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Successes and challenges of HIV treatment programs in Haiti: aftermath of the earthquake

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SUMMARY

Haiti's HIV/AIDS program is one of the most successful in the world, with a declining HIV prevalence, and treatment outcomes that rival those of industrialized nations. It is now on the way to providing universal treatment for HIV/AIDS nationwide. This success is tied to a strong foundation for HIV care that was in place before external funding became available that includes national guidelines prepared by the Ministry of Health, political commitment at the highest levels of government, non-governmental organizations that had been providing high quality care in Haiti for decades, and the assistance of the Global Fund to Fight AIDS, TB, and Malaria, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and other private donors.

While the challenges of human resource shortages, widespread poverty, and limited infrastructure cannot be overstated, these are being addressed through the provision of integrated, comprehensive services. Haiti's successful treatment models are being duplicated around the world.

Keywords

HIV/AIDS; antiretroviral therapy; adherence; quality of care; tuberculosis; Haiti

HISTORY, EPIDEMIOLOGY, AND PREVALENCE OF HIV/AIDS IN HAITI

History and Epidemiology of HIV/AIDS in Haiti

The history of the HIV/AIDS epidemic in Haiti is closely tied to that of the U.S., as these were the first two countries where the disease was recognized. In 1982, shortly after the syndrome erupted in the U.S., the Centers for Disease Control (CDC) described 34 cases in Haitians residing there [1,2,3]. Eleven likely cases were also reported in Haiti [4]. With the majority of HIV-positive Haitians in the U.S. not reporting the classic risk factors [5,6,7], the CDC inferred that Haitians represented a separate at-risk group, which led to the labeling of the "4H Disease", affecting Haitians, hemophiliacs, heroin users, and homosexuals. This resulted in unprecedented national discrimination that devastated Haiti's fragile economy.

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Haiti's first response to this new and worrisome epidemic was the formation of the Haitian Study Group on Kaposi's Sarcoma and Opportunistic Infections (GHESKIO) by a group of Haitian health professionals in 1982, with the support of Cornell University. One year later, GHESKIO published the first case series on HIV/AIDS in a developing country in the New England Journal of Medicine. Using CDC criteria, a total of 61 cases of AIDS were diagnosed retrospectively from June 1979 to October 1982 [8]. GHESKIO researchers also conducted a variety of studies to determine the most common risk factors for HIV/AIDS among Haitians. Careful analyses revealed that risk factors among the first Haitian patients were identical to those in the US. Eighty five percent of patients were male and 80% lived in Port-au-Prince, most in the suburb of Carrefour, a center for male and female prostitution [8]

After its introduction into the population, the HIV virus spread rapidly in Haiti, particularly among women, as the epidemic rapidly generalized. The proportion of cases attributed to homosexuality and bisexuality plummeted from 50% in 1983 to a mere 1% in 1987 [9]. Since 1985, heterosexual intercourse has been the dominant mode of transmission, as the blood supply was protected early in the epidemic, and intravenous drug use in Haiti is rare, and has never been a significant risk factor for HIV/AIDS. As the epidemic became generalized, an increasing proportion of cases have been female. In 1983, HIV was five times more common among males. The ratio decreased to 1.6:1.0 by 1990, and by 2000 an equal number of men and women were infected. The balance then shifted, and by 2006, more women were infected, with a ratio of 2.3:2.0 [10].

HIV Prevalence in Haiti

Throughout the 1990s, HIV prevalence remained high across the country, at one point reaching 8% in Port-au-Prince and 4% in the rural areas [11]. The highest rates were found in patients referred from other clinics for HIV testing (50% positive), hospitalized patients with TB (54% positive), sex workers on the street (from 53 to 72% positive), and patients with sexually transmitted infections (24%). Prevalence peaked in the late 1990s and has since been dropping.

