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A Diplomat’s Perspective on Use of Science and Evidence in Implementing PEPFAR

Jimmy Kolker

The President’s Emergency Plan for AIDS Relief (PEPFAR), the largest international health program by one country devoted to a single disease—HIV/AIDS—changed the way diplomacy and health intersect in many parts of the world, especially sub-Saharan Africa. This is the story of the program’s creation and early implementation from the perspective of the U.S. ambassador to Uganda, among the first countries on the continent to use data and evidence to describe, track, and treat HIV and AIDS patients through PEPFAR.

Global Context

PEPFAR is overwhelmingly viewed as a success story: an unprecedented program that saved, and continues to save, millions of lives globally. But when it was announced in President George W. Bush’s January 2003 State of the Union address, the program faced multiple unknowns and challenges. In many parts of

Ambassador Jimmy Kolker is a visiting scholar at the AAAS Center for Science Diplomacy. A foreign service officer for 30 years, he served as ambassador to Burkina Faso from 1999 to 2002 and Uganda from 2002 to 2005. Ambassador Kolker was Chief of the HIV/AIDS Section at UNICEF’s New York headquarters 2007-2011. From 2011-2017, he was Assistant Secretary for Global Affairs at the U.S. Department of Health and Human Services in Washington, DC.
the world, HIV and AIDS were still poorly understood by clinicians, scientists, politicians, and the public, resulting in fear and stigma. HIV continued to spread rapidly through populations, transmitted via sexual intercourse, intravenous drug use, blood transfusions, and from infected mothers to their babies.

The treatment regimen being used in the United States and other high-income countries by the mid-1990s—a combination of three drugs taken daily, known as antiretroviral therapy (ART)—was dramatically improving the health of HIV-infected individuals. ART reduced the HIV viral load of such individuals, either halting or substantially slowing their progression to immune deficiency and susceptibility to opportunistic infections. The majority of patients on ART showed encouraging clinical improvements. However, side effects were common, and the therapy was administered only under strict medical supervision and periodic expensive lab tests.

Many questioned whether the treatment regimen would be equally effective in Africa, given differences in medical access, nutrition, and health system capacity. Additionally, the initial high cost of the medications prevented access for many Africans.

Previous experience in Africa had already shown that a single ART tablet called nevirapine, given during labor and to the baby immediately after birth, reduced the likelihood that HIV-positive pregnant mothers would transmit the virus to their newborn babies. Prior to PEPFAR, the U.S. government and multilateral organizations helped establish maternity facilities in fourteen African and Caribbean countries as pilots for preventing mother-to-child transmission (PMTCT) of HIV. Uganda was one of these fourteen countries.

Situation in Uganda

The U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID) had worked for several years with local facilities on PMTCT, and by the time of my arrival as U.S. ambassador to Uganda in 2002, local support groups for people living with AIDS were actively referring HIV-positive pregnant women to the handful of facilities engaged in PMTCT.

Uganda was also the only African country where the U.S. government was providing ART to HIV-infected individuals. In partnership with The AIDS Support Organization (TASO), a Ugandan-founded and led NGO, the CDC initiated a home-based care project in the eastern Ugandan city of Tororo due to its high rates of malaria and diarrhea among persons living with HIV. Tororo was also the site for a prior intervention study that provided a low-cost basic care package.
including preventive antibiotic medication, bed nets, and clean water containers and purifiers, resources that had been shown to significantly reduce morbidity and mortality in both HIV-infected and uninfected household members.4,5

In the home-based project, medicines were delivered on motorcycle by trained lay providers to the homes of patients diagnosed with HIV. All TASO clients with low CD4+ T cell counts—confirming that HIV had developed into serious immune deficiency—were provided a supply of ART, per clinical guidelines, to be taken daily, along with weekly home-based and monthly clinic-based checks on their drug adherence and overall health.

Although the number of patients enrolled in the Tororo project was small (1,000), a number of initial findings helped inform President Bush’s decision in January 2003 to propose ambitious expansion of treatment to Africans without access to sophisticated medical centers or labs:

- Adherence was excellent; the patients took the various pills on schedule.
- The remission in symptoms was evident and confirmed by CD4+ T cell counts and viral load test results (high CD4+ T cells; low viral load).
- Side effects, while common, were generally manageable.

