

# Countdown

## Global HIV, Response, Results



Tanzania, 2014

## Introduction

In 2008, the Infectious Diseases Society of America's Education and Research Foundation launched its involvement in global health policy with a focus on the two most deadly infections worldwide: HIV and tuberculosis. The HIV pandemic had been recognized more than a quarter century earlier, but international responses launched in 2004 with the U.S. President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis and Malaria, to contain the impacts of the pandemics were nascent by contrast, seeking evidence, and direction to maximize the effectiveness of donor investments. Without smart policy decisions and more efficient treatment strategies, the HIV pandemic would still be growing in 2031, 50 years after it was first recognized, an article in *Health Affairs* from the Results for Development Institute assessing the state of the response at that time, said.

As the oldest and largest organization of infectious disease scientists and medical providers, and counting among its 11,000 membership many of the physician researchers leading pivotal studies seeking answers to HIV, as well as treatment and prevention programmatic responses to the virus, IDSA and HIV Medicine Association members provided some of that direction. Over the next several years, increased focus on biomedical answers to HIV that included definitive proof that medical circumcision offered significant protection from HIV to men as well as the **HPTN 052** findings that antiretroviral treatment for HIV prevents transmission of the virus as well as illness, led to accelerated scale-up of evidence-based HIV services.



In 2012, as the International AIDS Conference convened in the United States for the first time in more than two decades, those responses had led to a turning point, with the number of people receiving life-saving antiretroviral treatment for HIV exceeding the numbers of people becoming infected with the virus for the first time.

With time running out on the 2008 five-year reauthorization of PEPFAR and the Global Fund, a bipartisan congress renewed its commitment to U.S. leadership of the global AIDS response with the PEPFAR Stewardship and Oversight Act of 2013, legislation that called for continued investment as well as increased monitoring and accountability for quantifiable results.

UNAIDS added a framework for that accountability in October 2014 with goals and a deadline for its 90-90-90 targets, based on mathematic modeling that projected that if by 2020, 90 percent of people living with HIV were aware of their infection, if 90 percent of them were taking antiretroviral treatment, and the treatment in at least 90 percent of them was effective and consistent enough to suppress the virus, HIV would be ended as a global health threat by 2030.

As 2015 began, nations around the world agreed to the Sustainable Development Goals, which included ending the global pandemics of HIV and TB by 2030. The countdown toward the endpoint of the most ambitious effort ever made against a single disease began.



Tanzania, 2014

## 2015

According to the UNAIDS reports released at the end of the preceding year, 19 million of the 35 million people living with HIV globally did not know their HIV-positive status. This was a significant gap, UNAIDS noted, because people who discover they have the virus usually seek life-saving antiretroviral treatment. Almost 90 percent of people who tested positive for HIV in sub-Saharan Africa went on to access the medicine that prevents illness and transmission according to the reports. New data analysis had shown that every 10 percent increase in treatment coverage corresponded to a 1 percent decline in the rate of new HIV infections.

2015 opened with findings presented at the Conference on Retroviruses and Opportunistic Infections that highlighted the promise of antiretroviral drugs as pre-exposure prophylaxis against acquiring HIV – or PrEP. Answering questions not only on effectiveness, but on uptake, adherence, safety, and risks, the **PROUD** and **Ipergay** studies demonstrated that PrEP was acceptable to men who have sex with men and that using the measure did not increase sexual risk behaviors. Discussion shifted from how, not if to make the most of PrEP as a proven prevention measure. At the same time, disappointing results came from **FACTS 001**, in South Africa, a trial that had been hoped to replicate earlier findings that an antiretroviral vaginal gel for women could confer a modest HIV prevention benefit. Instead, with the same rates of HIV infection among women assigned the product and a placebo in a randomized trial, the results of the trial showed that women did not use the product consistently enough for it to be effective, dealing a setback to the quest for an effective and acceptable biomedical HIV prevention measure for women.



Zambia, 2013



Also in the beginning of 2015, findings from a **Demonstration Project of PrEP and ART** in Kenya and Uganda highlighted the growing promise of combined biomedical prevention measures, in this case with “the near elimination of HIV transmission” among couples considered at high risk for transmitting or acquiring the virus. In concert with the final results from **HPTN 052** that year confirming the role of treatment in preventing transmission of the virus, the findings added impetus to accelerate access to antiretroviral treatment in resource-limited settings and well-resourced countries alike.

