An Action Agenda to **End AIDS**

Where are we in realizing the promise of beginning to end AIDS?

September 2013

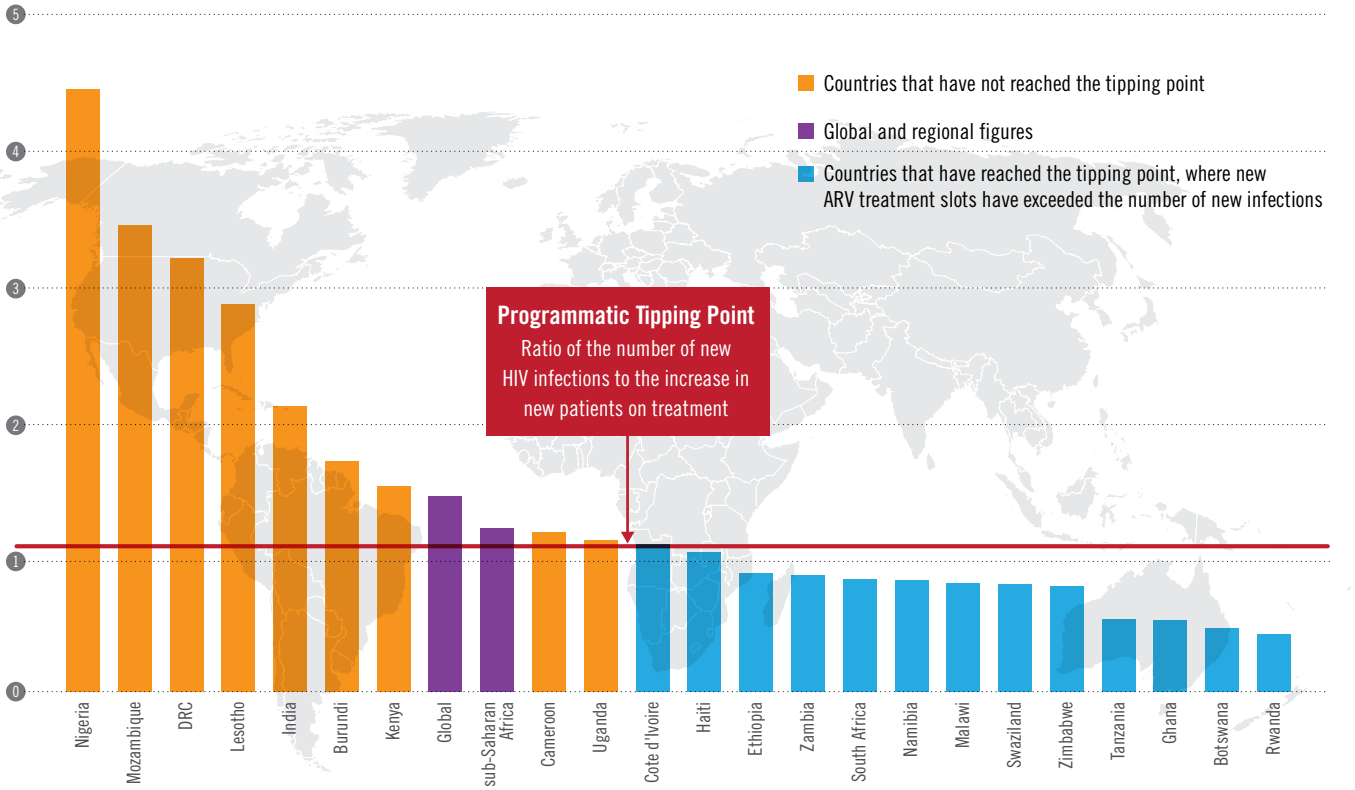
amfAR
MAKING AIDS HISTORY

AVAC
Global Advocacy for HIV Prevention

To bring critical focus and accountability to the effort to end AIDS, amfAR, The Foundation for AIDS Research, and AVAC released *An Action Agenda to End AIDS* at the International AIDS Conference in Washington in July 2012. The Action Agenda outlined strategic steps needed in 2012-2016 to establish a strong, sustainable foundation to end AIDS. The strategic actions outlined in the Action Agenda aim to reduce the time required for the pandemic to reach a "tipping point," with the yearly growth in the number of people on antiretroviral therapy outpacing the number of new infections – an important milestone on the road towards ending AIDS.

One year after the Washington conference, we see tangible progress in laying the foundation for the beginning of the end of AIDS. *However, we have yet to see the single-minded focus and accountability for results that will be needed to move the epidemic to the "end game."*

THE TIPPING POINT: Global progress in reducing new HIV infections and scaling up of antiretroviral treatment by 2012



CITATIONS

1. US PEPFAR. The Opportunity Proposition: Illustrative Country Scenarios for Accelerated Progress toward Achieving an AIDS-free Generation. www.pepfar.gov/documents/organization/201393.pdf
2. WHO, UNICEF, UNAIDS. Global Update On HIV Treatment 2013: Results, Impact And Opportunities. July 2013. www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20111130_ua_report_en.pdf
3. UNAIDS. UNAIDS report on the global AIDS epidemic 2013. www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf
4. UNAIDS. UNAIDS report on the global AIDS epidemic 2012. www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_with_annexes_en.pdf
5. PEPFAR. PEPFAR Blueprint: Creating an AIDS-free generation. November 2012. www.pepfar.gov/documents/organization/201386.pdf

KEY FINDINGS AND CONCLUSIONS

Where Countries have Brought Core Interventions to Scale, a Tipping Point in the Epidemic has been Reached

In at least 13 countries with generalized epidemics (Botswana, Cote d'Ivoire, Ethiopia, Ghana, Haiti, Malawi, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe), the growth in the number of people on ART in 2012 was greater than the number newly infected. At least four additional high-prevalence countries appear poised to pass this tipping point.[1] The *pace* at which responses are brought to scale appears to be critical, as countries that have increased treatment coverage most rapidly have seen far more substantial declines in HIV incidence and AIDS-related deaths.[2] Reaching the tipping point represents a critical milestone, but it is merely the first step towards the ultimate goal of ending AIDS.

Evidence on the Ground Shows that Rapid Scale up has Measurable Impact

The UNAIDS *Treatment 2015* framework,[3] released in July, demonstrates that countries that have increased access to HIV treatment more quickly have also seen faster reductions in HIV incidence — compelling evidence that stepped-up investment and delivery can have tangible results and accelerate progress.

This report offers a snapshot of how the world has responded to the historic opportunity to end AIDS. Using the *Action Agenda* as a framework, it summarizes where the world is making progress, where gains are too slow, and what needs to happen next to get the world on track to end AIDS.

Globally, We Have Yet to Reach the Tipping Point, Due to Slow Progress Preventing New Infections Among Adults and Adolescents and Failure to Get Treatment to People as Quickly as Needed

In 2012, the last year for which comprehensive coverage and epidemiological data are available, about 1.6 million additional people were receiving ART – well shy of the 2.3 million who were newly infected.[4] While the number of children newly infected with HIV fell 24% from 2009 to 2011, the decline in new infections among adults and adolescents has been much more modest (from 2.2 million in 2008 to 1.9 million in 2012).[5] It will be impossible to lay the foundation for the pandemic's end without dramatically greater progress in reducing new infections among both adults and children.