In 2005–2006, a demographic health survey, called EMMUS-IV (Enquete Mortalite, Morbidite et Utilisation des Services), was conducted to estimate HIV prevalence at the population level [10]. Between October 2005 and June 2006, 9,998 households participated in the study (99.6% of those surveyed). Ninety-six percent of participants accepted HIV testing. The study found that 2.2% of people aged 15 to 49 were HIV-positive (2.3% among females and 2.0% among males). Among females, the prevalence increased with age up to the range of 30–34 years, where it peaked at 4.1% (See Table 1). Among males, the prevalence peaked at 4.4% among those aged 40–44 years.

Sentinal surveys are also conducted regularly among pregnant women in Haiti, and facilitate the comparison of HIV prevalence over time. In 1986, 8.4% of women receiving prenatal care in the urban slum of Cite Soleil were found to be HIV-infected [12]. The prevalence increased to 9.9% in 1987, and 10.5% in 1989. In sentinel surveys conducted by the Ministry of Health, l'Institut Haitien de l'Enfance, and GHESKIO, prevalence among pregnant women decreased from 5.9% in 1996 to 4.5% in 2000, and by 2004, it had decreased to 3.44% [10]. While prevalence appeared to slightly increase from 2004 to 2007 (from 3.44% to 3.96%), no statistically significant difference was detected after controlling for confounding variables (age, income, zone of residence, syphilis co-infection).

HIV/AIDS PREVENTION EFFORTS

Nationwide HIV/AIDS prevention programs represent collaborative efforts between the Haitian Ministry of Health and a network of non-governmental organizations (NGOs), and

have focused on improving knowledge of HIV risk factors, safe sexual practices and access to condoms. In the most recent demographic health survey, across all gender and age categories, from 83 to 97% of Haitians reported that HIV could be prevented through abstinence, monogamy, and condom use [10]. Though significant progress has been made, important challenges remain that must be addressed. For example, the same survey found that 29% of sexually active females and 62% of males had high-risk intercourse, defined as sexual intercourse with a non-cohabitating or extra-marital partner, in the prior 12 months. Twenty six percent of females and 42% of males stated that they had used a condom with the last act of high-risk sexual intercourse [10].

Though ongoing efforts will be necessary to improve safe sexual practices, dramatic progress has been achieved in the treatment of sexually transmitted infections (STIs). Two decades ago, it was found that HIV transmission was associated with the presence of a second STI [13,14]. These studies were confirmed at GHESKIO, with findings that a genital ulcer increased the risk of HIV transmission by nearly seven times, and a positive syphilis test nearly tripled the risk (unpublished data).

As STI testing proved expensive and technically demanding, GHESKIO clinicians determined the types of infection responsible for common presenting genital symptoms (e.g., urethral discharge), and then developed algorithms for the diagnosis and treatment of STIs based on symptoms rather than test results. Multiple NGOs then worked with the government to develop a national plan for the prevention and treatment of STIs, training over a thousand health care providers from around the country in this strategy for diagnosis and therapy.

As safer sexual practices and algorithms for STI treatment were implemented around the country, the prevalence of STIs in Haiti declined. In national prevalence studies (conducted along with HIV testing), syphilis prevalence peaked at 7.6% in 1993, then dropped to 6.14% in 1996, and 3.9% by the year 2006 [10]. Though national prevalence studies have not been conducted for other STIs, it is expected that some of these may they have declined in parallel with HIV and syphilis.

COMMUNITY-BASED CARE IN RURAL HAITI - THE PARTNERS IN HEALTH MODEL

Partners In Health (PIH) is an NGO affiliated with Harvard Medical School and Brigham and Women’s Hospital in Boston, USA, working in Haiti with sister organization Zanmi Lasante. In 1985, PIH opened an ambulatory clinic in the squatter settlement of Cange, in Haiti’s Central Plateau, to provide services to a settlement of refugees that had been displaced decades before by a hydroelectric dam that flooded the surrounding land. The Central Plateau is one of the poorest parts of Haiti, lacking potable water, paved roads, and electricity. Most of the population lives in isolated dwellings, villages or very small towns spread throughout the countryside. In addition to providing health services, PIH also aimed to maximize the well-being of the community, developing clean water systems, building schools, planting trees, and initiating economic development projects.

