaborative mechanism for delivering technical and capacity building support to civil society networks at the global, regional and national level.
2. Expand the role of civil society in the AIDS response: PEPFAR's vision of country ownership is one that ensures civil society voices, particularly those of people living with HIV, are represented in conversations with partner governments. When communities face stigma, it is more difficult for them to band together into organizations that can interface with governments. And the response to care has often been led by community partners, particularly faith-based organizations. Partner governments should involve civil society in the development of national strategies and implementation of programs to enable more effective, sustainable and self-correcting HIV efforts. They should also be held accountable by civil society for achieving goals and ensuring that marginalized populations have equal access to HIV services. PEPFAR cannot mandate this involvement, but it can work to expand its own engagement with civil society as a way to spur greater civil society engagement by partner country governments. It will do so by adding civil society engagement as an explicit component within the COP process. Each country team should consult with local civil society prior to COP submission. Future COP guidance will require teams to outline civil society engagement as an element of the COP process; this outline of engagement will be made public along with the rest of the COP. And as part of the U.S. government's larger move toward global health diplomacy, PEPFAR is working to ensure that the concerns raised by marginalized civil society groups are represented in PEPFAR's discussions with country counterparts.

Action Step: Expand collaboration with multilateral and bilateral partners.

PEPFAR's history has been linked to that of other major bilateral and multilateral actors in the global response to AIDS. The Global Fund has, since 2002, mobilized almost $23 billion in 151 countries in the fight against these diseases. As the Global Fund's largest donor, PEPFAR has been instrumental in leading the Fund's reform agenda to maximize the impact of Global Fund resources. At the country level, PEPFAR works closely with partners involved with the Country Coordinating Mechanisms (CCM) to leverage PEPFAR funding and expand its effectiveness in the future.

PEPFAR is also working with UNAIDS and its 11 partner agencies around joint advocacy and political awareness. In particular, PEPFAR and UNAIDS—whose co-sponsoring agencies include, among others, WHO, UNICEF and UNFPA—are working to support country-led development of national investment cases, to help resource high-impact interventions under a single national strategic plan. And PEPFAR is expanding its collaboration with the World Bank and bilateral partners to create more effective partnerships at the country level. PEPFAR will continue to look to and learn from its multilateral partners as they implement best practices globally.

> “One of the things that makes me most proud as an American is PEPFAR, and when I have traveled the world and I have seen the benefits and seen it in the lives of people…my heart fills with pride.”
>
> \- Kay Warren, Saddleback Church

To implement this action step, PEPFAR is and will:

1. Strengthen global support for the Global Fund to Fight AIDS, Tuberculosis, and Malaria, including support for increased financial commitments. The Global Fund represents a critical multilateral vehicle for enlisting public and private sector donors to support country-led responses to the HIV, Tuberculosis, and Malaria pandemics. In leading the Global Fund’s reform agenda, the U.S. government has helped the Fund to strengthen its promise as an efficient, long-term channel for funding evidence-based, high-impact interventions. Working through the U.S. government diplomatic channels and mechanisms such as the G20, the United States will encourage nations with emerging economies and natural resource wealth to shoulder an increasing share of domestic HIV financing and to fund international efforts. The U.S. government will continue to work together with the Global Fund Secretariat and Board to target priority donors for new or increased contributions to the Global Fund. U.S. embassies in targeted countries will be tasked with raising this issue in diplomatic discussions, particularly through the upcoming Fourth Global Fund Replenishment process.
2. Invest PEFPAR and Global Fund resources in a coordinated, complementary and synergistic manner to achieve better health outcomes within the framework of national HIV plans developed by partner countries. PEPFAR is working closely with the Global Fund to exchange information, best practices and knowledge in order to better define their respective roles in addressing HIV epidemics in the countries where they are both working. One of the benefits of Global Fund reform is a much stronger focus on strategic investments grounded in science. To date, PEPFAR’s efforts at collaborating with the Global Fund have focused mostly on identifying areas of overlap and avoiding duplication of effort. PEPFAR has now entered a new era of cooperation with the Global Fund, which institutionalizes joint planning and implementation in countries where both organizations are making investments. Increasing program coordination, decreasing costs, and creating efficiencies and synergies between Global Fund and PEPFAR investments will help to increase coverage and save more lives. And to simplify country systems, PEPFAR will work with the Global Fund to harmonize monitoring, evaluation, and

expenditure analysis and reporting practices creating a basis for better decision-making by countries and their bilateral and multilateral partners.