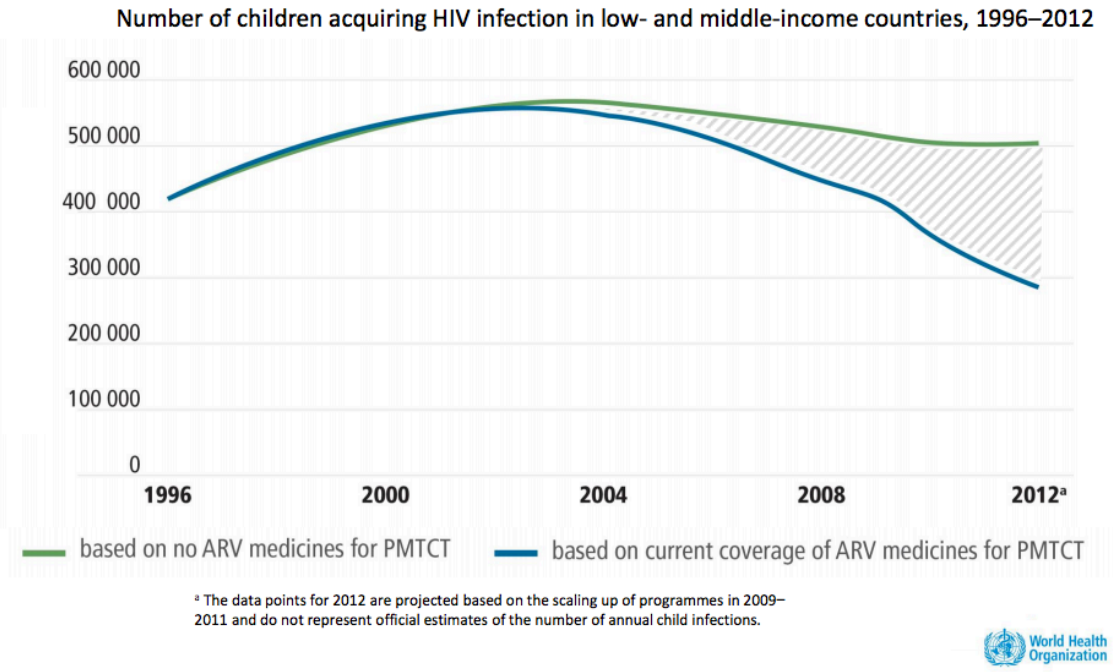
When it Comes to Bringing Greater Strategic Focus to the Response, We Meed to Translate Rhetoric into Results

UNAIDS released its landmark Investment Framework in 2011, arguing for smarter investments to achieve quicker, greater, more sustainable results.[6] There are encouraging signs of a greater strategic focus in the response. The PEPFAR Blueprint prioritizes rapid and strategic scale-up of core interventions (specifically ART, PMTCT and voluntary medical male circumcision),[7] a new funding model for the Global Fund calls for heightened funding for high-impact strategies,[8] and UNAIDS reports that a number of countries are working to develop investment cases to guide and support resource mobilization efforts. Two years after the Investment Framework was released, though, we await clear evidence that funding has substantially shifted in a significant number of countries toward accelerated scale-up of core interventions.

Continued Scale-up of ART and Services to Prevent Mother-to-Child Transmission (PMTCT) Show What can be Accomplished Through Focus, Smart Investments and Commitment

As the number of people receiving antiretroviral therapy rose by 1.6 million in 2012, the world was nearly two-thirds of the way (64%) toward the 2015 target of reaching 15 million people with HIV treatment. PMTCT utilization also continues to increase, with coverage of antiretroviral medicines among HIV-positive pregnant women rising to 63% in 2012,[9] although substantially greater gains will be needed if the world is to achieve its 2015 target of reducing the number of new HIV infections among children by 90% (2009 baseline).

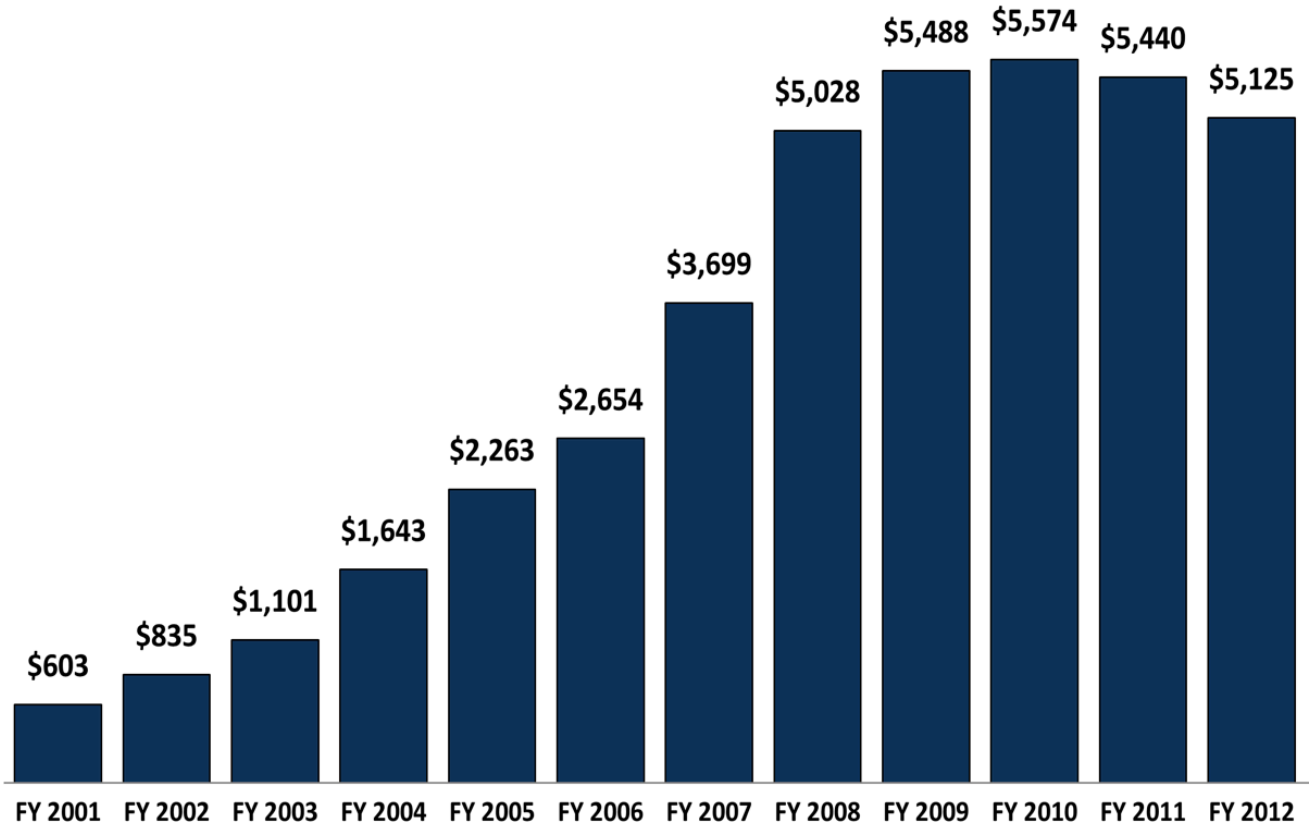
Impact: PMTCT averted more than 800 000 child infections



Flattening International Support Threatens Efforts to Lay the Foundation for an AIDS-Free Generation

To save money in the long run, the world needs to ramp up spending now in order to bring high-impact, high-value core interventions to scale. Although there are encouraging signs of greater domestic AIDS spending by many low- and middle-income countries,[10] it will be impossible to build the bridge to an AIDS-free generation without continued, steadfast support from the international community. In particular, while the U.S. has shown critical leadership in shoring up financing for the Global Fund to Fight AIDS, Tuberculosis and Malaria, recent cuts to PEPFAR, among the most successful global health programs in history, are especially concerning. Although PEPFAR is a pillar of efforts to scale up ART, services to prevent infections in newborns, and voluntary medical male circumcision, PEPFAR funding has fallen 12% since 2010, and the White House has proposed an additional $50 million cut to the program in next year's budget. Recent cuts to PEPFAR need to be reversed, and proposed reductions should be rejected by Congress. With the U.S. now providing two-thirds of all international HIV assistance, it's past time for other donor countries to devote resources towards the HIV fight commensurate with their national wealth.[11] In addition to the need to ramp up HIV assistance from European countries and other traditional donors, emerging economies (e.g., Brazil, China, South Africa) should increase their own aid to low- and middle-income countries to scale up core interventions.