In 1986, the first patient with advanced AIDS presented to the PIH clinic; shortly thereafter, PIH introduced voluntary counseling and testing for HIV. Services were free of charge, but uptake was low, as no treatment was available. Soon after, an inpatient facility was opened, and AIDS-related illnesses rapidly became a major cause of admission; in the early 1990’s about 40% of inpatients were HIV-positive [15]. Many patients were diagnosed with HIV when they presented with tuberculosis, and they clinically improved with TB treatment. Daily directly observed treatment and social support was provided by community health

workers, called *accompagnateurs*, who lived in the villages and were paid a modest stipend to provide care to their neighbors. All medications and follow-up care were provided free-of-charge to the patients, who were also eligible for social services, including nutritional support and transportation subsidies. In 1995, when studies showed that zidovudine could prevent mother-to-child transmission of HIV, PIH began offering zidovudine to all pregnant HIV-positive patients [16]. Over the next year, the rate of voluntary counseling and testing jumped from about 30% to over 90%.

By 1996, when HIV-related mortality plummeted in the industrialized nations due to the advent of highly active antiretroviral therapy, PIH had a highly-functional, community-based health care system in place for the treatment of HIV and TB. Antiretroviral therapy (ART) was all they lacked. At the time, it was widely assumed that ART was too complex and costly for use in resource-poor settings. Though PIH was a small NGO at the time, resources were found to provide ART for as many patients as possible, using the same directly-observed treatment model that was in place for TB care. From 1999 to 2002, the team relied on clinical algorithms to identify patients with advanced AIDS that were in greatest need of treatment, as CD4 cell counts were not available in rural Haiti at the time [17]. The dramatic clinical responses to treatment that followed led to further increases in demand for voluntary counseling and testing.

PIH's treatment outcomes for HIV/AIDS were outstanding, demonstrating that it was in fact feasible to treat HIV/AIDS with ART in a resource-poor setting. The clinical response to therapy was favorable in 59 of the first 60 patients. In a subset of 21 patients whose viral loads were monitored, 18 (86%) had no detectable virus in their blood [17,18]

The PIH model of HIV care was comprised of four integrated 'pillars' that included voluntary HIV counseling and testing in the context of primary healthcare, maternal health services, TB diagnosis and treatment and the diagnosis and treatment of STIs. By focusing on these pillars as the basic critical elements for success of HIV care in the community, by providing healthcare based on a human rights approach and not based on ability to pay, and by using a cadre of paid community health workers to accompany patients with their chronic disease, PIH leveraged resources targeted for HIV/AIDS to improve all aspects of the health system in rural Haiti [15,17,19,20].

PIH's program was one of the key success stories used to argue for the expansion of ART treatment in resource-poor settings through the development of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and PEPFAR, and has since been duplicated around the world.

HIV/AIDS TREATMENT IN PORT-AU-PRINCE - THE GHESKIO MODEL OF INTEGRATED CARE

Port-au-Prince has some of the largest, poorest, and most densely populated urban slums in the world. Many of the residents of these slums seek care at GHESKIO, an NGO dedicated to preventing and treating HIV/AIDS and related infections, training health care providers, and conducting operational research to improve the clinical management of the diseases they treat. GHESKIO is recognized by the Haitian government as a "Public Utility", a status conferred on only a few institutions, such as the Red Cross, that are deemed essential to the welfare of the Haitian people.

GHESKIO integrates HIV voluntary counseling and testing with services to diagnose and treat STIs, TB, and other communicable infections, and a program of comprehensive HIV/AIDS treatment [21]. Central to this model of care is the concept that an individual at risk or

already infected with HIV who comes to the center should be quickly identified and offered access to a complete and integrated package of primary care services. Patients are also provided with HIV and STI prevention counseling, family planning services, nutritional support, and access to micro-credit loans.

