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Past and Future Performance: PEPFAR in the Landscape of Foreign Aid for Health

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Abstract

This review traces the course of the US President's Emergency Plan for AIDS Relief (PEPFAR) as a foreign aid program. It illustrates how the epidemiologic and geopolitical environments of the early 2000s influenced PEPFAR's early directions, and contributed to its successes. In addition to scaling up infrastructure and care delivery platforms, PEPFAR led to large increases in the number of people receiving antiretroviral therapy and reductions in mortality. These successes, in turn, have brought its principal criticisms – its outsized budget, narrow focus, and problem of entitlement – into sharp relief. PEPFAR's recent evolution, then, has been in response to these criticisms. This review suggests that PEPFAR's early formulation as an emergency response relieved it from a need to articulate clear goals, and that this freedom is now leading to new challenges as it struggles to identify priorities in the face of expectations to do more with a flat budget.

Keywords

HIV/AIDS; Sub-Saharan Africa; Foreign Aid; Sustainability; PEPFAR; President's Emergency Plan for AIDS Relief; antiretroviral therapy

Introduction

On January 28, 2003, George W. Bush delivered his second State of the Union address. Nestled between assessing the US economy and laying out the arguments for invading Iraq later that year, President Bush asked congress to commit $15 billion over five years to "turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean." Noting that only 50,000 individuals were receiving antiretroviral therapy in Sub-Saharan Africa, and nearly 30 million HIV-infected, he encouraged action because "seldom has history offered a

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Compliance with Ethics Guidelines

Conflict of Interest

Eran Bendavid declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent

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greater opportunity to do so much for so many."[1] That announcement set the stage for the US President's Emergency Plan for AIDS Relief (PEPFAR), arguably the most positive of President Bush's legacies.[2,3]

The backdrop to PEPFAR's announcement made this commitment to HIV unprecedented. However, despite this headline beginning, PEPFAR was created, and remains, a foreign aid program, one among hundreds created by the US government. The perspective taken here examines PEPFAR through this lens – as a foreign aid program – including the historical arc of foreign aid into which it emerged, and which influenced expectations from the program and its goals. This perspective also helps in defining key challenges for the future sustainability and evolution of PEPFAR. In the short to medium term, PEPFAR is here to stay, but this analysis will propose ways it might evolve with the changing political, economic, and epidemiologic context in which it operates.

The Epidemiology and Response to HIV in Africa at the Turn of the Century

The year 1981 is often considered a watershed year in HIV history, the year when the first recognized cases were reported in the United States' Morbidity and Mortality Weekly Report.[4] No national estimates of HIV burden are available prior to 1981, but, already then, over 600,000 individuals were infected with HIV in Sub-Saharan Africa.[5] Over the next 20 years, HIV became a household name in the United States as it spread among homosexual communities and became the leading cause of death among young men.[6] If HIV in the United States elicited fear and a mobilization of enormous resources for basic science, epidemiology, diagnosis, and treatment, HIV spread under the radar, mostly unchecked and under-recognized in many regions of East and Southern Africa. By the year 2000, over 20 million people were infected in Sub-Saharan Africa, more than two-thirds of the global total. Only then did the awareness of HIV in the United States and the eventual recognition that HIV in Sub-Saharan Africa is posing a global threat tip the balance towards the mobilization of global resources against HIV.

It is important to recognize that even in 2000, HIV was not the dominant cause of deaths or disease burden in Sub-Saharan Africa. Infectious causes of child mortality – malaria, diarrheal illness, and lower respiratory infections – caused just as many (and often more) deaths and lost years of health life as HIV.[7] However, HIV was expanding rapidly, globally, including in Europe and the United States, and stealthily. Action on HIV soon followed.