U.S. Global Health Funding: Bilateral HIV, FY 2001-2012 (in millions)



Source: Kaiser Family Foundation. Information is pending final agreement on FY13 funding.

Ending AIDS will be Impossible Without Dramatically Stronger Efforts to Address the HIV-related Needs of Key Populations

There are signs that the relative HIV burden among key populations (such as men who have sex with men, people who inject drugs, sex workers and transgender people) in the AIDS pandemic is increasing over time.[12] Long believed to represent a relatively modest share of infections in generalized epidemics, it is now clear that key populations account for a substantial share of new infections in all parts of the world,[13] including in sub-Saharan Africa.[14] However, the world has yet to come to grips with the HIV-related needs of key populations. Countries allocate minimal resources for HIV programs for key populations,[15] stigmatizing attitudes of health care providers deter key populations from accessing testing, treatment and prevention services,[16] and every country in sub-Saharan Africa has laws in place that criminalize at least one key population.[17]

We Lack the Timely Data We Need to be Genuinely Accountable for Results

A major shortcoming of current global information on the epidemic is that figures are out of date almost as soon as they appear. Epidemiological trends are typically reported for 12 months earlier (although this year UNAIDS released global and regional epidemiological data in September rather than November), and the world has also often waited up to a year for service coverage data. Little evidence is systematically reported on ART coverage for key populations, and surveys currently used to estimate prevention coverage tend to be setting-specific (usually in capital cities) and are not nationally representative. Recently, there have been some encouraging moves that should be leveraged to build a more timely system for strategic information. PEPFAR collects coverage data every six months, and WHO in June 2013 reported ART coverage as of December 2012. Moving swiftly to make more timely reporting standard practice, we urgently need to strengthen our data collection and reporting systems in order to hold ourselves accountable for results. In particular, urgent attention is needed to strengthen epidemiological systems and methodologies to identify key "hot spots" within countries that require intensive attention.

Setting targets injects a sense of urgency that helps teams meet their goals. I personally experienced the truth of this when I headed the World Health Organization's HIV/AIDS efforts. I set a global target called the 3 by 5 Initiative, which aimed to put 3 million people living with HIV/AIDS on antiretroviral treatment by 2005.

We did not meet the target until 2007, but because we released data every six months on progress toward the goal, leaders in countries became more accountable and helped speed up the response. Likewise, the targets set by the Millennium Development Goals injected urgency into government efforts to meet crucial development objectives by the deadline of 2015.

Jim Kim
President, World Bank Group
April 2013

In the initial *Action Agenda to End AIDS* published in July 2012, amfAR and AVAC outlined activities in five strategic pillars that required urgent attention and that, if implemented with speed and to scale between 2012 and 2015, could begin to end the epidemic. The analysis the in the following pages reflects progress – or the lack thereof – under each of these five pillars:

IF WE DO THIS

- **Make hard choices by prioritizing rapid and comprehensive scale-up of core interventions along with specific, rights-based approaches to reach populations at greatest risk.**
- **Mobilize sufficient, sustainable resources to ensure the rapid and comprehensive scale-up of core interventions.**
- **Agree on clear roles and responsibilities and hold one another accountable for results through agreed timelines, target outcomes, transparent reporting and real-time assessment of results.**
- **Build the evidence base to end AIDS by prioritizing implementation research and the search for a preventative vaccine and a cure.**
- **Use every resource as effectively as possible by lowering the unit costs of core interventions, improving program management and strategically targeting services.**

WE CAN ACHIEVE THIS

2012	2013	2014	2015
9 million people on ART	At least 11 million people on ART	At least 13 million people on ART	At least 15 million people on ART
No more than 1.9 million new HIV infections	No more than 1.3 million new HIV infections – ***a tipping point, as the number of new ART slots surpasses the number of new infections for the first time***		No more than 1.0 million new HIV infections worldwide
No more than 280,000 new infections in children and 65% PMTCT coverage	No more than 200,000 new infections in children and 75% PMTCT coverage	No more than 100,000 new infections in children and 85% PMTCT coverage	At least 90% PMTCT coverage
No more than 1.6 million AIDS deaths and 20% fewer TB deaths than in 2010	No more than 1.5 million AIDS deaths and 30% fewer TB deaths than in 2010	No more than 1.4 million AIDS deaths and 40% fewer TB deaths than in 2010	No more than 1.2 million AIDS deaths and 50% fewer TB deaths than in 2010
At least 4.7 million voluntary medical male circumcisions (VMMC) supported by PEPFAR		At least 60% coverage of VMMC in 14 priority countries	80% coverage of VMMC in priority countries is within immediate reach
20% of African countries achieve Abuja Declaration	40% of African countries achieve Abuja Declaration	60% of African countries achieve Abuja Declaration	100% of African countries achieve Abuja Declaration
At least 10 countries pledge to increase funding to Global Fund	At least $18 billion available for HIV programs, with at least 10 additional countries pledging to increase funding to Global Fund	At least $20 billion available for HIV programs	At least $24 billion available for HIV programs, including $4.7 billion from the domestic public sector in sub-Saharan Africa

SCALE UP HIGH-IMPACT STRATEGIES

Important progress has been made in scaling up several core interventions, although progress is much slower for other strategies. Key populations are being left behind as programs are brought to scale for others.

WHERE WE ARE MAKING PROGRESS

The Number of People on ART Approaches 10 Million

As of December 2012, an estimated 9.7 million people were on ART in low- and middle-income countries – an increase of 1.6 million over December 2011.[18] This represents important progress but is slightly off the pace of what is needed to reach 15 million people on HIV treatment by 2015.

PMTCT Services Expand by One-Third Over Three Years

The number of pregnant women living with HIV who received antiretroviral in 2012 (900,000 worldwide) increased, with coverage rising from 57% in 2011 to 63% in 2012.[19]

An Estimated 4 Million African Men Will be Circumcised by End of Year

An estimated 3.2 million men in sub-Saharan Africa have received VMMC since WHO and UNAIDS issued their recommendation for scale-up in 2007. After slow progress in the years immediately after WHO formally recommended VMMC for HIV prevention in 2007, PEPFAR now projects that at least 4 million men will have been circumcised in the 14 priority countries by December 2013.[20] That represents 20% of the 80% coverage target and a four-fold increase in circumcised men since 2009.