In addition to clinical service, training and research are critical to GHESKIO's mission. Since its inception, GHESKIO has trained over 35,000 physicians, nurses, lab technicians, faith-based leaders, and community health professionals. GHESKIO researchers have also conducted many landmark studies on HIV/AIDS, TB, and STIs. For example, they characterized the epidemiology and natural history of HIV/AIDS, identified the causes and treatment for diarrhea in AIDS patients, and demonstrated that prophylactic treatment decreases the incidence of TB and prolongs life expectancy among those living with HIV [22,23,24,25,26,27]. In 2002, GHESKIO became an international clinical trials unit of the AIDS Clinical Trials Group of the National Institutes of Health (NIH). GHESKIO is also a site for the Vaccines Trials Network of the NIH.

PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

In the United States, the rate of mother-to-child vertical transmission of HIV/AIDS is lower than 1% due to effective maternal therapies [28]. By contrast, before treatment for the prevention of mother-to-child transmission (PMTCT) was available in Haiti, up to 27% of infants contracted HIV through vertical transmission [29]. As described above, in 1995, PIH developed a community-based approach to PMTCT with the goal of providing an equivalent level of care to that which was available in industrialized nations. They found that the provision of PMTCT led to dramatic increases in the number of pregnant women accepting voluntary counseling and testing for HIV, and contributed to a lower rate of vertical transmission of the virus [30]. Prenatal care and maternal health services are provided alongside HIV treatment in a broader, comprehensive medical care context.

The Ministry of Health has worked with PIH, GHESKIO, and a network of other organizations to develop national PMTCT guidelines for Haiti. Initially, they recommended the use of zidovudine, starting at 36 weeks gestation for mothers and for the infants' first week of life. Due to concerns about the development of drug resistance, a single-dose of nevirapine administered at the onset of labor was used only for women who presented too late for zidovudine treatment. Since 2003, triple drug ART is recommended for use when feasible. The PMTCT programs also include family planning and treatment of co-existing infections. In addition, pregnant women receive ferrous sulfate, folic acid, and tetanus toxoid. Mothers are educated about their choices and encouraged to use formula feed where this is feasible and safe, and infants are treated with cotrimoxazole prophylaxis, and tested for HIV; those that test HIV-positive are treated with immediate ART. All PMTCT services throughout the country are provided free-of-charge.

GHESKIO has published outcomes with these strategies. They analyzed data from 551 infants born to HIV-infected mothers between 1999 and 2005. Until 2003, HIV-infected infants and their mothers were given antiretroviral monotherapy for prophylaxis. Since 2003, triple drug ART is given when clinical and laboratory criteria are met. Among women who received triple drug ART during pregnancy, the rate of vertical transmission was 1.9%, similar to transmission rates reported in developed countries [31]. Among all women treated in the program, the transmission rate was 9.2% (73% received zidovudine, 3% received nevirapine, and 10% received triple-drug therapy, which became available in 2003) [32].

At PIH, pregnant women with HIV that are not already on ART for their own health are offered triple drug regimens of ART at 28 weeks gestation. They are encouraged not to breastfeed and are provided with formula and with the materials and support that are needed

to ensure a safe environment in which to prepare the formula. In one study of 241 women designed to evaluate the outcomes of this program, among the 86% of women who exclusively formula fed and received presented before delivery, rate of vertical transmission of HIV was 1.8% [33].

While PMTCT programs have dramatically decreased vertical transmission rates for those women who receive it, and rates of prenatal testing have more than doubled in the past four years (See Table 2), extension of these services through a national referral network is still needed, particularly to adequately reach women in rural areas. Nationwide, fewer than 40% of pregnant Haitian women currently receive HIV counseling, with an even lower percentage actually being tested (See Table 3). This low compliance rate is mainly due to the fact that over 80% of births occur in the home, without the services of formal healthcare providers. Awareness regarding PMTCT is also low. Over 80% of Haitians are aware that the virus can be passed from mother-to-child, but fewer than half of men and women across all age, income, and education categories are aware that transmission can be decreased with medication (See Table 4). With education and formal health services, however, the provision of prevention strategies is high – in the GHESKIO and PIH networks, over 90% of pregnant women receive treatment to decrease mother-to-child transmission of HIV.