TASO also provided information, support, and limited services to people living with or affected by HIV throughout Uganda.7

The other main actor in HIV care and treatment in Uganda at this time, the Joint Clinical Research Center (JCRC), was founded in 1990 in the capital, Kampala, as a partnership among the Ugandan Ministries of Health, Education, and Defense. Its clinic, affiliated with Makerere University, conducted clinical trials and by 2003 was providing ART to a few thousand individuals who were self-financing or supported through other private channels. Its director, Peter Mugyenyi, was therefore knowledgeable about treatment initiation in low-resource settings, and he had a history of collaboration with international researchers, including National Institute of Allergy and Infectious Diseases (NIAID) director Anthony Fauci and NIAID AIDS expert Mark Dybul.

While much has been written on the threat that AIDS posed to the economies, political stability, and even security of high-prevalence countries,8 it was the limited availability of newly advanced medical treatment and corresponding issues of equity that drove U.S. involvement in a scaled-up AIDS response in Uganda.
Initiating PEPFAR

Like TASO, the JCRC had thousands of clients who had tested positive for HIV but could not afford ART, which in developed countries at the time cost about $10,000 per patient annually. There were, however, new generic compounds, for as little as $30 a month, which the JCRC was using in clinical trials with promising results.

Fauci and Dybul were the only two U.S. scientists brought into the White House discussions prior to the public announcement of PEPFAR. They, in turn, brought Mugyenyi to Washington to describe his experiences and advocate for the practicality of ART expansion.

The HIV treatment model for PEPFAR was developed with Uganda in mind. The goal was to rapidly begin ART for adults whose immune system was already compromised and who were involved in the TASO and JCRC networks and therefore had access to regular monitoring for side effects, symptom abatement, and follow-up testing. Since few, if any, other African countries had comparable organizations with rosters of eligible patients, PEPFAR needed to be considerably retooled after it launched, but Uganda was established as the showpiece and linchpin of PEPFAR’s rollout and early success.

This was nowhere better highlighted than during President Bush’s visit to Uganda in July 2003. Although dismissed by some as a PEPFAR “victory lap” before the program even started, U.S. and Ugandan partners gathered all the key stakeholders, including HIV-positive TASO clients who lacked access to treatment, in the crowded space at TASO Entebbe to explain what Uganda could do if only they had the money.

During my ride with the president and first lady to the airport directly following the TASO site visit, his fascination by what the U.S. visitors had just seen was clear. He noted that Uganda was doing things that he had heard on his last stop, in South Africa, were impossible. He wanted confirmation that people could be kept alive for $30 a month as long as the money existed, and when I confirmed that this was true, he told me, “Don’t worry, you’ll get it.”

With those words, the president affirmed that he understood the opportunity PEPFAR in Uganda offered. More important, he recognized that PEPFAR could not achieve its objectives unless it embraced generic alternatives to the expensive branded drugs that had market exclusivity in the United States.
Controversy and Skepticism over the U.S. Role

When now considering the stunning subsequent expansion of ART treatment in Africa and PEPFAR’s leading role, it is easy to forget the widespread controversy and bitter criticism that the PEPFAR announcement sparked. For example, UN secretary-general Kofi Annan’s first reaction was pushback that the PEPFAR initiative would detract from the recently established Global Fund to Fight AIDS, TB and Malaria, and would lead the United States to back off its Global Fund pledge and finance only PEPFAR.

At the beginning of 2003, overall political opposition to President Bush was intense owing to the launch of the U.S. invasion of Iraq. While welcoming the commitment of a remarkable $15 billion over five years to fight AIDS internationally through PEPFAR, U.S. and European AIDS and health interest groups and activists were highly skeptical of the effort. These doubts were intensified as Bush appointed Randall Tobias, an executive of Eli Lilly pharmaceuticals with no AIDS or Africa expertise, to head PEPFAR. The move was seen as a signal that money would go to U.S. manufacturers for high-priced patented drugs. Further criticism centered on Congress, which included many earmarks in PEPFAR authorization and appropriation, the most controversial being that at least one-third of HIV prevention money in each PEPFAR country had to go to promote abstinence and marital fidelity.¹¹

Procedural Innovations and the Use of Evidence in Early Funding Decisions

To decide which existing programs should receive additional funds, the programs were reviewed against PEPFAR criteria, a case that usefully exemplifies the benefits—and limitations—of bringing data and evidence into a policy and funding discussion. The criteria for spending PEPFAR money were established by Congress and by guidance issued by Tobias, known as the global AIDS coordinator, and his deputies, Joe O’Neill (medical) and John Lange (diplomatic). The U.S. government decided that ambassadors should be empowered to manage the programs and be held accountable for results. Furthermore, embassies would be allocated money based on estimated need; they would not have to apply for it via traditional USAID mechanisms.