3. Support the development of systems for financial accountability. Along with other allies in the fight against HIV, the U.S. government has a strong interest in ensuring that global resources are directed to recipients with the least capacity to finance their own response, and that funding flows are directed to the areas of greatest need in the health sector. At the same time, countries are increasingly financing their responses to the epidemic, and are in need of donor resources to supplement domestic efforts. Information about these financial flows is critical to understanding a country's epidemic and appropriate response. PEPFAR will expand engagement with the donor community, including the Global Fund, World Bank, U.S. Treasury and other U.S. government agencies to better measure and track external and internal funding flows for health, and support greater transparency and accountability in the deployment of those resources. PEPFAR will also work to establish baseline data and implement incentives for annual progressive increases in domestic co-financing that complement strategic investments by donors. And PEPFAR will work with UNAIDS around ensuring a strong investment case at country level that supports targeting of resources toward high-impact interventions.

4. Expand high-impact technical assistance in conjunction with the Global Fund. Since 2005, a portion of the U.S. government's annual contribution to the Global Fund has been withheld to provide high quality, short-term, demand-driven technical assistance to countries receiving Global Fund resources. These resources have complemented the efforts of our PEPFAR country teams and have historically provided critical support in the areas of County Coordinating Mechanism (CCM) governance, Principal Recipient/Sub-Recipient project and financial management, procurement and supply chain management, and monitoring and evaluation. Going forward, PEPFAR will strengthen the ongoing technical assistance efforts in these areas and work with the Global Fund to identify areas for additional technical support, including program quality, transition and scale-up of Global Fund-financed services, and use of

strategic information to guide country priorities and drive future funding decisions.

5. Achieve greater value for money through deeper collaboration and targeted investments. As we move aggressively to a sustainable response, PEPFAR and its multilateral partners are working more closely together, expanding services at a lower cost. The Global Fund's new funding model will draw upon national planning processes using disease-specific Strategic Investment Frameworks, along with other tools such as unit-cost benchmarks (where feasible), demand forecasts, and portfolio analyses to better inform resource allocation and investment decisions. The U.S. government will support UNAIDS playing a leadership role as a convener of national governments and key stakeholders to apply a strategic investment approach to guide domestic and international investments in HIV. These efforts offer a practical and common reference for strategic interventions in different country or epidemiological settings, which then guide the dialogue between governments and partners about how to collectively ensure funding maximizes impact. And PEPFAR is working with the World Bank to identify ways for the Bank's resources to better support a sustainable, country-led response to HIV, in conjunction with PEPFAR.

Action Step: Increase private sector mobilization toward an AIDS-free generation.

Private sector engagement (PSE) and public-private partnerships (PPPs) play a critical role in strengthening and extending the principle of shared responsibility to achieve an AIDS-free generation. The ultimate goal of each PPP is to allow more people to benefit due to the additional resources—whether monetary or technical—brought to the partnership by the private sector organization. Doing so can increase efficiency, increase effectiveness and harness the comparative advantages of all partners. It can also be a tool to build capacity of local country partners. A key piece of PSE and PPP activities going forward is the maintenance and expansion of current partnerships, as well as the development of new partnerships that enhance country ownership and shared responsibility.

> "Our work with PEPFAR over the last five years has demonstrated how the private sector can effectively apply its technologies and expertise to have a positive impact on healthcare in the regions most heavily burdened by disease."
>
> \- Vincent A. Forlenza, Chairman of the Board, Chief Executive Officer and President, BD

PEPFAR's private sector engagement has mobilized financial and human capital resources from a variety of diverse stakeholders that have matched or surpassed resources from U.S. government partners. Through these partnerships, PEPFAR has leveraged the private health sector's infrastructure and utilized the core business expertise of multinational firms, small indigenous business owners and civil society. It has also helped to expand PEPFAR's engagement with philanthropic organizations, including private foundations and faith-based organizations.