The game-changer came with the release in May of findings from the international **START** trial showing that the most Strategic Timing of Antiretroviral Treatment is upon diagnosis, and demonstrating that starting treatment early reduced risks of coming down with a serious illness by 53 percent. The findings led National Institute of Allergy and Infectious Diseases Director Dr. Anthony Fauci to note that while adopting immediate treatment as a standard of care would be expensive, “at the end of the day, there’s no doubt that it’s going to cost less money.”

That September, the World Health Organization released guidelines recommending for the first time that all people diagnosed with HIV be considered for immediate access to antiretroviral medicine. The guidelines also expanded the numbers of people recommended to be eligible for PrEP beyond “key populations” including men who have sex with men, people earning income through sex work, and people who inject drugs, to cover people at “substantial risk,” defined as living in a community with HIV incidence of greater than 3 percent, and heterosexual men and women who have sexual partners with undiagnosed or untreated HIV infection.

As plans to expand treatment access accelerated, a future of HIV treatment not dependent on daily dosing moved closer with early findings from the **LATTE 2** trial showing an injected combination of two antiretroviral medicines given monthly or every two months effective in controlling HIV among people whose virus was already suppressed. The findings offered hope of simplified treatment for patients worldwide in resource-limited settings where obstacles to daily treatment remain greatest.

Just ahead of World AIDS Day UNAIDS Director Michel Sidibé noted that the number of people receiving life-saving HIV treatment had doubled every five years since the peak of the epidemic in 2000. Doubling that number one more time, he added, would break the epidemic. UNAIDS estimated that of the 36.9 million people living with HIV and eligible for antiretroviral treatment, 15.8 million were receiving it. New HIV infections had fallen by 35 percent since their peak in 2000 and AIDS-related deaths had fallen by 42 percent since peaking in 2004.

By the end of the year, also, the World Health Organization certified that Cuba had eliminated parent-to-child transmission of HIV, and noted that other nations were nearing that milestone. But with an estimated 37 million people living with HIV, fewer than half the people who needed treatment were receiving it and the numbers of people living with HIV continued to increase. In the preceding year, 1.2 million people had died of HIV-related causes, including 400,000 people from tuberculosis, a treatable, curable illness.

Still, funding for HIV research remained essentially flat, and funding for HIV treatment and prevention globally was lower than it had been five years earlier.

## 2016

A new UNAIDS report in 2016 showed that progress in the numbers of people knowing their HIV status and accessing treatment had not extended to people and places deemed hard to reach, including long neglected regions, and marginalized populations. The data showed also that over the years since 2010, HIV deaths among women had dropped at nearly double the rate of deaths among men, with more than 10 percent higher treatment rates among women leading to the difference. In addition, the report pointed to a continuing discrepancy between exposure to risks and access to treatment, with laws, policies, and bias serving as healthcare barriers to some of the hardest hit populations, including transgender women, men who have sex with men, sex workers, and people who inject drugs.



Tanzania, 2014



In June of 2016, the United Nations held a second High-Level Meeting on HIV where member nations agreed to a *Political Declaration on HIV and AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030*. The declaration set new targets and noted gaps in HIV service access, but did not address them with concrete strategies, leaving the future of responses to populations most affected by the pandemic in question.

In July, however, the International AIDS Conference to Durban in South Africa in 2016 provided a forum for an assessment of successful strategies, as well as challenges.

Findings presented there included data from the **SEARCH** study, an ongoing trial across 32 communities in Kenya and Uganda, examining the impact of bringing testing, treatment and streamlined access to services for not just HIV, but multiple diseases and chronic common health concerns. Interim data presented showed that two years into their access to these services, 97 percent of participants with HIV had been diagnosed, 94 percent were on treatment, and in 90 percent of those, treatment was effectively controlling their viruses – all of those results exceeding UNAIDS “90-90-90” goals. But the study also confronted persisting challenges, including a “youth gap” of adolescents as the least likely to access HIV services, while remaining at significant risk.