It is also notable that, from the earliest days of the response to HIV in Sub-Saharan Africa, the United States has been a global leader. In hindsight, the commitments made by high-income countries to help African nations confront HIV towards the end of the 1990s seem meager. The United States' flagship program for combating HIV during the Clinton Administration, termed Leadership in Investment in Fighting an Epidemic (LIFE), committed $100 million to all partnering Sub-Saharan countries in 1999. That now-paltry amount was less than that committed for increasing childhood vaccinations, but about double the sum total of commitments made by all other high-income countries at the time.

The year 2000 was a tipping point for global HIV response, after a session of the United Nations Security Council was wholly dedicated to HIV, the first time the Security Council

focused on a health issue. This heralded the inflection point of the global response, and was followed in rapid succession by the creation in 2000 of the World Bank's Multi-Country AIDS Program, the first time a program has committed resources in the "Bs" (billions of dollars) rather than the "Ms" (millions); a convening in 2001 of a special session of the United Nations general assembly and culminating in the signing of the Declaration of Commitment on HIV/AIDS by all UN member nations; and the establishment in 2002 of The Global Fund to Fight AIDS, Tuberculosis and Malaria.

Early Implementation Strategies and Challenges

The announcement of PEPFAR, then, came early, but not at the beginning of, the "handle of the hockey stick" phase of the HIV donor resource boom, especially in Sub-Saharan Africa. The support for an increasingly recognized cause does not mean that PEPFAR's establishment was uncontroversial. Establishing a large foreign aid program early in the 21st century went against the grain of much thinking on foreign aid at the time. Between 1960 and 2003, the United States has committed over 80 billion USD in foreign aid to Sub-Saharan Africa, mostly targeting economic development.[8] By the early 1990s, as economic development in most Sub-Saharan African countries remained sluggish at best, a host of economic analyses indicted foreign aid, especially to Sub-Saharan Africa, as ineffective at best, and quite possibly harmful.[9–13] First, by channeling aid through weak governments, aid seemed to help entrench regimes without evidence of reaching the intended beneficiaries. Second, aid often failed to achieve its intended goals such as infrastructure or education improvements. Third, by providing a source of income to the recipient government, aid reduced the incentives to create sustainable and solid institutions for generating domestic incomes. One damning empirical finding followed another, and the general message of these analyses was: foreign aid is not the way to help poor countries escape poverty.[14] This research was highly influential, and between 1990 and 2000, after decades of substantial and mostly growing investments, US foreign aid to Sub-Saharan Africa mostly stagnated or declined.[15] PEPFAR was conceived at a time when the popularity and expectations of foreign aid were at a low point.

It is important to recall that PEPFAR was not an overnight success; in fact, more often than not, the view in the early years was that PEPFAR was heading in the wrong direction or doomed to fail.[16–19] In a now-infamous interview, Andrew Natsios, then head of the US Agency for International Development, mused on the futility of providing ART to Africans because many do not keep "Western time" and are therefore unable to take scheduled medications.[20] Additional criticism directed at the leadership of the newly-created Office of the Global AIDS Coordinator further fueled skepticism about PEPFAR's future.[21,22]

How Did PEPFAR Succeed?

It is now commonly acknowledged that PEPFAR, viewed as a whole, has been a highly effective program.[23,24] The 2013 Institute of Medicine evaluation noted that "PEPFAR has been globally transformative."[24] As early as 2007, a commissioned evaluation noted PEPFAR's success in forging partnerships and establishing the procurement and supply chains needed to scale up the delivery of ART.[23] Anecdotal evidence accumulated, of new hope for highly affected communities, of people rising from their deathbeds, the "Lazarus

effect" of hundreds of thousands starting ART.[25] Large-scale evaluations isolating outcomes in PEPFAR's so-called "focus countries" have consistently linked PEPFAR's implementation with population-level changes in HIV and all-cause mortality.[26,27] That is, the implication was that PEPFAR was not a local or narrow program, with a localized impact; rather, its impact could be observed on a national scale.