To implement this action step, PEPFAR is and will:

1. Create collaborations around private health sector delivery of services to expand coverage and quality of care. In sub-Saharan Africa, the private sector is a significant provider of health services for both HIV and other infectious and chronic conditions. Cooperation with private providers can help strengthen systems and expand basic HIV services. PEPFAR will work to increase the representation of and linkages between these private providers and government strategies to ensure that all forms of care are included in strategies to fight AIDS. Areas for expanded partnership include mapping of private and government facilities to determine how to optimize locally-driven shared service and referral agreements for underserved regions or populations. Furthermore, expansion of pooled private co-insurance models that encourage fair market reimbursement for premium service packages for middle-income families can help to extend current resources and sustain access to care and treatment. To

Photo Credit: State Department

effectively engage the private health sector as a long-term successful partner for an AIDS-free generation, PEPFAR and other partners will support countries as they strengthen standardization of quality of care guidelines by private providers, provide supervision and accreditation of private facilities, and invest in continuing medical education for health workers within the private health sector.

2. Support reporting and evaluation of private sector engagement. Strengthening methods for assessing the impact of private sector engagement and specific partnerships are key areas for ongoing development. Evaluations may consider level of impact (systems, organization, or human capacity) and functional areas, including health services and health systems strengthening. Additionally, reports may categorize percentage of partnership investments by stage (catalyst, regional, and national expansion) to showcase maturity of programs and high priority areas for future investment. PEPFAR has taken initial steps to mine some of this data, but will be working to expand efforts to evaluate impact of private sector engagement.
3. Actively seek and apply the core competencies of the private sector in strengthening the global response at every level. A strength of PEPFAR's private sector engagement is that it leverages core experiences and competencies. Examples of shared value created by partnerships include leveraging the private health sector's infrastructure, delivery services and supply chain to target at-risk populations and utilizing the management, marketing and core business expertise of private business enterprises. By establishing global partnerships with multinationals or collaborations with small indigenous business owners, PEPFAR can multiply the impact of its investments.

ROAD MAP FOR DRIVING RESULTS WITH SCIENCE

PEPFAR GOAL: Science Must Continue to Guide Our Efforts

ACTION STEPS

- Leverage greatest impact by continuing to invest in implementation science.
- Support implementation research.
- Evaluate the impact of optimized combination prevention.
- Support innovative research to develop new technologies for prevention (e.g., microbicides, vaccines) and care (e.g., new treatments or treatment regimens).
- Develop evidence-based approaches to reaching people early enough in their disease progression to help maintain a strong immune system, stave off opportunistic infections, particularly TB, and reduce new HIV infections.
- Support the deployment of suitable technology for measurement of viral load, both through tiered laboratory networks and 'point-of-care' tests as they become available.
- Assist countries in adopting breakthrough new technologies with proven impact, such as new molecular-based TB tests that have dramatically reduced time to diagnosis and treatment for people living with TB and HIV.

Science is the foundation for all PEPFAR programs, and the latest scientific evidence underlies all road maps contained in this blueprint. As is the case with all scientific knowledge, our programs, guidelines and blueprints are subject to change as new evidence becomes available. PEPFAR will also continue to engage with our Scientific Advisory Board and research partners to update our programmatic portfolio based on the most recent scientific evidence.

Given PEPFAR's increasing focus on sustainability, programs must demonstrate value and impact in order to be prioritized within complex and resource-constrained environments. In this context, there is a greater demand to causally attribute outcomes to specific programs. To address these requirements, PEPFAR is using an implementation science framework that focuses on methods to improve the delivery, uptake and translation of research findings into real-world use and to ensure that science is ultimately driving results. The objective is to identify opportunities for improving program performance that can be translated into immediate answers by addressing what worked, why and under what circumstances.

Acceleration of this effort will permit PEPFAR to support strategic interventions and focus them where they will have the most impact while simultaneously improving implementation effectiveness, efficiency and sustainability. An implementation science framework also positions PEPFAR to actively develop and contribute knowledge about HIV/AIDS program implementation to the global community.