Due to the low rate of deliveries that take in the hospital and the associated morbidity and mortality associated with poor prenatal services, the WHO has provided funding for the major hospital in each medical department to expand obstetrical services, including prenatal care, the management of third trimester catastrophes, mother-to-child prevention, transportation to medical visits, and food during hospitalization. Preliminary outcomes at one hospital demonstrated a 16% increase in the number of women delivering in the hospital within six months of the intervention [34].

HIV AND TUBERCULOSIS

Haiti has one of the highest rates of TB in the hemisphere, with a TB prevalence of 402 per 100,000 people [101]. As in the rest of the world, HIV/AIDS has exacerbated the TB epidemic. Up to 10% of patients dually infected with HIV and latent TB develop active TB each year, and over 50% will have TB by the time they develop another opportunistic infection. Approximately 23% of TB patients in Haiti are HIV-positive [101].

Until recently, it was felt that multidrug-resistant (MDR)-TB rates were low. However, GHESKIO conducted a cross-sectional study of MDR-TB prevalence at their HIV testing center between January 2000 and December 2002 [35]. Drug susceptibility testing of all Mycobacteria tuberculosis isolates (n = 330 patients) documented MDR-TB in 16 (6%) of the 281 patients with primary TB. Of the 115 patients who were HIV-positive with primary TB, 11 (10%) had MDR-TB. Of those with recurrent TB, 10 (20%) of 49 patients had MDR-TB.

PIH developed one of the world's first programs for the treatment of MDR-TB in Haiti, Peru, and Russia, with treatment outcomes among the best in the world [36]. PIH was instrumental in the formation of the DOTS-Plus strategy for directly observed treatment of second-line medications, and the Green Light Committee of the WHO, a procurement program that has decreased the cost of MDR-TB medications by over 90%, and made them available to the poorest countries free of charge.

Until recently, PIH was the only organization treating MDR-TB in Haiti, serving as the national referral center for all cases. In 2008, GHESKIO began the second organization to treatment MDR-TB, duplicating the PIH treatment model for MDR-TB in collaboration with

the Ministry of Health in a public TB sanatorium in Leogane, a town south of Port-au-Prince.

The GHESKIO laboratory has the capacity to conduct mycobacterial culture and drug susceptibility testing (DST) for first-line medications (isoniazid, rifampin, ethambutol, streptomycin), and rapid molecular testing for isoniazid and rifampin mutations using polymerase chain reaction. When a patient is diagnosed with MDR-TB, they are initially treated with an empiric regimen, while awaiting the results of second-line DST testing, which is conducted at the Massachusetts State Laboratory. Each patient is changed to an individualized regimen when DST results are available.

SCALE-UP OF ANTIRETROVIRAL THERAPY

Early efforts at scaling-up HIV/AIDS treatment in Haiti were significantly limited by financial constraints. Initially, ART was only administered to a limited number of patients at either PIH or GHESKIO. In 2002, Haiti submitted a request with the first round of applications to the newly formed Global Fund to request support for the development of a Haiti-wide program for the comprehensive management of HIV/AIDS and TB, and a year later was the first recipient of HIV/AIDS support from the Global Fund, a 5-year, $US 67 million dollar grant. With this financial assistance, the widespread use of ART in Haiti finally became feasible, and treatment scale-up was implemented throughout the country.

More funding became available from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in 2003, which committed $US 320 million to Haiti through FY 08. PEPFAR has provided funding for the development of laboratory infrastructure and for counseling and testing centers, mother-to-child prevention services, treatment of TB and other opportunistic infections, and ART. In addition to expanding services at existing centers, PEPFAR has provided funding for new partner institutions and public private partnerships whose services seek to complement and expand upon the groundwork already laid by established institutions.