In the field of aid effectiveness, PEPFAR was central in separating health aid from aid targeting economic development. Even ardent aid skeptics now acknowledge that foreign aid targeting health improvements has often achieved its intended goals, and PEPFAR was a paradigmatic example.[28] The most direct effects from the scale-up of ART have been the easiest to detect. Declines in HIV-specific and all-cause adult mortality have been very closely associated with PEPFAR investments.[26,27] On an even broader scale, after a decade in which 50 years' worth of gains in life expectancy had been erased in most southern and eastern Africa countries, life expectancy stopped receding and started increasing where PEPFAR was most intensively implemented.[29,30] Recent evidence also suggests that PEPFAR was associated with increasing employment among men, possibly helping economic development even without directly targeting that sector.[31]

By the time George W. Bush left office in January 2009, his popularity in Africa was more than twice his approval ratings in the United States. As the President's approval ratings in the United States hovered around 30% in early 2009, the portion of the population having a favorable view of the United States was around 65% in Tanzania, and upwards of 70% in Zambia and Kenya.[32,33] Besides PEPFAR, the Bush record also includes the formation of the President's Malaria Initiative (PMI), increased support for The Global Fund to Fight AIDS, Tuberculosis, and Malaria, and new commitments for programs battling neglected tropical diseases. The United States led the way in propelling health into the ranks of a major foreign aid sector, accounting for the greatest share of the increase in health aid from $10 billion in 2000 (from all sources to all causes) to over $25 billion in 2008. Over the same period, aid for HIV increased from 0.5% to nearly 30% of all health aid.[34,35]

What made PEPFAR successful, when the record of so many foreign aid programs is neutral at best, and occasionally negative?[14,36–38] Several avenues of research have focused on elements of PEPFAR that have been particularly effective. People intimately involved with PEPFAR wrote that its commitment to country ownership – an expectation that partner countries would be closely involved with the design and implementation of within-country programs – was a central tenet guiding PEPFAR's development and deployment within each country.[39] However, PEPFAR's commitment to country ownership does not sufficiently explain its success. A similar commitment has guided many aid projects that did not succeed.

In trying to identify distinguishing features between PEPFAR and approaches of other development programs, a striking feature is that PEPFAR's principal implementers were US-based organizations and academic institutions. The Elizabeth Glaser Pediatric AIDS Foundation, Columbia University's International Center for AIDS Care and Treatment Programs, Catholic Relief Services, and Harvard School of Public Health were the principal recipients of support from PEPFAR to scale-up HIV treatment and care program in many of

PEPFAR's focus countries.[40] By 2011, these four organizations and their many sub-partners received more than $2.2 billion to support PEPFAR's goals. The choice to drive the scale-up through US-based organizations, while raising questions about the true extent of country ownership, also highlights important qualities of PEPFAR that may have contributed to its success.

Driving the scale-up through US-based organizations has been associated with several features that may not have been realized had PEPFAR partnered directly with in-country implementers. First, these so-called Track 1.0 implementers had enormous capacity to expand and scale rapidly. This capacity included the creation of an extensive supply chain management system that enabled the procurement and delivery of a large portion of all antiretroviral drugs used in PEPFAR-supported programs.[40,41] This supply-chain system was, like the Track 1.0 implementers, US-based, and the effective delivery of ART to sub-Saharan Africa was undoubtedly facilitated by the familiar systems and operation styles of the various structures involved in PEPFAR's implementation.

The concentration of support to a few implementers also enabled a critical factor in PEFAR's success: a dramatic reduction in ART prices. A more permissive FDA regulatory environment, good will on the part of many pharmaceutical companies, the expansion of generic options, effective advocacy, streamlining of regimens, and large-scale purchasing power from PEPFAR all combined to yield a dramatic reduction in the per-patient annual cost of providing ART.[41–44] At the per-patient costs of providing ART in 2004, PEPFAR would have been tapped out after supporting about one half of the patients it supported by 2012.