PEPFAR is committed to a comprehensive and leveraged approach to implementation science. Through a whole-of-government approach, NIH has played a key role leading in

> "We now have an unprecedented opportunity, based on solid scientific data, to control and ultimately end the AIDS pandemic."
>
> - Dr. Anthony Fauci, NIAID Director

development of new technologies and in leading an international approach to core research questions using broad requests for proposals. Accordingly, PEPFAR is able to draw on current research capacity while supporting the development of implementation science through PEPFAR implementing agencies for enhanced use of data for decision-making.

PEPFAR Goal: Science Must Continue to Guide Our Efforts

To implement this goal, PEPFAR is and will:

1. Leverage greatest impact by investing in continued implementation science through agency-specific mechanisms, rigorous evaluations of new PEPFAR programs, and promotion of innovative methods of delivery. The implementation science agenda examines methods that:
   a) Achieve scale as measured by population level impact.
   b) Ensure that program data are sufficient to support rigorous evaluations, simple to collect and useful (e.g. electronic health information systems).
   c) Rigorously analyze and rapidly apply program data and newly generated knowledge through continual feedback loops to and from:
      i. The field for adoption of new knowledge.
      ii. Decision-makers including PEPFAR and country governments for accountability, resource allocation, and program improvement.
      iii. Global and local normative agencies to inform WHO and national guidelines.
      iv. The global research community to improve the field of implementation science.
   d) Reach multiple populations (including key populations) in different settings.

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   e) Deliver programs effectively and efficiently in combination.
   f) Examine comparative health-systems strategies for optimal program delivery
2. Support implementation research:
   a) On decentralization strategies to help reach and retain more people in care (and put people more in charge of their care), such as community-based testing and treatment strategies
   b) On interventions that can help address gaps in the continuum of care—plugging the holes in the leaky cascade—including ways to increase testing, improve linkage to care for people testing positive, and reduce attrition by helping people remain in care.
   c) Test interventions, including innovative technologies and other strategies to reduce the burden on patients, the cost of the package of care and the requirements of the health system to deliver.
3. Evaluate the impact of optimized combination prevention.
4. Support innovative research to develop new technologies for prevention (e.g., microbicides, vaccines) and care (e.g., new treatments or treatment regimens).
   a) Work with NIH and others to move forward the scientific agenda to develop new technologies including the search for a cure.
5. Develop evidence-based approaches to reaching people early enough in their disease progression to help maintain a strong immune system, stave off opportunistic infections, particularly TB, and reduce new HIV infections.
6. Support the deployment of suitable technology for measurement of viral load, both through tiered laboratory networks and 'point-of-care' tests as they become available. This technology is particularly important in helping people on ART and their care providers monitor how their treatment is working and assist them in achieving an "undetectable" level or virus in their bodies.
7. Assist countries in adopting breakthrough new technologies with proven impact, such as new molecular-based TB tests that have dramatically reduced time of diagnosis and treatment for people living with TB and HIV.

GLOSSARY

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Clinic
ART	Antiretroviral Therapy
ARV	Antiretroviral Drug
CCM	Country Coordinating Mechanism
CDC	Centers for Disease Control and Prevention
COP	Country Operational Plan
EID	Early Infant Diagnostics
EQA	External Quality Assurance
FP	Family Planning
GBV	Gender Based Violence
GHI	Global Health Initiative
HIV	Human Immunodeficiency Virus
HIVDR	HIV Drug Resistance
HTC	HIV Testing and Counseling
LCI	Local Capacity Initiative
LGBT	Lesbian Gay Bisexual Transgender
MNCH	Maternal, Neonatal, and Child Health
MOVE	Models for Optimizing Volume and Efficiency
MSM	Men who have Sex with Men
NGO	Non-Governmental Organization
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institute of Health
OVC	Orphans and Vulnerable Children
PEP	Post-Exposure Prophylaxis
PEPFAR	President’s Emergency Plan for AIDS Relief
PHDP	Positive Health, Dignity, and Prevention
PLHIV	People Living with HIV
PMTCT	Prevention of Mother-to-Child Transmission
PITC	Provider-Initiated HIV Testing and Counseling
PPP	Public Private Partnerships
PSE	Private Sector Engagement
PWID	People Who Inject Drugs
SMS	Short Message Service
STI	Sexually Transmitted Infection
SW	Sex Workers
TB	Tuberculosis
UNICEF	The United Nations Children’s Fund
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

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