New ART Guidelines Recommend Earlier Therapy, Simpler Regimens

New WHO ART guidelines, released in June, recommend earlier initiation of ART and use of simplified, more durable regimens.[21] For many people living with HIV, treatment is now medically indicated immediately upon HIV diagnosis, regardless of CD4 count. The new guidelines, which aim to maximize the therapeutic and preventive benefits of ART, increase the estimated number of people eligible for ART from roughly 15 million to 26 million.

The new **WHO consolidated antiretroviral guidelines** released in June 2013 call for use of a CD4 cell count threshold of 500 cells per mm^3 for most adults living with HIV. This contrasts with the 350 CD4 count threshold recommended by the 2010 WHO guidelines. The 2013 guidelines also recommend initiation of HIV treatment, regardless of CD4 count, for all pregnant women living with HIV, HIV-negative partners in serodiscordant couples, all HIV-positive people with TB and all people with HIV/HBV co-infection.

WHERE WE ARE FALLING SHORT

Coverage Gaps Persist in Scaling Up Core Interventions

Under the new WHO guidelines, ART currently reaches only 34% of those who are eligible for treatment, and many countries are lagging in bringing ART to scale. Angola, Democratic Republic of Congo, Mozambique and Nigeria – which together have nearly 2.5 million people who are eligible for ART – each reach fewer than 50% of those in need of HIV treatment under the earlier 2010 WHO guidelines.[22] The pace of scale-up of services to prevent mother-to-child transmission will need to quicken to reach the 2015 elimination target for new infections among children; VMMC programs are largely failing to reach the older men who are most in need of circumcision;[23] and while utilization of HIV testing services is increasing, 1 in 4 people in low- and middle-income countries have CD4 counts below 100 when they initiate HIV treatment.[24] Earlier diagnosis and effective intervention to close gaps in the HIV treatment cascade will be critical to improving health outcomes for people living with HIV.

Stigma and Discrimination Remain Widespread

Where stigma and the fear of discriminatory treatment remain widespread, many people are deterred from seeking essential HIV services. Surveys under the People Living with HIV Stigma Index demonstrate that stigmatizing attitudes and discriminatory practices toward people living with HIV remain common in many countries.[25] Nearly 4 in 10 countries lack laws prohibiting HIV-related discrimination; 60 countries criminalize HIV transmission, exposure or non-disclosure; more than 40% of countries criminalize same-sex sexual relations; and punitive approaches to sex work and drug use exist in nearly all countries.[26]

Inadequate Access to Key Diagnostic Tools Undermines Treatment Programs

Access to CD4 and viral load testing remains insufficient in many resource-limited settings, undermining the long-term effectiveness of antiretroviral treatment.[27] Access to viral load testing becomes increasingly important to monitor responses to therapy, support patient adherence, and avoid unnecessary switches to more expensive second-line therapies.

WHAT NEEDS TO HAPPEN NOW

Scale Up Core Interventions

By focusing resources on select high-impact, high-value interventions, expedited progress will be achieved in reducing AIDS-related deaths and new HIV infections. According to a recent economic analysis, merely reallocating existing resources toward core interventions and away from less strategic non-core approaches would increase the impact of efforts by 20%.[28]

Improve Strategic Data

PEPFAR, the Global Fund, WHO, UNAIDS and national health ministries should, by the end of 2013, develop and begin implementing plans for 6-month reporting on key epidemiological and service coverage indicators. As part of this new reporting system, indicators should be launched and reporting systems developed to permit ongoing monitoring of prevention and treatment coverage, HIV incidence and AIDS-related deaths among the population as a whole as well as specifically among men who have sex with men, people who inject drugs, sex workers and transgender people. Donors should support countries in undertaking focused HIV-specific studies, such as the recently released update of the Kenya AIDS Indicator study, to inform and guide program implementation and promote accountability.

Align Legal and Policy Frameworks with Human Rights Principles

Over the next two years, all countries must ensure that laws are in place to prohibit HIV discrimination. Urgent steps must be taken to remove legal provisions that criminalize same-sex sexual relations, authorize mandatory detention and treatment for people convicted of drug offenses, and criminalize aspects of sex work.

Scale Up Prevention and Treatment for Key Populations

The international community, including donors and national governments in low- and middle-income countries, should launch a well-resourced, rigorously monitored three-year campaign to ensure equitable treatment coverage for key populations and at least 80% coverage for evidence-based prevention services for key populations.

Scale Up Viral Load Testing

Optimizing HIV treatment demands that clinicians have access to technologies that permit timely identification of treatment failure. Intensive focus is needed to scale up viral load monitoring tools, including prioritized research on affordable, point-of-care technologies.

MOBILIZE RESOURCES NEEDED TO SCALE UP CORE INTERVENTIONS

While many low- and middle-income countries are increasing domestic HIV spending, efforts to achieve an AIDS-free generation are undermined by flagging support from international donors.

WHERE WE ARE MAKING PROGRESS

Many Developing Countries Have Increased Investments in HIV Programs

In 2011, for the first time ever, domestic resources accounted for more than half of all expenditures on HIV activities in low- and middle-income countries.[29] Driven in large measure by the increased resource mobilization by developing countries, total HIV expenditures rose by 10% in 2012, reaching $18.9 billion.[30] A number of countries – including Kenya, South Africa and Zambia – have increased domestic public sector financing for HIV.[31] Among countries reporting expenditure data to UNAIDS for 2012, two-thirds reported increasing HIV domestic investments.[32] In 2012, the African Union outlined a roadmap on shared responsibility for AIDS that pledges to intensify efforts to increase domestic HIV spending and diversify funding sources.[33]

The Strength of the Global Fund Improves

Several countries, including the U.S., made major new funding commitments to the Global Fund, which is in the process of implementing a visionary new strategy that is poised to enhance the predictability of Global Fund support and the focus on tailored, innovative approaches. President Obama's budget request for FY2014 calls for a 27% increase over the U.S. contribution in FY2012.[34] During the transition period toward implementation of the it's new funding model, the Global Fund will make up to $1.9 billion available for new health grants.

The UK Prioritizes Development Aid in the Midst of Austerity

The U.K. has continued to increase official development assistance in order to achieve the ODA target of 0.7% of gross national product. In 2013, the U.K. made a new multi-year commitment to the Global Fund that doubles the British contribution.

WHERE WE ARE FALLING SHORT

Cuts to PEPFAR Jeopardize Future Progress

Even as the prestigious Institute of Medicine lauded PEPFAR's extraordinary achievements in an independent evaluation,[35] decision-makers in Washington have cut PEPFAR funding by 12% since 2010, and President Obama has proposed an additional $50 million cut for Fiscal Year 2014.

Flagging International Commitment to Development Aid Threatens Future AIDS Funding*

Overall, official development assistance by traditional donor countries fell by 4% in 2012, the second straight year in which donor support for health and development has fallen.[36] While the G8, beginning in 2000, devoted high-level attention to global AIDS issues at annual summits, AIDS has barely been mentioned in G8/G20 summit declarations in recent years, and the G8/G20 has made no new AIDS commitments since its six-year $60 billion funding target expired in 2012.[37] Many international donors aren't pulling their weight, with the U.S. government accounting for 61% of all international HIV assistance in 2009-2011.[38]

Developing Countries Could Do Much More to Help Finance the AIDS Response

Many developing countries, especially low-income African countries with high HIV prevalence, remain highly dependent on external support.[39] Only six African countries have kept their pledge to allocate at least 15% of domestic public sector resources to health.[40] Almost all funding for programs for key populations comes from international donors.[41]

* For additional information, please see the new report by the Henry J. Kaiser Foundation on donor funding for HIV, released September 23, 2013: www.kff.org/global-health-policy/report/financing-the-response-to-aids-in-low

WHAT NEEDS TO HAPPEN NOW

International Donors Must Help Fund the Push to Achieve an AIDS-Free Generation

At the Global Fund replenishment meeting in the fall of 2013, donors must collectively commit at least $15 billion, which the Global Fund projects will be needed to finance essential AIDS and other health programs in 2014-2016.[42] The U.S. Congress and the Obama administration should return PEPFAR funding to its 2010 levels. At its 2014 summit, the G20 should make ambitious, time-bound commitments for global AIDS funding, with substantially scaled-up contributions from emerging economies such as the BRICS countries.