Two other related factors deserve important mention in explaining PEPFAR's success. At over $6 billion a year for over 10 years, PEPFAR has been a *huge* program with a *focused mission*. Such a singular focus has not gone uncriticized. Most commonly, PEPFAR's approach was perceived as siloed, focusing on HIV to the exclusion of – and possibly to the detriment of – other basic priorities such as strengthening health systems or primary care.[45] Analogous examples of successful health aid programs include smallpox eradication, and – ongoing – polio elimination and malaria control. By the yardstick of reduction in global burden, the smallpox and polio health aid programs have been even more effective than PEPFAR, but they have not come under the same scrutiny, perhaps because they never reached PEPFAR's size.[46,47] Some have argued that the concerns over PEPFAR's size may be justified, as the health aid directed towards HIV is inversely proportional to its global burden of disease, although counter-arguments suggest that, in health aid recipient countries, the portion of health aid directed to HIV is less than the portion of disease burden made up by the disease.[48,49] While the concerns may have some merit, PEPFAR's size and singular focus have been distinguishing features that cannot be ignored in accounting for PEPFAR's success.

The Price of Success

PEPFAR attracted more attention than any other health aid program. As of January, 2016, PubMed contains more indexed articles about PEPFAR than on The Global Fund to Fight AIDS, Tuberculosis and Malaria, the US President's Malaria Initiative, and GAVI Alliance

(formerly the Global Alliance for Vaccines and Immunisation), combined. The criticisms about its siloed ("vertical") structure, singular focus, and exceptional status among health aid programs eventually led to changes in its funding and focus. Between 2004 and 2009, PEPFAR funding increased by about 20% annually; between 2009 and 2015, funding has remained essentially flat at about $6.7 billion annually.[50] Moreover, during the period of flat funding, PEPFAR was called upon to broadly expand its activities and set higher goals. Towards the end of 2011, President Obama and Secretary of State Hillary Clinton called on PEPFAR to engage more fully in the "AIDS-free generation" agenda, with the goals of eliminating mother-to-child transmission, increase voluntary medical male circumcision, and expand ART coverage.[51] PEPFAR was asked to go wider in addition to going higher: while continuing to scale up HIV treatment and care programs under a flat budget, new efforts were launched to strengthen health systems. In particular, PEPFAR got involved in building new medical education systems, a substantial departure from its core areas of experience.[52] Efforts to demonstrate that PEPFAR's core activities – supporting ART and HIV care and prevention programs – yielded large positive spillover benefits beyond HIV did not ease the pressure from PEPFAR to build on its success and do more with unchanging resources.[53,54]

The price of success was also facing PEPFAR in foreign policy circles. Some viewed PEPFAR as an entitlement program. That is, because antiretroviral drugs are lifesaving, and because HIV-infected patients were living much longer after initiating ART, and because withdrawing support for ART would thus be unethical, PEPFAR was committed to supporting ART for all those who ever started treatment in PEPFAR-supported programs for a long time.[55] Former US ambassadors to PEPFAR focus countries bemoaned the loss of leverage in diplomatic operations borne of PEPFAR's large budget. Upwards of 80% of US support to Nigeria, Ethiopia, and Uganda, they claimed, was committed to PEPFAR.[56] This issue came to public attention when fears over the loss of US donor support were expressed on the front page of the *New York Times* by physicians and leaders in Uganda's HIV treatment programs.[57] Many thought that a different approach was needed.

Transitions Raise Normative Questions

It may not be surprising that PEPFAR's success eventually led to pressures to broaden its scope, but what may be surprising is the relative freedom PEPFAR enjoyed over the first few years in interpreting the normative framework in which it operated. What does that mean? It may appear readily evident that PEPFAR was created to halt the humanitarian crisis unfolding in Sub-Saharan Africa, but this is an incomplete picture. The leadership of organizations such as the World Health Organization and UNAIDS succeeded in bringing HIV to the top of the foreign aid agenda in the US and Europe by positioning the African epidemic as an economic and security threat.[58,59] The extent to which PEPFAR was viewed as a humanitarian, security, or economic foreign aid program could have had important implications for its structure and activities, but this debate, if it were explicit, was not made public, and PEPFAR's leadership did not have to respond to any proscribed missions such as to protect the US or control the economic cross-border harms from HIV. In hindsight, similar questions can be asked about PEPFAR's choice of partner focus countries. Why was Zambia selected as focus country, but neighboring Malawi with a similar population and HIV prevalence not? Why were Ethiopia and Nigeria – where HIV prevalence among adults 15–

