PEPFAR Turns 10: Success at a Crossroads

As history's largest international response to a disease hits a major milestone, there is cause both for celebration of great successes and for reflection on the challenges ahead.

December 2, 2013 By Benjamin Ryan

They said it could never be done.

At the dawn of the 21st century, Africa, the birthplace of humanity, was ravaged by an unchecked plague. Vast swaths of the population were threatened with extinction. Only 50,000 people in the sub-Saharan region of the continent were receiving the antiretroviral (ARV) treatment that had sent Westerners with AIDS to rise out of their hospital beds like Lazarus and return to robust health. A staggering 17 million sub-Saharans had already died in the pandemic, and 25 million more were living with the virus.

"Country after country resembled a graveyard," recalls Stephen Lewis, co-founder and co-director of AIDS-Free World, who was the United Nations secretary-general's special envoy for HIV/AIDS in Africa from 2001 to 2006. "It was emotionally and objectively annihilating."

Confronted with the moral imperative of helping rescue an entire continent from destruction, many in the American public health sector voiced doubts that there was much hope in getting lifesaving drugs to Africans. They said that there were insufficient doctors and nurses, that there wasn't the health infrastructure, nor were there the proper roads through which to deliver ARVs; instead, they put their bets on HIV prevention. Most notoriously, Andrew Natsios, the head of the U.S. Agency for International Development, said in 2001 that many Africans couldn't tell time and therefore couldn't master an ARV dosing schedule. The broad-stroke dismissal of Africans' mental capacities aside, the statement ignored the fact that many HIV drug regimens had already been reduced to simple morning-and-night protocols.

Then, in his January 2003 State of the Union address, President George W. Bush surprised the world by announcing a massive U.S. aid program to provide HIV-related care, treatment and prevention to foreign nations in need, with efforts focused mostly in Africa. The President's Emergency Plan for AIDS Relief, or PEPFAR, as it came to be known, enjoyed robust bipartisan support, and Congress authorized Bush's request of $15 billion for the first five years.

In the decade since, the U.S. government has gone on to spend more than $40 billion through PEPFAR and has provided an additional $10 billion to the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria—making the United States its largest donor. Together these efforts amount to the largest international response to a disease in history. And as a consequence of such largesse global health officials are now considering the once unthinkable possibility of actually turning the tide of the ever-swelling epidemic and forcing it into retreat.

In a December 2 speech marking World AIDS Day, President Barack Obama announced that PEPFAR had put 6.7 million people ARVs by September of this year, up from just 1.7 million in 2008 and exceeding the goal of 6 million set in 2011. PEPFAR also announced success in reaching the target of providing ARVs to 1.5 million pregnant women with HIV in order to prevent mother-to-child transmission (MTCT) of the virus.

Consequently, there is much cause for celebration. Over the summer, the 1 millionth baby was born HIV-free thanks to PEPFAR's MTCT push. Worldwide, new HIV infections have fallen by a third since 2001, to an estimated 2.3 million in 2012. New infections among children have tumbled 52 percent during the same period, to 260,000 cases. Peaking in 2005, AIDS-related deaths have since dropped 30 percent. Also, 13 hard-hit nations each recently hit an important tipping point: A greater number of people are getting on ARVs each year than are newly infected with the virus.

Reflecting on recent visits to Africa, AIDS-Free World's Lewis says, "The difference is palpable and striking."

"Proving the so-called public health experts wrong is fun," revels Mark Dybul, MD, executive director of the Global Fund, who was a founding architect of PEPFAR and led the organization from 2006 to 2009.

Peter Staley, the longtime AIDS activist who co-founded Treatment Action Group as well as AIDSmeds.com, calls PEPFAR "genuinely just a massive success and massively important program. Bush deserves some credit, and everybody that started it deserves a huge amount of credit. It's really Bush's only positive legacy."

Not that PEPFAR has been free from doubt and immune to harsh criticism across its history. Conservative Christian ideology, critics have long argued, clashed with science and seriously hobbled the initial effectiveness of the program.

"No one should diminish the legitimate criticisms at the outset," Lewis says, "because while the $3 billion [yearly PEPFAR budget] was intoxicating, the implementation was not."

Following the example of an apparently successful program in Uganda, PEPFAR initially adopted support of what is known as the "ABC" method, which boils down, most simply, to: Abstinence, Be faithful and use a Condom. The initial law stated that, of the 20 percent of PEPFAR funds to be spent on HIV prevention, a third had to go programs that supported abstinence-until-marriage messaging—an HIV prevention method with the weight of science against it, and one which many

argued alienated men who have sex with men (MSM), who, without the ability to marry legally, could not follow the directive to abstain until marriage.

Also, the so-called Global Gag Rule prevented U.S. funds from going toward any organization that supported abortion. A separate law insisted groups working with the Americans sign a loyalty oath stating that they opposed prostitution and sex trafficking, undermining efforts to promote health among sex workers. And policies forbidding needle exchange programs further hampered efforts to stem the tide of the epidemic among injection drug users (IDUs).

Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID), who designed the initial PEPFAR proposal in 2002 after what he describes as a stunningly exciting request from President Bush himself, says that the political reality of the time was that PEPFAR's passage depended on appealing to conservatives.

"In the very beginning there were some people who felt that PEPFAR should not be involved in the distribution of condoms," Fauci recalls.

Fauci told Bush administration officials this was an untenable position and that the program should, on the contrary, put a strong emphasis on latex.

"It was really a give and take," Fauci says. "The conservatives were very much in favor of abstinence. In order to win support for the condom component, it was felt that we also had to have flexibility and compromise and promote what the conservative and faith-based groups wanted."

While Fauci says he didn't think an abstinence push would prove effective, he considered the Ugandan ABC program and ultimately conceded.

"I think a lot of damage was done by the ABC stuff," Lewis says, arguing that while the Americans may have thought they were sending a nuanced message about abstinence, "[i]n Africa the message was clear: abstinence was meant to trump everything else. No question, I ran into it everywhere and constantly had to deal with it."

Dybul bristles at criticisms of the ideological elements of PEPFAR's design. "'Abstinence' never meant abstinence," he insists, "it meant delaying sexual debut. It wasn't 'never have sex'; no one ever taught that. There was never any money dedicated to that. So that was more of a public mythology, which people like to use. The reality is the data are pretty clear. Marked reductions in new infections didn't start last year, they started 10 years ago. So I hope we get past the polemics of all this nonsense. Now, were mistakes made? Absolutely. Are mistakes still being made? Absolutely."

In the 2008 five-year PEPFAR reauthorization, the abstinence-until-marriage directive was axed and the language specifying how prevention dollars were to be spent became more equivocal. The law now required "balanced funding" for HIV prevention, ensuring "activities promoting abstinence, delay of sexual debut, monogamy, fidelity and partner reduction are implemented and

funded in a meaningful and equitable way." The law further stipulated that Congress receive a report if less than half of prevention dollars in any particular country fail to go toward these aims. As a part of the 2013 World AIDS Day festivities, President Barack Obama signed another five-year reauthorization into law, maintaining the same language on this front.

The Obama era of PEPFAR has seen the ideological restrictions regarding abortion and sex workers fall by the wayside, although support for needle exchange remains mired in politics. Meanwhile, a much stronger emphasis on scientifically-proven interventions has risen to the forefront of the program's ethos. But to the shock of many it has been a Democrat who has put the brakes on spending for a public health initiative begun by a Republican. Going against campaign promises, President Obama has essentially flat-funded the organization, keeping its budget within the range of $6.4 billion to $6.8 billion a year since entering office. Meanwhile, spending for the Global Fund has risen from $1 billion to $1.65 billion. [See editor's note below.]

Activists have long pressured the president to keep his promises for greatly increased international AIDS funding, stressing that, in pure financial terms, paying more now to curb the pandemic means saving money down the road. Indeed, a recently published study showed that using HIV treatment as a means of preventing new infections is cost-effective overall in poorer countries.

Acknowledging the 2008 market crash, the subsequent recession and the recent political turmoil over federal budget deficits, Myron Cohen, MD, associate vice chancellor for global health at the University of North Carolina at Chapel Hill Medical Center and the cost effectiveness study's author says, "Austerity has to be put in context of a stitch in time. So you've got a crack in your foundation, and either you fix the crack or you realize water seeps in and the next heavy rain you've destroyed your house."

According to Dybul it was in fact the Bush administration that made the decision in its latter years to transition into a more bilateral funding approach for both PEPFAR and the Global Fund, preferring to stress the importance of shared responsibility. But activists like Amirah Sequeira, national coordinator of the Student Global AIDS Campaign (SGAC), members of which, to Obama's apparent consternation, heckled the president on several occasions as he stumped for the Democrats during the 2010 midterm election campaign, lament this redistribution.

"That's a case of robbing Peter to pay Paul," Sequeira says. "They both need to be funded."

PEPFAR's interim director, Deborah Von Zinkernagel, demurred at a question as to whether she would like to see more money come PEPFAR's way, saying, "You know, we all live in interesting times, and we're doing the best we can with what we have."

A recent open congressional letter sent to President Obama has called for an ambitious new goal of getting 12 million people on HIV treatment by the end of the 2016 fiscal year. The letter is notable for its bipartisanship: Coming out of the offices of Representative Barbara Lee (D–Calif.) and Senator Tom Coburn, MD (R–Okla.), it boasts over three dozen signatures from across the

political spectrum, including those of presidential contender Senator Marco Rubio (R–Fla.) and New York's senators, Charles Schumer (D) and Kirsten Gillibrand (D).

Today, PEPFAR is entering a new phase of its development, charged with an ongoing transition from an emergency plan to a sustainable health initiative. Part and parcel of this shift is coaxing nations into contributing more of their own efforts, financially and otherwise, toward combatting HIV on the ground.