All African Countries Must Take Immediate Steps to Meet Their Abuja Commitments

In addition to the 6 African countries that have allocated at least 15% of domestic government spending to health, an additional 4 countries have allocated at least 14%.[43] As rapid economic growth continues to strengthen national tax bases in Africa, all countries in the region need to step up to the plate and keep their Abuja commitments.

BE ACCOUNTABLE FOR RESULTS

Although there is growing clarity about what needs to happen to lay the foundation for an end to AIDS, a genuine culture of accountability has yet to take hold in the AIDS field.

WHERE WE ARE MAKING PROGRESS

Momentum Builds to Include Health in Post-2015 Development Agenda

Nearly 200 civil society organizations petitioned members of a high-level panel, meeting in Bali in April 2013 to consider options for the post-2015 development agenda, including specific health targets (especially for AIDS, TB and malaria).[44] In June 2013, a high-level panel advised the international community to build on the MDGs to accelerate gains on poverty, hunger, education, health, sanitation and other priority issues; the panel recommended that the post-2015 development agenda adopt as its primary aim the eradication of extreme poverty and that it address key cross-cutting challenges that impede progress across the development agenda.[45] Continuing pressure will be needed to ensure that HIV and global health challenges generally are prominently featured in the post-2015 agenda.

Independent Evaluation Lauds PEPFAR

In February 2013, a blue-ribbon panel of independent experts convened by the Institute of Medicine released a comprehensive evaluation of PEPFAR that found the program to be "globally transformative."[46] In July 2013, the U.S. Government Accountability Office also lauded PEPFAR for its historic achievements but urged the program to improve information management systems and practices to maximize programmatic efficiency, report results and improve program evaluations. Initiatives to address these recommendations are under way.[47]

WHERE WE ARE FALLING SHORT

Out-of-Date Data Impedes Evidence-Informed Action

UNAIDS, historically the primary source for strategic information on HIV, relies on major donors and countries to submit epidemiological and coverage data. As a result of delays in receiving these reports, each November UNAIDS summarizes epidemiological data as of the *previous December*. Even though the AIDS field is rapidly changing and scientific developments make up-to-date information more urgent than ever, the AIDS field in mid-2013 continued to rely primarily on data from December 2011.

Methodological Weaknesses Undermine Usefulness of Existing Data

The UNAIDS National Commitment and Policies Instrument (NCPI), the primary resource on HIV-related policy frameworks, provides useful information, but draws heavily from each national government's own assessment of its actions. UNAIDS' prevention service coverage estimates for key populations are typically drawn from single surveys in capital cities, which have divergent sample sizes and often use varying methodologies.[48] In the context of generalized HIV epidemics, which also tend to be among the most stigmatizing environments for key populations, these coverage estimates are generally regarded as unrepresentative and unreliable and are seldom cited as authoritative, leaving the AIDS field without a meaningful mechanism to monitor trends in coverage for the populations most heavily affected by the epidemic. Due to stigma, discrimination and the all-too-frequent criminalization of behaviors of key populations, it is challenging to collect meaningful data. However, given the critical need for strategic information on the HIV response among key populations, all stakeholders involved in the collection or use of data (including national governments, UNAIDS and its UN partners, international donors, civil society and representatives of key populations) should collaborate to develop more reliable methods to estimate HIV prevalence and service coverage in these groups.

WHAT NEEDS TO HAPPEN NOW

Move to Six-Month Reporting of Strategic Data

Drawing from the successful experience of PEPFAR and the "3 by 5" campaign with more frequent reporting, UNAIDS should immediately undertake a prioritized collaboration with international partners and national governments to implement reporting of key service coverage and epidemiological trends every six months. As UNAIDS relies on the cooperation of key data custodians (e.g., national health ministries, PEPFAR, Global Fund, UNICEF, WHO), it is unable to make this move on its own, underscoring the importance of broad-based collaboration to improve the timeliness of data reporting for key indicators. In addition to measuring service coverage, regular reporting systems should also routinely measure such indicators as linkage to care and retention in care.

Preserve and Strengthen Program-Specific Targets for PEPFAR and the Global Fund

While overall service coverage, HIV incidence and AIDS-related deaths remain the ultimate measures of progress in the AIDS response, targets and rigorous monitoring for individual programs remain critical for continuous quality improvement and overall accountability. Targets for coverage and impact drive progress and help stakeholders focus on strategic actions to achieve specific results. This is critically important for the two largest sources of HIV funding – PEPFAR and the Global Fund. Especially as PEPFAR targets are due to expire in the near future, it is critical that PEPFAR and the Global Fund set new, ambitious, time-bound targets for their own respective performance.

Ensure that the 2014 International AIDS Conference Focuses on Accountability and Charts a Clear Way Forward

Drawing on the involvement and leadership of civil society, planners of the 2014 conference in Melbourne need to ensure that the meeting helps build and strengthen a culture of genuine accountability in the AIDS response. In particular, the conference should advance a consensus toward clear outcomes with time-bound targets in the quest to end AIDS.

Intensify Efforts to Include AIDS in the Post-2015 Development Agenda

The global community must recognize that AIDS is not over and that, as an unfinished Millennium Development Goal, the response to AIDS warrants continued high priority on the global political agenda. UNAIDS, WHO, and the Secretary General should accelerate their work with country leaders and civil society to build political support for inclusion of AIDS and other critical health issues in the post-2015 development framework.

BUILD THE EVIDENCE BASE TO END AIDS

Never before has the power of AIDS research been clearer, as the world unites around the dream of an AIDS-free generation. We must continue the search for a cure and a preventive vaccine, and we need to build the evidence to effectively implement the biomedical tools that have emerged.

WHERE WE ARE MAKING PROGRESS

Innovative Research Efforts Aim to Strengthen HIV Prevention Efforts

Numerous large clinical trials are underway to evaluate the community-level impact of treatment as prevention. In addition, the Bill & Melinda Gates Foundation is offering prize money to anyone who can generate the "next generation condom";[49] with Gates Foundation support, the International Initiative for Impact Evaluation has announced plans to fund at least 8 projects to evaluate innovative strategies to increase demand for voluntary medical male circumcision;[50] and isolation of additional neutralizing antibodies, including the first ever identified from the global South, has prompted researchers to follow numerous new leads in the search for a preventive vaccine.

Research Findings Build Optimism Regarding a Possible Cure for HIV

Researchers determined that initiation of antiretroviral therapy to an HIV-exposed infant 31 hours after birth succeeded in curing the infant of HIV.[51] In early 2013, French researchers reported that 14 individuals were functionally cured after being treated with antiretrovirals during acute infection.[52] In July 2013, two additional individuals were reported to be HIV-free after receiving bone marrow transplants, although experts cautioned that further follow-up was needed before drawing definitive conclusions.[53] Although no broadly applicable cure for HIV is now available, these research results nevertheless increased optimism that a more widely available cure might someday be feasible.