The impact of these procedural innovations cannot be overstated. They saved literally years of staff time and permitted the country teams to move immediately to consider specific in-country programs—ongoing and new—and weigh them against estimated cost and likely impact. Many of these programs benefited from U.S.-based technical or NGO partners, but it was the embassy team, not the agency
headquarters or NGO contract proposals, that presented options and put together a country operating package.

As ambassador, I chaired the decision-making process in Uganda. Existing programs were reviewed for proven effectiveness in HIV prevention, treatment, or care, but one challenge involved the lack of data. For example, no data were available to show any positive impact of the AIDS money that had gone to Africare, a USAID partner that provided AIDS information to beneficiaries of its agriculture program. Ultimately, this money was reprogrammed. Nor was there clear evidence that another partner, Straight Talk, could demonstrate impact from its popular weekly radio show aimed at teens, discussing sex and AIDS. However, I approved investing additional PEPFAR resources in Straight Talk for at least two reasons. First, the radio-based Straight Talk could be scalable, easily adaptable for effective messaging and ultimately measurable in impact, since we were assembling baseline incidence figures for teenage populations. (This turned out to be correct.) The second reason was policy driven—Straight Talk money could be attributed to the “abstinence earmark,” which otherwise could be difficult to spend.

Since putting HIV-positive people on treatment was PEPFAR’s primary goal, deciding that PEPFAR should raise its investment in TASO and the JCRC was not difficult. In considering other local treatment partners proposed by USAID and the CDC, the standards of evidence were simply whether they had sound medical and financial practices and a system to track results. We put a significant amount of early PEPFAR money into local NGOs that specialized in pediatric AIDS care (even in the absence of pediatric formulations of ART), urban home-based care (roughly mirroring the successful Tororo model), an underresourced national HIV testing organization, and a local end-of-life care facility, which provided unique and valuable care for the many untreated Ugandans suffering from AIDS. Not all public-sector partners met PEPFAR criteria. For example, we provided money to the Ministry of Health for laboratories and training, but not directly for patient care or treatment.

Decision Making at the U.S. Embassy in Uganda

The AIDS team at the U.S. embassy in Kampala in 2003 was larger than outsiders might have imagined. For example, USAID and the CDC already had nearly twenty professional staff, U.S. and Ugandan, working full time in embassy offices on AIDS-related issues. Several U.S. Department of Defense entities, the Peace Corps, and the National Institutes of Health had ongoing AIDS cooperation with Ugandan counterparts as well.
USAID health chief Robert Cunnane and CDC country director Jonathan Mermin led substantive discussions and worked closely and collaboratively across agency lines to set the parameters for presenting and recommending options. As chair, I often asked questions centered on how the proposals would contribute to Uganda’s share of PEPFAR quantitative targets: 2 million people on treatment, 7 million new infections prevented, and 10 million people (including orphans) in care.

Those numbers meant that each proposal needed to have data sets and cost-per-result estimates. After the initial meeting and some additional refinement over a relatively short period in the second half of 2003, Cunnane and Mermin devised a set of options that either had interagency agreement or were referred to me for decision.

I tried to balance the imperative to meet the quantitative targets with policy goals and good science, while establishing systems that would be scalable and sustainable in Ugandan institutions. Some examples of decisions that required a balance of evidence, science, and policy are as follows:

- The most important new program was focused on treatment. The CDC argued for basing the program with TASO, which had tens of thousands of grassroots members already on its rolls whose only hope of survival was rapid access to ART. USAID advocated centering treatment efforts at the JCRC, as a government-connected treatment center with ambitious plans to provide ART care through training Health Ministry staff across Uganda. I saw strong evidence that each approach had distinct advantages and therefore decided that each would be funded directly, not one subordinate to the other.