ART Scale-up at Partners In Health

PIH used this increase in funding to immediately expand services throughout the Central Plateau, in collaboration with the Ministry of Health. They began by refurbishing a small public clinic in the market town of Lascahobas. As described by Walton et al., in their baseline assessment, they found a demoralized staff with few tools, and a clinic that saw few patients in the morning, and was closed by noon. HIV testing was not available. Though TB services were supposedly available free of charge, the PIH staff estimated that based on expected incidence in the region, only about 5% of cases were being diagnosed and treated [15].

PIH worked closely with the Haitian Ministry of Health to provide comprehensive services for the diagnosis and treatment of TB, STIs, and HIV/AIDS, and to provide maternal health services, including PMTCT and treatment for obstetric emergencies. They developed an essential drug list of 30 medications and stocked them in the pharmacy, improved the capacity of the laboratory to permit testing for HIV, syphilis, TB, and basic chemistries and hematology studies, and provided a generator as a reliable source of electricity. Staff were hired (e.g., physicians, nurses, pharmacists, and administrators) as needed to provide comprehensive medical, pediatric, and obstetric care. In addition, a network of paid health workers (*accompagnateurs*) was established, just as in Cange.

As these improvements were being made, the team tracked the number of diagnoses of TB, HIV, and STIs, and the number of prenatal, pediatric, and women's health visits. The impact

of the clinic expansion was immediate and profound. By the end of the first year, nearly 2000 patients were being tested for HIV every month, hundreds had tested positive, and 120 were being treated with ART. In addition, nearly 200 patients were diagnosed and treated for TB, and the number of primary care visits skyrocketed to over 300 patients per day [15].

In addition to the provision of comprehensive primary care and sub-specialty services, social support remains a cornerstone of the PIH model. Within the means available, patients are provided with economic and psychosocial counseling and nutritional support. For all newly diagnosed patients with HIV or TB, a social worker conducts a detailed assessment of a household's financial situation, evaluates the patient's social network, and identifies potential barriers to adherence or treatment response. Monthly patient meetings are conducted to exchange information and strengthen program responsiveness [37]. Out-of-pocket costs are minimized by waiving all user fees, providing all hospitalizations, surgeries, medications and tests free-of-charge, and providing transportation subsidies for patients with chronic illnesses.

Having demonstrated that resources targeted for HIV/AIDS treatment scale-up could be leveraged to strengthen primary health care services, PIH and the Ministry of Health have continued to use this model to improve healthcare throughout the region. By 2009, in addition to Cange, they were operating a network of nine public health clinics and hospitals together, providing services to Haiti's entire Central Department, with an estimated population of 620,000, and to the lower Artibonite Department, with an estimated population of 550,000.

In 2008, PIH provided 1.9 million patient encounters (clinic, laboratory, pharmacy visits or hospital admissions), and followed 13,647 HIV-positive persons; 3,562 of these patients are on ART. An additional 2.5 million patient visits were provided at home by community health workers or other medical personnel. One study reviewed outcomes of this program and demonstrated that 2179 patients were started on ART between October 2002 and December 2005. Median follow up time for the cohort was 25 months. Among patients who survived the first two months of therapy, 12-month survival rate was 94%. Overall loss to follow up at 12 months was only 5.4% [38].

ART Scale-up at GHESKIO

In March 2003, as soon as external funding became available, GHESKIO began offering ART to adults and adolescents with an AIDS-defining illness or a CD4 cell count < 200 mm^3, according to the WHO guidelines [39]. For children, HIV is diagnosed and staged based on serologic testing, clinical findings, and the percentage of T cells that are CD4-positive.

Patients are seen by a physician in the clinic every two weeks for the first three months of therapy, and by a nurse on monthly basis thereafter. Medications are directly dispensed to the patients at each visit. As recommended by the WHO and the Haitian government, the first-line ART regimen for adults and adolescents consists of zidovudine, lamivudine, and efavirenz. Stavudine is substituted for patients with toxicity to zidovudine (such as anemia). Nevirapine is substituted for those with toxicity to efavirenz (such as central nervous system symptoms). For children under three years of age, nevirapine is used in place of efavirenz.