49 years old peaked at just over 3% – selected as early partners, while Swaziland and Lesotho, with HIV prevalence over 20%, had to wait 5 years for PEPFAR support? Surely, there are good reasons for these choices, such as Nigeria's and Ethiopia's large populations, but the point is that, in the first 5–10 years, PEPFAR operated within a relatively loose normative environment and made decisions with relatively loose guidance about its goals.

The normative fabric of foreign aid commonly includes goals such as poverty alleviation, democracy, and shared growth.[60–62] What are PEPFAR's overarching goals? What is the program striving for? What would it consider success? Is it to eradicate incident infections? To eliminate preventable HIV-related deaths? To enable all Sub-Saharan countries to finance and implement comprehensive HIV control programs? Does it include reducing the global security threat from HIV? Buttressing African economies at a time of difficult transitions to middle-income? These goals may appear lofty, and the point is not to articulate realistic goals, but to contrast such goals with the current articulation of PEPFAR's goals:[63]

1. Transition from an emergency response to promotion of sustainable country programs.
2. Strengthen partner government capacity to lead the response to this epidemic and other health demands.
3. Expand prevention, care, and treatment in both concentrated and generalized epidemics.
4. Integrate and coordinate HIV/AIDS programs with broader global health and development programs to maximize impact on health systems.
5. Invest in innovation and operations research to evaluate impact, improve service delivery and maximize outcomes.

A wide-angle view of PEPFAR's goals leaves an impression that their articulation is a response to shifting pressures. The first two goals – transition to a sustainable response and strengthening of partner country capacity – directly address the criticisms about PEPFAR's outsized growth and the problem of entitlement, described above. The next two goals – expand HIV care and integrate operations to improve health systems – respond to the calls to build on PEPFAR's success and expand both vertically and horizontally. Only the last goal appears to reflect intrinsic priorities as opposed to extrinsic priorities, but its generality leaves open the possibility of expanding PEPFAR's disease and health priorities.

In setting goals in response to extrinsic pressures, PEPFAR is encountering new challenges. A practical implication of the efforts to transition ownership to partner countries is the reduction of support to partner countries with greater domestic resources. Thus, PEPFAR's planned support to Botswana declined from over $90 million in 2009 to around $40 million in 2014, and planned funding in South Africa followed a similar trend.[64] In South Africa, these budget cuts led to clinic closures and referral of patients to government-funded facilities, resulting in the loss of 10–30% of patients in the transition alone.[65,66]

Conclusions

The importance of articulating explicit norms is taking hold in the health aid field. In 2015, The Global Fund to Fight AIDS, Tuberculosis and Malaria convened a meeting of large multinational organizations with a stake in global health (including the World Bank, UNAIDS, and GAVI, among others) to formulate shared principles on financing decisions and selection of partner countries.[67] For example, to what extent should average country income matter for funding eligibility (as opposed to, say, the size of the population living in poverty)? Or how should organizations decide on the use of resources for global public goods (such as vaccine research, for example) relative to direct programmatic support? One outcome of this Equitable Access Initiative is to formulate coherent principles that provide long-term guidance and relieve organizations from the need to change strategies in response to shifting opinions and environments. The early progress of the Equitable Access Initiative did not include PEPFAR.

The future of PEPFAR is not known. To date, it has enjoyed bipartisan US Congressional support in part because of its effectiveness and popularity. However, what would be the implications to PEPFAR of a bad funding year or two? Would it (and could it) mobilize resources from the private sector or through development impact bonds to pursue its goals during lean times?[68] Perhaps. Having a clear and focused articulation of its goals would help in preserving and reinforcing global support for its efforts.

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