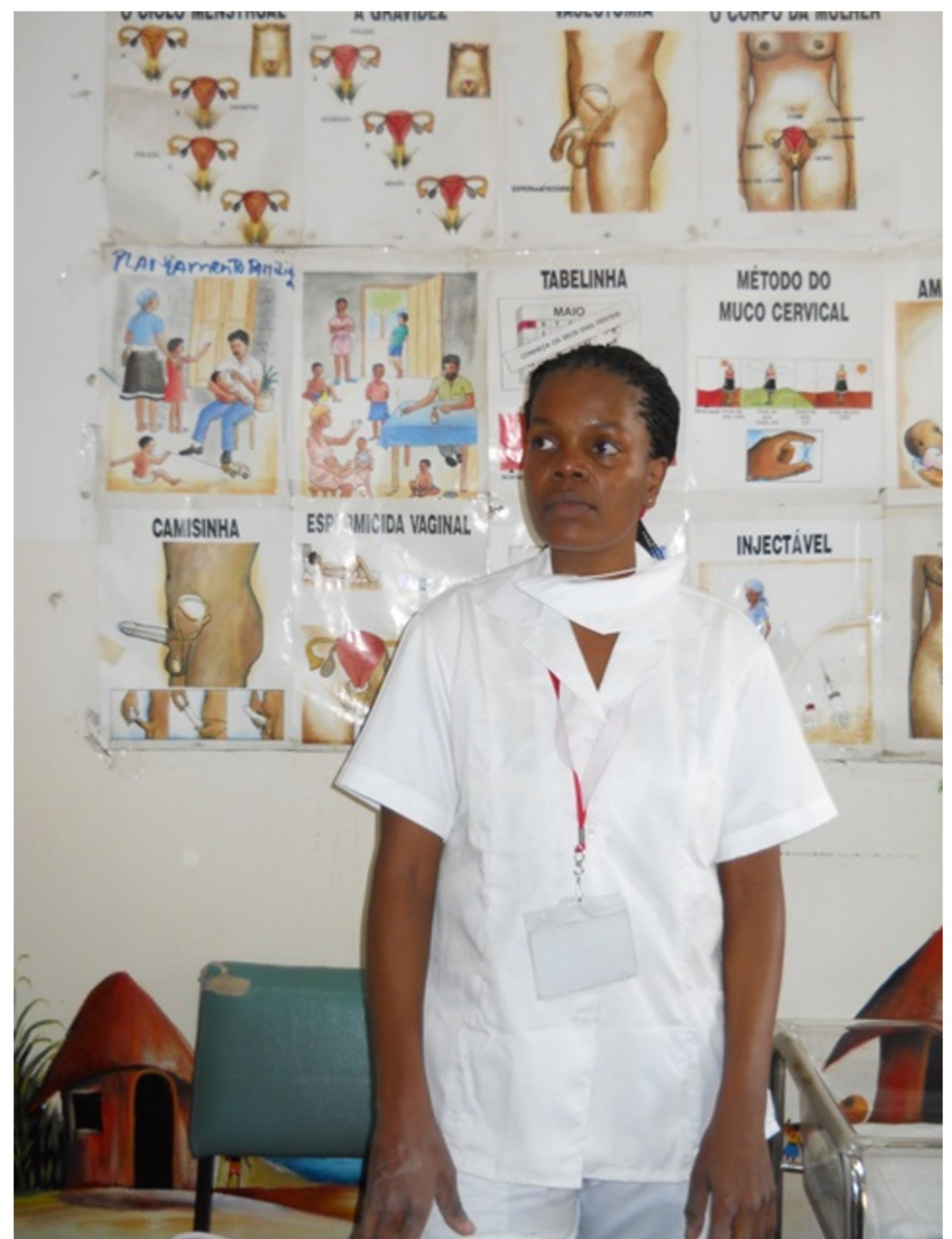
Final results from the **Partners PrEP** study presented at the conference showed that access to immediate HIV treatment for a person living with HIV, along with access to immediate prophylactic antiretroviral medicine for the person’s uninfected partner nearly eliminated risk of HIV transmission between partners. Contrasted with the estimated 63 HIV transmissions that modelling indicated would have been expected to take place over the course of the study, the results showed that the approach of providing antiretroviral treatment immediately to infected partners, and until treatment succeeded in suppressing the virus, PrEP as a protective “bridge” intervention for the uninfected, is feasible and effective.

At the end of 2016, a report in the U.S. Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report* showed that four of seven sub-Saharan African countries followed by researchers could now track the effectiveness of HIV treatment among all patients receiving it with tests to measure the levels of virus in their bodies at least once a year. But while the time from viral load testing to results should be within two weeks, the average test turnaround time was four to seven weeks in five of the countries — with delays caused by equipment breakdown, supply interruption, and staff shortages.