As for the public face of PEPFAR, Gregg Gonsalves, co-director of the Global Health Justice Partnership at Yale Law School, says that when spelling out a program's ambitions, "You need to put metrics on it. You need to put a number, a dollar figure and a timeline on it."

On the contrary, the promise of an "AIDS-free generation" has become the cornerstone of the Obama administration's public relations push. Secretary of State Hillary Clinton introduced the slogan into the political lexicon in a November 2011 speech at the National Institutes of Health. She stated that the world stood on the precipice of the opportunity to usher in the first generation in which virtually no children are born with the virus, in which, thanks to effective HIV prevention, these young people have a much better chance at avoiding infection as they become sexually active, and in which they have access to treatment to prevent a progression to AIDS if they do contract the virus.

On December 2, at a conference in Washington, DC, in which global stakeholders met to consider future pledges for Global Fund, Secretary of State John Kerry touted the bright prospects of a public health goal that would by its very verbiage take a bare minimum of a generation to achieve, with the clock only starting after newborn transmissions are virtually eliminated, saying that "we actually have put an AIDS-free generation within sight."

Gonsalves laments that the Obama administration has "collapsed into empty slogans." Lewis denounces the "glib use of these phrases," which he says prejudices the international community and "makes it seem as though this chronic disease is well in hand and 'Don't worry about it anymore.'"

Mark Dybul counters, saying, "The reality is you need different messages for different audiences, right? A global campaign of 'completely controlling new HIV infections while treating everyone who needs it' is not exactly catchy."

At the same time, Von Zinkernagel stresses, "We don't ever want to minimize the importance of continuing to provide that support and health care to someone who's living with HIV infection for all of their life."

While noting that, "you've got to be careful that when you say 'the end of AIDS' that people don't think, 'Now it's on automatic pilot,'" NIAID head Anthony Fauci says that it is indeed possible to one day end the AIDS pandemic, at least in terms of the precise scientific definition of that word. Parameters for reducing the pandemic to what's known as a low-level endemic include crossing

the tipping point at which new infections are outpaced by new people put on treatment, getting new infection rates among at-risk groups down to less than a fraction of a percent, and coming as close as possible to wiping out MTCT.

In addition to the knowledge that ARVs can effectively prevent MTCT, two other major recent finds during PEPFAR's history have helped guide its course toward this lofty goal of shattering the pandemic: the discovery that circumcision reduces the risk of female-to-male transmission of the virus by 60 percent, and the news that antiretroviral treatment reduces the risk of transmission of the virus between a serodiscordant heterosexual couple by 96 percent. By the end of the year, PEPFAR will have supported the voluntary circumcision of 4.7 million males worldwide, and the organization has fully advocated for treatment as prevention, or TasP, as a means of curbing the pandemic.

"Given the scientifically-based treatment and prevention interventions that are available today," Fauci says, "if we aggressively implement these interventions, it is entirely feasible to reverse the trajectory of the pandemic and start to see a dramatic deflection in the curve of new infections and a significant decrease in deaths due to HIV/AIDS as more and more people are tested, enter care and are put on life-saving medications that will not only keep them healthy, but will also dramatically diminish the likelihood that they will transmit HIV to their sexual partners."

However, Dybul stresses that the ultimate benefits of the global HIV fight need to be for everyone.

"And that's one of the areas where we've failed," Dybul says, pointing to countries such as Kenya and even the United States that have succeeded in beating back HIV transmission rates in the vast majority of the population, but where high-risk groups such as MSM, transgender people, sex workers and IDUs still experience large numbers of new HIV cases each year.

AmfAR, the Foundation for AIDS Research, released an August 2013 report criticizing both PEPFAR and the Global Fund for giving these key populations, as they are known, the short shrift. While both organizations have worked to target the demographic groups, the report states that programs geared toward the key populations are often the first to lose funding in the face of budget reductions. Also, members of these demographics often don't access HIV treatment because of discrimination from health workers and what the report describes as "legitimate fears" that receiving health care will land them in the hands of "hostile law enforcement officials."

As PEPFAR looks for a new director following the November 1 retirement of Eric Goosby, MD, who led the organization for the past four years, Lewis cautions against what he sees as the dangers of over celebrating the recent successes.

"I don't know what all the crowing is about," Lewis says. "What kind of a world would it be if you can't show progress over 10 years of tremendous application of money and energy? There's too much self-congratulatory stuff and not enough recognition of the very real, continued struggle of the grassroots."

But of course in the beginning the prevailing wisdom was that none of this could be accomplished at all.

[Editor’s note: On December 3, the Global Fund announced its new round of funding pledges, which amount to $12 billion from all nations over the course of the next three years, short of the hoped-for $15 billion. The Obama administration had offered to pay up to $5 billion over that period; but the offer came in the form of a two-for-one challenge grant. Consequently, the U.S. contribution will drop to $4 billion, or $1.33 billion per year.]

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