- One question involved whether to provide ART to facilities in refugee camps, since refugees were by definition impermanent. U.S. government support would normally come through the UN High Commissioner for Refugees, and treatment would not be available in their home countries (e.g., Democratic Republic of the Congo, South Sudan) upon return. While I initially decided against funding treatment for refugees, I later realized through some data on refugee permanence from the Bureau of Population, Refugees, and Migration, within the U.S. Department of State, that this was a wrongheaded and heartless distinction. In subsequent years, refugee organizations and institutions received PEPFAR funding in Uganda.

- The World Health Organization (WHO) had proposed a “3 x 5” program (3 million people on ART by 2005), and after visiting Uganda and meeting with the PEPFAR team, Jim Yong Kim, the physician and anthropologist who then headed
the WHO AIDS program, proposed that PEPFAR use its resources to advance this initiative. Acknowledging that the programs had the same aims, the U.S. team did not recommend cobranding PEPFAR with 3 x 5, nor did it recommend funding WHO. Kim’s visit did, however, lead to WHO subsequently endorsing door-to-door HIV testing in countries with generalized epidemics, a CDC/PEPFAR innovation questioned by some because it had lacked normative approval from WHO. Indeed, the scientific validation role of WHO and other international organizations is poorly appreciated by many diplomats and policy makers.

- USAID argued for an active treatment component to be added to AIDS education and prevention work being advanced by the private sector through a USAID-funded program to promote private-sector growth. The CDC opposed this funding because it did not target populations most in need and was duplicative in geographic coverage. After some refinement to address CDC concerns, I endorsed the private-sector funding, seeing Ugandan employers as key opinion leaders and potential cofunders, as well as a non-faith-based “new partner.” In this case, the policy arguments carried more weight than the medical perspectives.

**Expansion and New Partners**

The wisdom of the decision to directly fund both TASO and the JCRC was borne out as Uganda met and hugely exceeded the 2004 and 2005 treatment targets set for the country. But the path to meet those targets required unprecedented program growth and innovation. The JCRC’s Mugyenyi said he would set up twenty-two treatment centers in Ministry of Health hospitals and clinics around Uganda, which would be operational with fully trained staff within one year after receiving PEPFAR money. I was highly skeptical that this goal could be achieved due to the shortage of doctors and health personnel outside Kampala and the known dysfunction pervading the Health Ministry, but, with USAID’s promise to track progress and the political need to reach large numbers fast, I concurred.

The JCRC established not twenty-two but twenty-seven functional ART clinics within one year after receiving PEPFAR funds and fenced their operations off from the Health Ministry kleptocracy. As impressive as the JCRC’s overachievement was the success of TASO and community-based voluntary organizations. Within a year, TASO clinics, associated with or separate from JCRC affiliates, also achieved nationwide coverage for ART and integrated treatment into the model of providing care and public messaging as well as clinical interventions. TASO became the prototype for several other neighborhood-based AIDS clinics and organizations.

One standout organization was Reach Out Mbuya, which initially had no major source of funds and no ART drugs. After seeing an influx of HIV-infected
patients flood the clinic while volunteering, a Danish doctor named Margrethe Juncker convinced the CDC’s Jonathan Mermin that Reach Out’s need for PEPFAR drugs was even more urgent than that of TASO and the JCRC, which had a small number of patients already on ART.

In March 2004, when the first airfreight parcel of PEPFAR-funded ART arrived in Uganda, the drugs were delivered to Reach Out, and John Robert Engole—a secondary school teacher from a small town two hundred kilometers from the capital who had been expelled from home by his wife and family because of his HIV status—became PEPFAR’s first beneficiary. Dr. Juncker recalled to me that Engole’s CD4+ T cell count was 2 (healthy is 800–1000), meaning that his immune system was so challenged that virtually any microbial pathogen would have killed him quickly. After treatment, Engole made a miraculous recovery and visited my residence a year later to meet PEPFAR ambassador Randall Tobias. A year later, he traveled to the White House to appear in the Rose Garden with President Bush. At Reach Out, he tutored other patients during his convalescence and checkup visits, stayed in Kampala to earn a master’s degree, remarried, and returned to teaching secondary school. In October 2017, he welcomed then CDC director Brenda Fitzgerald to Reach Out on her first trip to Africa.

Engole’s story is more dramatic than most, but it represents the impact that increased access to ART had in Uganda. Just as everyone in the country knew personally many who had died of AIDS, virtually every Ugandan by 2005 saw an HIV-infected family member or neighbor now surviving and returning to productive life.