## 2017

In early 2017, with a new administration in Washington setting priorities for the nation, PEPFAR released an annual report to Congress telling a success story at its halfway point, from the handful of people — 50,000 — across Africa with access to life-saving treatment for HIV in 2003, to more than 18 million with access to treatment in the beginning of the year. In the years since its inception, PEPFAR had provided treatment keeping 11.5 million people alive, 1.1 million of them children. The program had provided HIV counseling and testing to more than 74 million people, provided care and support services for more than six million orphans and other children made more vulnerable by the pandemic, protected nearly two million babies from being born with HIV, and given access to medical circumcision to more than 11.5 million men and boys, greatly reducing their risks of infection. In the process, it had trained 220,000 health workers, who now could provide life-saving services to their own communities. The story of PEPFAR was not yet a success story but a story of strategy that, if allowed to continue, would lead to historic success.

By then however, days after entering office, President Trump had signed an order reinstating and expanding the “Mexico City Policy”, instructing heads of the departments of State, Health and Human Services and of USAID to ensure that no foreign health provider funded with any form of support from the United States offer counseling, referrals or services to terminate a pregnancy.



Mozambique, 2015



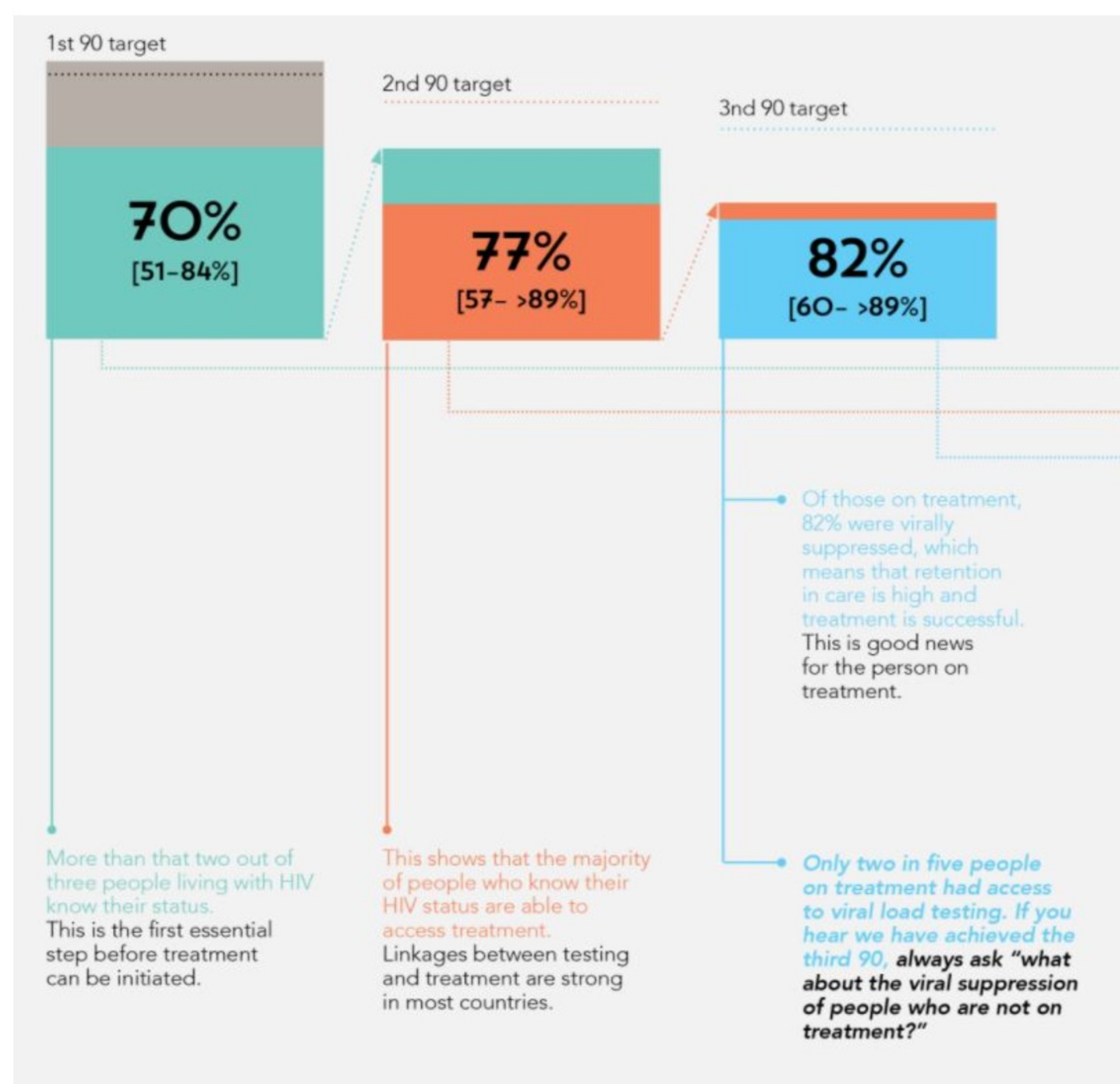
With that he returned to a policy long criticized by advocates and providers of global maternal and reproductive health care, HIV treatment access, and infectious diseases responses – while extending its impacts to global health assistance furnished by all departments or agencies including those to prevent, test and treat HIV.