The GHESKIO staff encourages treatment adherence through the use of home visits by paid community health workers, peer counseling by others living with HIV, pill counts conducted by the pharmacist, and the provision of free telephone cards for patients to call clinic staff. Nutritional support is provided to those in need, and transportation subsidies are provided.

GHESKIO evaluated treatment outcomes for the 910 adult and adolescent ART-naïve patients consecutively treated with ART from March 2003 to May 2004 [27]. The outcomes were similar to those of patient treated in the United States, with a one-year survival rate of 87%. This was a dramatic improvement from one-year survival of about 30% in the pre-ART era.

Immunologic and virologic results were also remarkable. The median CD4 cell count at enrollment was 131 cells/mm^3, and it increased by a median of 163 cells/mm^3 (interquartile range, 77 to 251 cells/mm^3) at 12 months. Viral load testing, which was too expensive for routine use, was conducted in a subgroup of 100 patients who were followed for 48 to 56 weeks. The Amplicor HIV-1 Monitor PCR Test (Roche), with a lower limit of detection of 400 copies of HIV RNA per milliliter, was used. Seventy-six patients had fewer than 400 copies of human immunodeficiency virus RNA per milliliter.

During the 14-month study period, 127 deaths occurred. Death was due to persistent wasting syndrome in 43% (n=55), TB in 16% (n=20), bacterial pneumonia in 5% (n=6), and toxoplasmosis, cancer, cryptosporidiosis, sepsis syndrome, congestive heart failure, and trauma in fewer than 5% each; in 18% (n=23) it was due to unknown cause. The majority of deaths (n=100; 79%) occurred within six months after ART initiation. Mortality was associated with the presence an AIDS-defining illness, a CD4 cell count < 50 cells/mm^3, and a body weight in the lowest quartile for sex at the time of ART initiation.

Medication side effects were common, resulting in a change of first-line medication in 102 of 910 adult and adolescent patients (11%) during the study period. Anemia and central nervous system symptoms were the most common side effects. Nevirapine was suspected in the two cases of Stevens–Johnson syndrome, and one case was fatal. Gynecomastia developed in 15% males who were taking efavirenz.

GHESKIO has also evaluated long-term outcomes. Though the mortality rate is highest in the first 6 months of treatment, deaths have continued to occur throughout follow-up (See Table 5). Among patients who started ART in 2008, 88% are alive and in-care, 5% have been lost to follow-up, 5% have died, and 3% have been transferred. Mortality is higher among those who have been on treatment longer. Among those who started ART in 2003, 62% are alive and in-care, 8% have been lost to follow-up, 22% have died, and 8% have been transferred.

In 2009, GHESKIO launched the Institute for Infectious Diseases and Reproductive Health (IMIS) in the Tabarre region of Port-au-Prince, which doubles their capacity for training, providing care, and conducting research. The laboratories contained at IMIS will be the most advanced in the Caribbean (BSL-2 and BSL-3) and will permit the detection of HIV virologic failure and associated resistance mutations. As described above, the laboratory already has the capacity to conduct molecular diagnostic techniques to test for multi-drug resistant TB, which has improved the rate of detection and decreased delays in diagnosis of MDR-TB.

GHESKIO and the Ministry of Health are also supervising ART for a network of 16 public and private sites throughout Haiti. PEFPAR is implementing a system of electronic medical records and pharmacy databases at each clinic. All but two centers have a hospital on-site, and each ART clinic is well-staffed, with 2 to 5 physicians and 5 to 18 nurses. Most sites also have a pharmacist, a social worker, and paid community health workers.