Antiretroviral Drug Pipeline Remains Robust

The annual HIV research pipeline review by the Treatment Action Group and HIV i-Base found that the ARV pipeline remains extremely active, although the report raised questions about pricing for newly approved compounds. The pediatric antiretroviral pipeline also has expanded, with expedited review of a promising new pediatric formulation underway.[54]

Funding for HIV Prevention Research and Development Increased in 2012

The amount spent on HIV prevention R&D rose by 6% in 2012, although it is believed that some of this increase stems from improved reporting by donors.[55]

Study Confirms Efficacy of Pre-Exposure Antiretrovirals for Prevention of Transmission among People Who Inject Drugs

Consistent with earlier study findings regarding the efficacy of PrEP for men who have sex with men and heterosexuals, a Thai study determined in June that a daily antiretroviral regimen reduced the odds of HIV acquisition among HIV-negative people who inject drugs by 49%.[56] While a positive result, this trial also highlights the challenges of prevention research among particularly marginalized populations; unfortunately, this trial did not provide access to clean injecting equipment that should be the core of all harm reduction programs for people who inject drugs. The practical effects of these results are unclear, as policy makers and program implementers continue to struggle with design, implementation and coordination of demonstration projects that can help translate clinical trial results into public health impact among the wide range of populations that could benefit from PrEP.

WHERE WE ARE FALLING SHORT

Adherence to Daily Topical and Oral Antiretroviral-Based HIV Prevention Appears to be a Major Roadblock

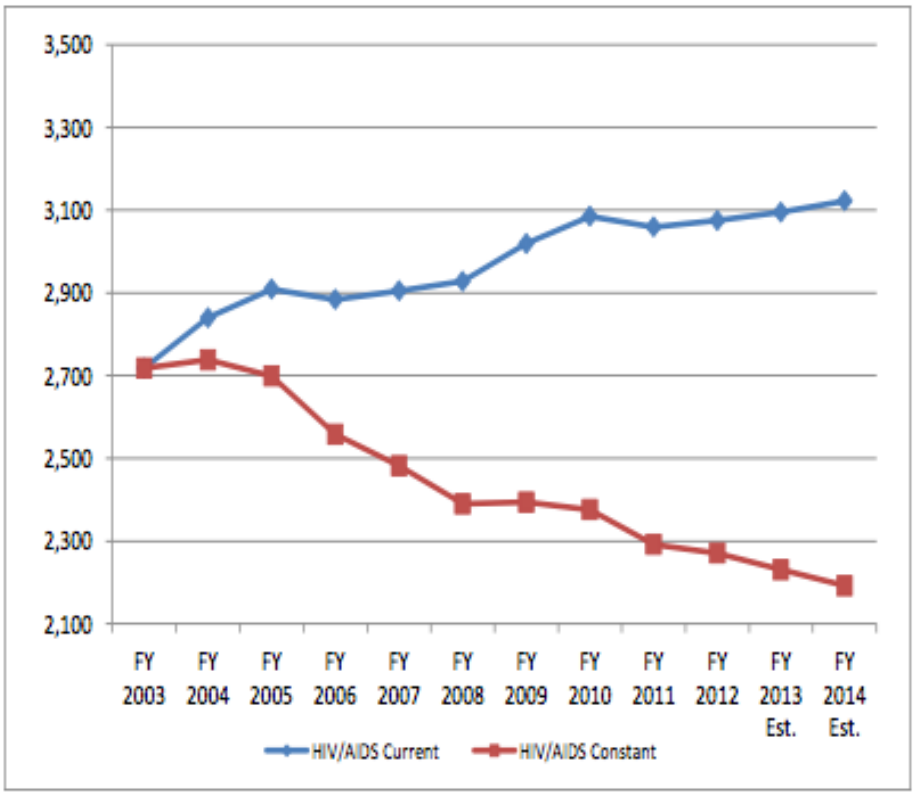
The VOICE trial found that daily use of a prophylactic intervention, whether a vaginal gel or an oral pill, was not effective in reducing new infections, apparently because trial participants who reported having taken the interventions failed in reality to do so.[57] Although controlled clinical studies have demonstrated the efficacy of a microbicide gel and oral pre-exposure prophylaxis, much work needs to be done to develop more effective strategies to encourage adherence to daily prevention regimens. In this regard, the slow pace at which demonstration projects for pre-exposure prophylaxis are being rolled out is cause for concern.

The Latest Trial Results Underscore the Challenges Associated with Development of a Preventive Vaccine

In April 2013, the National Institute of Allergy and Infectious Diseases terminated the HVTN 505 trial early due to futility. The trial was testing a prime-boost vaccine regimen. Meanwhile, follow-up from the only promising vaccine trial to date – the Thai trial of the RV144 combination vaccine – remains slow, with follow-up trials scheduled to launch only in 2016.

Budget Cuts at NIH Threaten Potentially Important HIV Research Projects

Budget sequestration in the U.S., which took effect March 1, 2013, led to a cut in AIDS research funding of $153.7 million as part of a broader $1.5 billion reduction in NIH funding, resulting in the loss of funding for an estimated 700 research grants this year. Cuts due to sequestration come on top of stagnating funding for U.S.-sponsored biomedical research since 2003, which has had the effect of reducing the purchasing power of the U.S. National Institutes of Health by 22% over the last decade.[58]



Source: National Institutes of Health

WHAT NEEDS TO HAPPEN NOW

Prioritize the Pursuit of a Cure and Vaccine

In a July 2013 commentary in the *Washington Post*, Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, stated that creating an AIDS-free generation will require a preventive vaccine.[59] In the case of HIV vaccines, researchers urgently need to develop a clear, prioritized plan for managing the pipeline of vaccine candidates in order to prevent duplication and to accelerate study of the most promising products.

Scale Up Investments in Implementation Science

Recognizing that translation of efficacy trial results into effective programs remains a major stumbling block, the National Institutes of Health and other research funders should increase support for studies to inform program implementation. Particular attention is needed to implementation questions pertaining to key populations, who often benefit least from programs rolled out in mainstream service settings. Focus should be on "learning by doing," with research projects embedded in the actual roll-out of services.

Respond to Growing Evidence Regarding the Pivotal Role of Adherence for New Prevention Tools

A balanced approach is needed that improves adherence in clinical trials, uses targeted roll-out of pre-exposure prophylaxis to build the evidence base for future roll-out of additional antiretroviral-based prevention methods, and intensifies efforts to develop new prevention methods that are less user-dependent. The AIDS field also needs to learn from acceptability studies and experience with roll-out of previous prevention tools to develop products that consumers actually want to use – an approach that has animated a Grand Challenge grant competition from the Bill & Melinda Gates Foundation for the development of a new, more user-friendly condom.

USE RESOURCES AS EFFECTIVELY AS POSSIBLE

Program efficiency is improving as services are being brought to scale, although failure to focus programs on those most at risk diminishes the impact of our efforts.