A week after the release of PEPFAR’s 2017 report, the White House released its *America First* budget proposal outline – a plan of government spending that would cut nearly a fifth of the budget for the National Institutes of Health and slash funding for the Department of State and USAID. The outline also proposed eliminating the NIH Fogarty International Center which, with a \$70 million budget, supports global health research partnerships between institutions investigating HIV, Ebola, and other chronic and infectious diseases in the U.S. and abroad, and trains scientists to address global public health threats, building scientific capacities in resource-limited countries.

In June Secretary of State Rex Tillerson described to members of the Senate Appropriations State and Foreign Operations Subcommittee the administration’s plans “to sustain the HIV/AIDS treatments in 11 countries to continue to take those to conclusion.” (HIV necessitates life-long treatment) He added “As patients roll off those rolls, new treatments can be available.” This approach also was spelled out in the administration’s *Major Savings and Reforms* document, which described plans to “continue to work towards epidemic control” in just 12 countries, in contrast to the more than 50 countries with which PEPFAR is engaged.



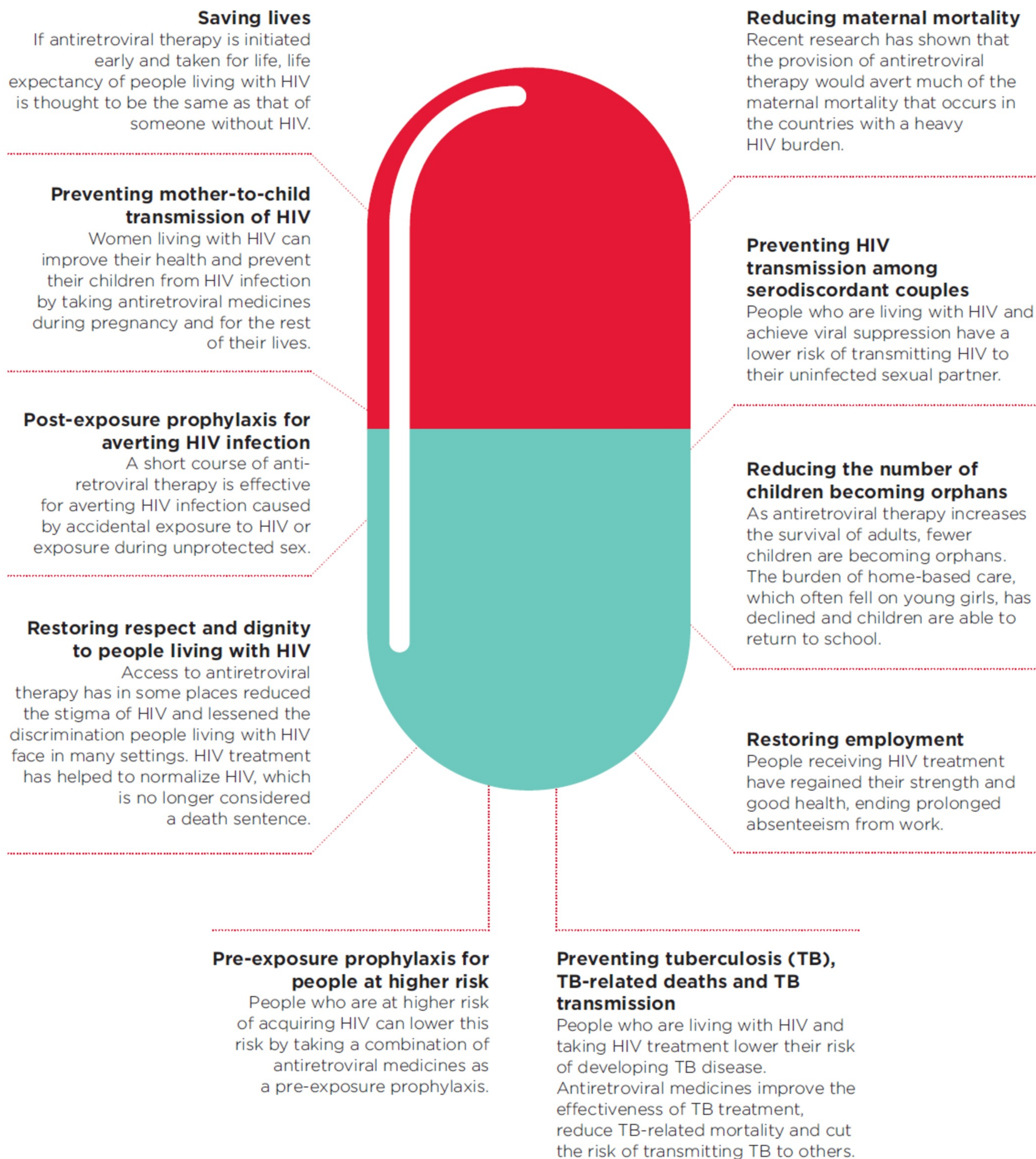
Mozambique, 2015



In July, a UNAIDS presentation on the eve of the International AIDS Society Conference on HIV Science in Paris showed an achievable trajectory from the 19.5 million people on treatment at the end of 2016, to the 30 million people who must receive treatment by 2020 to control HIV as a global health threat within the 10 years that then follow. Averaged out across the world, the midpoint numbers from UNAIDS of 70 percent of people with the virus diagnosed, 77 percent of them on treatment, and 82 percent of them with suppressed viruses, showed, presenters said, that a goal once considered out of reach could be attained. But the 10.5 million yet to access treatment, the countries where numbers continue to show more people undiagnosed, and untreated than not, and where new infections continue to climb, showed also that the effort ahead had to be strengthened, rather than weakened, with a leader of the **SEARCH** trial noting: “yesterday’s approach is going to fall short of today’s aspirations.”



A presentation from researchers at the Imperial College in London on the final day of the IAS conference included a look at what would have happened if PEPFAR and the Global Fund had never been launched. Prices for treatment would have remained high, researchers said, with effective access limited to a miniscule single-digit percent of all people living with the virus by the end of 2016. About four million more people would have been infected with HIV by then, and five million more people would be dead.