The rapid scale-up and unprecedented budget ($120 million geofor Uganda in 2006, PEPFAR’s largest country program) attracted seemingly every AIDS organization in the world to the country to potentially partner in PEPFAR. The U.S. government interagency team set criteria by which potential partners, and their U.S. government agency advocates, would be judged in allocating resources. These centered on clear contribution to the numerical goals of PEPFAR, especially increasing numbers of people on treatment, and on measurability of results. Medical interventions (ART, PMTCT, subsequently medical male circumcision) were easier to justify in these criteria than behavioral or systems-strengthening programs, but the mission did try to invest in promising interventions, both biomedical and behavioral.

I attempted to meet with any of the development or advocacy groups that had a U.S. connection and posed three questions to each:
• How does what you’re proposing fit in with Uganda’s national AIDS strategy?

• Who in Uganda is already working in the area of your proposed activities, and how do you plan to relate to or add value to their work?

• What results do you expect to see within two years?

None of these questions required a reply citing quantitative data or scientific evidence, but the best answers—and partners whose value to PEPFAR was clearer—could quantify the problem they were addressing, explain how they would bring or apply research or technical expertise not already available in Uganda, and outline how success could be measured.

**Relying on Science and Diplomacy to Create a Sustainable PEPFAR Program in Uganda**

During this time, Uganda was experiencing the height of disruption from the Lord’s Resistance Army, led by guerrilla leader Joseph Kony, a campaign that terrorized nearly a fifth of the country’s population and territory in the north and east. TASO and the JCRC did have relations with health centers and organizations in the affected areas, but security concerns severely limited travel and supply chains.

Remarkably, PEPFAR treatment expansion and other programs were successful in conflict areas, but the first year’s results showed little prospect that TASO or the JCRC could increase scale beyond their initial sites. After considerable internal debate and consideration, I opted to enlist partners, such as the Italian NGO AVSI and International Rescue Committee (IRC), to become the PEPFAR leads in conflict areas in which they were already on the ground, though not yet working in AIDS—or, in the case of the IRC, in health at all. This turned out to be a best practice that was adopted in other conflict regions. Partners familiar with doing business in insecure areas were better at providing AIDS services than traditional AIDS organizations were at replicating their usual services in conflict areas.

PEPFAR’s strict focus on prevention, treatment, care, and support meant that the other needs of HIV-positive individuals and their communities would not be addressed through PEPFAR funding, at least prior to 2006. One particular challenge was nutrition. Ill patients had little appetite and no strength to contribute to family obligations to grow food. But once initiated on ART, hunger was frequently the leading complaint of patients on treatment and organizations supporting them. PEPFAR’s patients needed better access to food, but PEPFAR had to look to
“wraparound” programs, such as the World Food Programme or USAID Food for Peace, to address this gap.

Another key broad challenge that PEPFAR could not meet in the initial years concerned lack of health workforce capacity, quality of health systems, and the prospect that emphasis on fighting AIDS as a disease-specific program shortchanged primary care or other unmet health needs. Here, the Uganda PEPFAR team did try to identify health system problems and justify spending for those that had a direct impact on the AIDS program. Two skill deficits that directly hindered scale-up of the AIDS response were lab technicians and HIV-test counselors. Training for these key personnel were part of PEPFAR in the early years, and more comprehensive attention to health systems and workforce was introduced in later years.

Internally, the greatest challenge to the embassy PEPFAR team was matching what we saw as Uganda’s national priorities and its unprecedented opportunities to fight AIDS with the funding allocation required by PEPFAR congressional language and U.S. administration guidance.

The overwhelming scientific evidence that ART was effective in keeping HIV-positive people alive was frequently cited in embassy team discussions, and PEPFAR’s goal that half its money go to treatment meant that treatment interventions were favored ahead of general population prevention measures, for which data were scarce and hard to verify. Initial doubts about treatment—patient adherence, percentage failure of first-line regimens, side effects, inadequacy of follow-up—all faded as the first thousands of people responded to treatment more favorably and with fewer complications than many experts imagined.