WHERE WE ARE MAKING PROGRESS

Efficiency of Treatment Programs Is Increasing

The continued rapid expansion of HIV treatment programs at a time when international financing has flattened indicates that programs are becoming more effective and efficient as ART is brought to scale. In 2013, the U.S. Government Accountability Office reported that per-patient treatment costs for PEPFAR fell by well over half from 2005 to 2011 as a result of declines in antiretroviral drug prices and programmatic efficiencies.[60] In 2013, UNITAID announced a major new effort to introduce point-of-care CD4 diagnostics in resource-limited clinical settings.[61] PEPFAR is also supporting research projects to evaluate strategies to reduce patient loss across the HIV treatment continuum, which would enhance the impact of treatment investments.

Some Progress Made Toward Ensuring Affordability of Antiretrovirals

In a closely watched decision, the Indian Supreme Court ruled in April 2013 that Novartis should not receive patent protection for its cancer drug, Gleevec, because it was too similar to a prior version of the drug; the ruling against the practice of so-called "evergreening" of drugs that don't represent a major advance was lauded by health advocates, who believe it could help preserve the ability of Indian generic manufacturers to produce low-cost drugs for developing countries, including antiretrovirals.[62] In the meantime, African leaders have embarked on a regional effort to strengthen manufacturing capacity in the region to produce generic antiretroviral drugs.[63]

In July 2013, results from a multi-country trial funded by the Bill & Melinda Gates Foundation found that lowering the recommended dosage of the antiretroviral efavirenz from 600 mg to 400 mg was safe, effective and associated with lower rates of regimen discontinuation; were this dosage to be widely implemented (a step that will require the manufactures to make a 400 mg formulation), it could lower the cost of first-line regimens in low- and middle-income countries.[64]

First Non-Surgical Circumcision Device for Adults Approved for Use in Resource-Limited Settings

In May, WHO prequalified the PrePex non-surgical device for use in VMMC for adult males. The non-surgical PrePex device requires only a fraction of the time as surgical circumcision,[65] although a recent study suggested that PrePex would not likely result in cost savings for VMMC programs in sub-Saharan Africa.[66] WHO is also reviewing a number of other non-surgical devices for VMMC.

PEPFAR Implements Annual Expenditure Reporting

PEPFAR has begun requiring annual reporting of partner expenditures, which permits more transparent and timely assessments of the efficiency, effectiveness and accountability of spending.

WHERE WE ARE FALLING SHORT

Trade Policies of Donor Countries Threaten to Undermine Efforts to Lower Costs for Essential Health Commodities

At the same time that they fund HIV treatment programs, donor countries in North America and Europe reportedly continue to seek provisions in various Free Trade Agreements (FTAs) that could undermine the ability of pharmaceutical companies in the global South to make affordable generic alternatives for use in developing countries. In April 2013, AIDS activists rallied in New Delhi, urging the Indian government to reject a proposed FTA that includes intellectual property provisions that could undermine future drug access.[67]

There is No Clear Evidence of a Shift Toward More Strategic Resource Allocation

While PEPFAR and the Global Fund have taken steps to increase the strategic focus of their investments, concrete evidence that allocations in countries have shifted toward an alignment of national spending with investment principles is incomplete. In particular, the persistent under-prioritization of programs for key populations at highest risk reduces the strategic impact of programs.

Greater Transparency is Needed Regarding HIV Resource Tracking

Although PEPFAR has made the move to annual expenditure reporting for partners, this information is not routinely made public, undermining the ability of stakeholders to assess the efficiency and effectiveness of resource flows. Obtaining clear information regarding the types of services associated with the Global Fund is similarly challenging. Promoting accountability demands easier and more timely access to strategic data on spending patterns for these two most important sources of HIV assistance.

WHAT NEEDS TO HAPPEN NOW

Service Delivery Should Be Decentralized

It will be difficult, if not impossible, to reach universal access to ART solely through facility-based approaches. Decentralized approaches that include task-shifting and community delivery channels will be critical to success. Embedding HIV interventions in high-profile, multi-disease health campaigns offers an excellent opportunity to extend the reach of HIV programs.

Point-of-Care Diagnostics Should Be Rapidly Brought to Scale

International donors should allocate emergency funding to facilitate scale-up of CD4 and viral load diagnostics in clinical settings.

Remain Vigilant to Ensure Long-Term Viability of Generic Alternatives

Although the India Supreme Court's recent ruling on Gleevec is heartening, multiple obstacles remain to ensure the long-term availability of generic alternatives manufactured in India, especially with regard to second- and third-line antiretrovirals. The G8/G20 should commit at its 2013 summit in St. Petersburg to mainstream health across its diplomatic work on trade issues, to ensure that positions taken in trade negotiations do not undermine the impact of health assistance. In the meantime, developing countries should increase utilization of the flexibilities under the TRIPS agreement to increase access to essential medicines.

Aggressively Use Market Interventions to Lower Commodity Costs

WHO, the Global Fund, donors and other partners should actively collaborate with UNITAID to implement market interventions (e.g., bulk purchases, assistance to accelerate WHO pre-qualification, etc.) to lower costs of essential HIV tools. Further expanding ART access will also generate economies of scale that will permit additional reductions in unit costs of treatment services.

WORKS CITED

[1]WHO (2013). *Global Update on HIV Treatment: Results, Impact and Opportunities* ("*WHO Progress Report*").

[2]UNAIDS (2013). *Treatment 2015*.

[3]UNAIDS (2013). *Treatment 2015*.

[4]UNAIDS (2013). *Report on the Global AIDS Epidemic*.

[5]UNAIDS 2013 Global Report.
Available: www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_FactSheet_Global_en.pdf.

[6]Global Fund (2012). New Funding Model. Available: www.theglobalfund.org/en/activities/fundingmodel/.

[7]Schwartlander B et al. (2011). Towards an improved investment approach for an effective response to HIV/AIDS. *Lancet* 377:2031-2041.

[8]PEPFAR (2012). *PEPFAR Blueprint: Creating an AIDS-free Generation*.

[9]WHO Progress Report (2013).

[10]UNAIDS 2012 Global Report.

[11]Henry J. Kaiser Family Foundation (2013). *Mapping the Donor Landscape in Global Health: HIV/AIDS*. Available: kaiserfamilyfoundation.files.wordpress.com/2013/06/8449-mapping-the-donor.pdf.

[12]Baral S, Phaswana-Mafuya N (2013). Rewritng the narrative of the epidemiology of HIV in sub-Saharan Africa. SAHARA: *Journal of the Social Aspects of HIV/AIDS* 9:127-130.

[13]amfAR (2013). Tackling HIV/AIDS Among Key Populations: Essential to Achieving an AIDS-Free Generation. Available: www.amfar.org/uploadedFiles/_amfarorg/Articles/On_The_Hill/2013/Key%20Populations%20Issue%20Brief%20-%20Final%20(2).pdf.

[14]UNAIDS (2013). *Getting to Zero: HIV in Eastern & Southern Africa*.

[15]UNAIDS 2013 Global Report.

[16]amfAR (2010). *The Shifting Global Health Landscape: Implications for HIV/AIDS and Vulnerable Populations*. Available: www.amfar.org/uploadedFiles/In_the_Community/Publications/VulnerablePop.pdf.

[17]Baral S, Phaswana-Mafuya N (2013).

[18]WHO Progress Report (2013).

[19]WHO Progress Report (2013).

[20]Reed J, personal communication (April 2013).

[21]WHO (2013). *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV infection*.

[22]WHO Progress Report (2013).

[23]Cherutich P. Progress in Voluntary Medical Male Circumcision Service Provision – Kenya, 2008-2011. *MMWR*. 2012;(61): p. 957-961.