UNAIDS infographic on the power of antiretrovirals



Instead, treatment was preventing transmission and illness for 38 percent of people living with the virus worldwide. If the continued expansion of effective interventions were to stop now, as described by Secretary of State Tillerson and the White House *Major Savings and Reforms* document, the numbers of people on treatment would remain the same, but as new infections occurred, the numbers of people losing their lives to HIV, having dropped steeply, would level off, and nearly 300,000 more people would die as a result of the treatable disease each year. The number of people becoming infected with HIV would climb steeply each year, with, by 2030, the year currently targeted to end HIV as a global health threat instead seeing 2 million new infections. But, the presentation showed, increased U.S. global and domestic funding would, by 2020, put the world on track to end HIV as a global health threat by 2030. If that funding were allocated in accordance with the best evidence of needs and effective interventions, the presentation showed, deaths would drop below 200,000 by next year.

In late August 2017, a modeling study reported in the *Annals of Internal Medicine* used data on funding as well as HIV service-related data from South Africa and the West African nation Côte d'Ivoire, to show the outcomes of choices that would need to be made if funding were scaled back. "Scale-back" strategies, included delaying care for HIV by limiting opportunities to be diagnosed with the virus, cutting spending on measures to retain patients in care, and – the measure that would bring the largest immediate cost savings while representing a retreat to the approach of a decade and a half earlier – of no new initiations of antiretroviral treatment. Those measures would save from 13 percent to 24 percent of current spending over the next 10 years — or the researchers calculated, about \$900 for every year of life lost as a result of those reductions in services. Other options included not monitoring patients' viral loads and risking unnoticed treatment failure and resistance, and eliminating access to second-line antiretroviral treatment for patients whose virus is resistant to first lines of treatment. All would result in preventable deaths, illnesses, transmissions of the virus, and larger costs to health systems over time. The results of cutbacks could be even more destructive than the findings in this study, the researchers noted, because their calculations did not include the coming "youth bulge" over the next two decades when the numbers of young people at greatest risk of HIV exposure and infection will increase dramatically.

That next generation reflects both the challenges and the stakes ahead, as the countdown continues.



Zambia, 2013



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