In Uganda and most of Africa, women in heterosexual relationships were by far the demographic with the highest HIV incidence. There was a strong correlation between being a victim of domestic violence and HIV incidence. PEPFAR rules prohibited providing family planning services to clients at PEPFAR-supported facilities, although the embassy mission in Uganda did make a point of supporting HIV information and referral at family planning centers and some referral of HIV-infected clients to family planning services. Quite a few country teams, however, interpreted the PEPFAR rules as prohibiting even this association with contraceptive providers.15

The hardest congressional earmark to fulfill for Uganda and many other country teams was the 10 percent of PEPFAR money designated for “orphans and vulnerable children” (OVC). Few partners or mechanisms were available in Uganda to reach the surviving parents and extended families who were overwhelmingly
taking care of children who had lost a parent or parents to AIDS. Orphanages quickly applied for OVC funds, and some did receive them. And even in 2003–2005, suspicion prevailed—later supported by evidence—that outcomes for long-term orphanage residents were poor, given the trouble they had integrating or reintegrating into communities. But the alternative—community organizations with little capacity to offer sustained help to caretaker families—could not absorb the level of funds required to pursue “care and support” of AIDS-affected individuals and, especially, their children.

The most controversial congressional earmark in the first phases of PEPFAR, as implied earlier, was the requirement that funds go to promote abstinence as a recommended HIV prevention method. Some PEPFAR money was used to provide information and advocacy for abstinence, being faithful, and condom use—deemed the “ABC approach” for the first letter of each term—which was also consistent with Uganda’s HIV prevention strategy. Fundamentally, prevention practices based on never having sex, having sex only with a confirmed HIV-negative partner, or consistently using a condom are all scientifically sound. In the long run, however, people at risk of HIV transmission from an infected partner—particularly women—can rarely practice abstinence forever, have limited leverage over men’s condom use, may have little awareness of the partner’s HIV status or extramarital relationships, and likely want to have children. Nationally representative surveys in Uganda showed that half of married HIV-infected persons were married to vulnerable HIV-negative partners. It soon became clear that A, B, and C were not having the desired impact on reducing the number of new HIV cases. In fact, new HIV cases in Uganda went up in 2006–2007.

Nonetheless, the abstinence prevention earmark was fulfilled largely because I agreed with the recommendation that this share of the prevention funds be spent primarily on in-school and education-connected programs such as Straight Talk. For students under fourteen years old, this centered on life skills and responsible behavior. For older children, curriculum and messaging emphasis was on delaying sexual debut and empowering girls to resist pressure for sex. These activities were chosen for policy reasons, not based on persuasive data, and it would be difficult to attribute even ultimately declining rates of HIV incidence in Uganda to the funds spent on abstinence in those years.

Lessons Learned for Science and Health Diplomacy

From my experiences as a U.S. ambassador, as well as a dozen years working on global health issues for the U.S. government and the United Nations, I learned that in adapting arguments to persuade other governments and putting our priorities on their agenda, the growing field of science and health diplomacy is highly
relevant. Diplomats can benefit, more than most do already, from the insights of scientists. By working together, both sides can be a force for evidence-based policy and create the political will to tackle the great challenges of our time.

Endotes

1. Two nucleoside reverse transcriptase inhibitors (NRTIs) along with one protease inhibitor (PI).
7. Tens of thousands of TASO members were enrolled in care and support services that helped them prevent and seek treatment for opportunistic infections and gain access to local services. Both the CDC and USAID supported TASO and its activities.
10. When President Bush introduced PEPFAR during his 2003 State of the Union address, he explained as follows: “This comprehensive plan will prevent 7 million new AIDS infections, treat at least 2 million people with life-extending drugs and provide humane care for millions of people suffering from AIDS and for children orphaned by AIDS. I ask the Congress to commit $15 billion over the next five years, including nearly $10 billion in new money, to turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean.” The full text of the speech is available at http://www.washingtonpost.com/wp-srv/onpolitics/transcripts/bushtext_012803.html.
12. This proved wise in light of the experience of the Global Fund, which during the same period supported programs in Uganda directly through the Health Ministry and lost millions of dollars to organized fraud.
13. Reach Out Mbuya was started by a priest in a Catholic parish in a poor area of Kampala, home to a large number of people displaced by the Lord’s Resistance Army’s brutal insurgency in northern Uganda.
15. Abortion was illegal in Uganda, so the U.S. government’s “Mexico City policy,” which prohibits U.S. federal funding to any organization providing abortion referrals, did not apply.