[24]WHO Progress Report (2013).

[25]www.stigmaindex.org/89/publications/latest-publications.html.

[26]UNAIDS 2012 Global Report.

[27]WHO Progress Report (2013).

[28]Hallett T (2013). Historic Gains in the Fight Against HIV Are Within Reach and Within Budget. *Global Fund blog*, May 27. Available: www.theglobalfund.org/en/blog/32206/?mkt_tok=3RkMMJWWfF9wsRonua7Ndu%2FhmjTEU5z16OslUaC1lMI%2F0ER3fOvrPUfGjI4HSsNqI%2FqLAzICFpZo2FFcH%2FaQZA%3D%3D.

[29]UNAIDS 2012 Global Report.

[30]UNAIDS 2013 Global Report.

[31]African Union (2013). *Delivering Results Toward Ending AIDS, Tuberculosis and Malaria: African Union accountability report on Africa-G8 partnership commitments ("AU/G8 Accountability Report").* Available: www.unaids.org/en/media/unaids/contentassets/documents/document/2013/05/20130525_AccountabilityReport_EN.pdf.

[32]UNAIDS 2013 Global Report.

[33]African Union (2012). Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa. Available: www.au.int/en/sites/default/files/Shared_Res_Roadmap_Rev_F[1].pdf

[34]Henry J. Kaiser Family Foundation (2013). *U.S. Funding for Global Health: The President's FY2014 Budget Request*. Available: kff.org/global-health-policy/fact-sheet/u-s-funding-for-global-health-the-presidents-fy-2014-budget-request/.

[35]Institute of Medicine (2013). *Evaluation of PEPFAR*.

[36]Tran M (2013). Aid from rich countries falls for second year in a row, says OECD. *Guardian*. April 3. Available: www.guardian.co.uk/global-development/2013/apr/03/aid-rich-countries-falls-oecd.

[37]AU/G8 Accountability Report (2013).

[38]Kates J et al. (2013). Mapping the Donor Landscape in Global Health: HIV/AIDS. Henry J. Kaiser Family Foundation.

[39]UNAIDS 2012 Global Report.

[40]AU/G8 Accountability Report (2013).

[41]UNAIDS 2012 Global Report.

[42]Global Fund (2013). Needs Assessment: Fourth Replenishment 2014-2016. Available: www.theglobalfund.org/en/donors/replenishment/fourth/.

[43]AU/G8 Accountability Report.

[44]www.post2015hlp.org/wp-content/uploads/2013/04/JointStatement-Health-MDGs-Post-2105-HLP-Bali-March2013.pdf.

[45]High Level Panel of Eminent Persons on the Post-2015 Development Agenda (2013). *A New Global Partnership: Eradicate Poverty and Transform Economies Through Sustainable Development*. Available: www.post2015hlp.org/wp-content/uploads/2013/05/UN-Report.pdf.

[46]Institute of Medicine (2013). *Evaluation of PEPFAR*. Available: www.iom.edu/Reports/2013/Evaluation-of-PEPFAR.aspx.

[47]U.S. Government Accountability Office (2013). *Millions Being Treated, but Better Information Management Needed to Further Improve and Expand Treatment*. Available: www.gao.gov/assets/660/655764.pdf.

[48]UNAIDS 2012 Global Report.

[49]Lubkin S (2013). Bill Gates Offers Grant for 'Next Generation Condom.' *ABC News*. Mar 25. Available: abcnews.go.com/blogs/health/2013/03/25/bill-gates-offers-grant-for-next-generation-condom/.

[50]www.3ieimpact.org/en/funding/thematic-window/thematic-window-3-voluntary-male-medical-circumcision/

[51]Johnson R (2013). *Three Types of HIV Cure: What do they mean, where do we go?* Available: www.amfar.org/three-types-of-hiv-cure/.

[52]Pollack A, McNeil DG (2013). French Study Indicates Some Patients Can Control H.I.V. After Stopping Treatment. *New York Times.* Mar 15. Available: www.nytimes.com/2013/03/16/world/europe/french-study-indicates-some-patients-can-control-hiv-after-stopping-treatment.html.

[53]McNeil DG (2013). After Marrow Transplants, 2 More Patients Appear HIV-Free Without Drugs. *New York Times*. July 3. Available: www.nytimes.com/2013/07/04/health/post-transplant-and-off-drugs-hiv-patients-are-apparently-virus-free.html.

[54]TAG, HIV i-Base (2013). *2013 Pipeline Report*. Available: www.pipelinereport.org/sites/pipelinereport.drupalgardens.com/files/201306/2013%20Pipeline%20Report.pdf.

[55]HIV Vaccines & Microbicides Resource Tracking Group (2013). *From Research to Reality: Investing in HIV Prevention Research in a Challenging Landscape*.

[56]McNeil DG (2013). Study Shows Pill Prevents HIV Among Drug Addicts. *New York Times*. June 12. Available: www.nytimes.com/2013/06/13/health/pill-prevents-hiv-among-drug-addicts-in-a-study.html

[57]Microbicides Trials Network (2013). Daily HIV prevention approaches didn't work for African women in the VOICE study. News Release. Mar 4. Available: www.avac.org/ht/a/GetDocumentAction/i/49174.

[58]Testimony of Francis Collins, NIH Director, Hearings on Fiscal Year 2014 Budget Request for the National Institutes of Health, Labor, HHS, Education Subcommittee of Senate Committee on Appropriations, May 17, 2013.

[59]Fauci AS (2013). An AIDS-free generation is closer than we might think. Washington Post. July 11. Available: www.washingtonpost.com/opinions/anthony-fauci-an-aids-free-generation-is-closer-than-we-might-think/2013/07/11/80ab000c-e70b-11e2-a301-ea5a8116d211_story.html.

[60]U.S. Government Accountability Office (2013). President's Emergency Plan for AIDS Relief: Per-Patient Costs Have Declined Substantially, but Better Cost Data Would Help Efforts to Expand Treatment. GAO-13-345.

[61]UNITAID (2013). UNITAID Announces Important Diagnostic Projects for HIV and Tuberculosis. Press Release. Mar 11. Available: www.unitaid.eu/en/resources/press-centre/releases/1172-unitaid-announces-important-diagnostics-projects-for-hiv-and-tuberculosis.

[62]India's Novartis Decision (editorial). *New York Times*. Apr 4. Available: www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartis-decision.html.

[63]African Union Roadmap (2012).

[64]Hoffman L. Lower antiretroviral dose suppresses HIV. Medical Observer July 9. Available: www.medicalobserver.com.au/news/lower-antiretroviral-dose-suppresses-hiv.

[65]Mutabazi V et al. (2012). One arm, open label, prospective, cohort field study to assess the safety and efficacy of the PrePex device for scale-up of non-surgical circumcision when performed by nurses in resource-limited settings for HIV prevention. *XIX International AIDS Conference*, Washington D.C., 22-27 July, Abstract No. TUAC0405.

[66]Obiero W et al. (2013). The PrPex Device Is Unlikely to Achieve Cost-Savings Compared to the Forceps-Guided Method in Male Circumcision Programs in Sub-Saharan Africa. *PLoS ONE* 8:e53380.

[67]Chang A (2013). India-EU FTA will imperil lives, local industry, activists say. *FirstPost Economy*. Apr 10. Available: www.firstpost.com/economy/india-eu-fta-will-imperil-lives-local-industry-say-activists-693949.html