With the use of the electronic medical record and the pharmacy databases, GHESKIO is beginning to prospectively monitor outcomes at the scale-up sites. Best practices meetings are planned, with highly performing sites explaining the reasons for their success. Sites that

are under-performing will be visited by a mobile supervisory team, who will help them to improve their outcomes. With the GHESKIO monitoring system, monthly outcomes will be reported, including the number and percentage of patients who died or were lost to follow-up (no visit in the past 3 months), and median adherence. These outcomes will be stratified based on year of ART initiation, as mortality is time-related.

Pediatric ART Outcomes

Ninety-four children (age < 13 years) were also included in the GHESKIO outcomes study described above, and the findings were even better than those of the adults and adolescents [27]. Only two of the 94 children died during the 14-month study period, and both died within one month after enrollment, one from a sepsis-like syndrome and the other from a respiratory tract infection of unknown cause. The median CD4 cell percentage rose from 13% at baseline to26% (interquartile range, 22 to 36%) at 12 months. Side effects were also less common than in adults; only 5 children required a change in medication due to side effects throughout the study period.

GHESKIO conducted a second study of 236 children (age < 13 years) who were consecutively initiated on ART from 2003 to 2005. Twelve months into ART, median CD4 cell percentages had increased by 15%, 11%, and 5% in children with baseline percentages of </=5%, 6%–24%, and >/=25%, respectively. The median weight-for-age Z score at 12 months increased by 1.0, 0.6, and 0.2 in children with baseline scores of less than −2, 2 to −1.1, and −1 or more, respectively. After 36 months of follow-up, 191 children (81%) were still alive and in care [35].

However, treatment of adolescents presents greater challenges. GHESKIO recently conducted a study of survival, viral load and HIV drug resistance patterns after 12 months of ART in 146 patients from 13 to 25 years of age. Survival was similar to that of adult patients (87% at 12 months, 83% at 24 months, and 80% at 36 months). However, the rate of virologic failure was much higher, with 51% of patients having a viral load ≥ 50 copies/ml at 12 months after ART initiation; detectable viremia was associated with poor adherence. Virologic failure was also associated with significant resistance mutations. Of 29 patients with a viral load of at least 1000 copies/ml, 23 (79%) had detectable mutations to non-nucleoside reverse transcriptase inhibitors (NNRTIs), 21 (72%) had detectable mutations to both NNRTIs and lamivudine, and 10 (35%) had detectable mutations to NNRTIs, lamivudine, and other nucleoside reverse transcriptase inhibitors. One hundred and six participants (73%) reported sexual intercourse without condoms, and 35 of the 96 females (36%) were pregnant during follow-up [41].

Based on the results of this study, GHESKIO opened an adolescent HIV clinic with the support of the United Nations Children's Fund to provide primary care services, nutritional support, and psychological and social support services targeted to adolescents living with HIV. Teenage peer counselors and social workers who specialize in adolescent health provide group and individual counseling sessions in the clinic. Mobile telephone communication is also used to monitor therapy; patients are given phone cards so that they can call the clinic free of charge with questions, and nurses call patients to remind them to take medications and to attend appointments [41]. GHESKIO is also initiating a new care-giving effort for 6,000 orphans and vulnerable children who seek services there.

Early Mortality on ART

Though ART has dramatically prolonged survival worldwide, the one-year mortality rate remains substantially higher in resource-poor settings, compared with higher-income countries. The majority of these first-year deaths occur within three to six months after ART

initiation in patients with advanced AIDS [42,43,44,45]. These findings have also been reported among GHESKIO and PIH patients.

Predictors of mortality at GHESKIO include: body weight in the bottom quartile for gender (HR 3.3; 95% CI: 2.9 to 3.7; p-value < 0.0001); AIDS-defining illness (HR 2.1; 95% CI: 1.7 to 2.5; p-value < 0.0001); and CD4 cell count < 50 cells/mm^3 (HR 1.6; 95% CI: 1.1 to 2.1; p-value 0.04); three-quarters of deaths occur in patients with CD4 cell counts < 100 cells/mm^3 [27]. At PIH, preliminary data suggest that 36% of mortality occurs in the first two months on therapy, and 66.5% in the first 12 months [38].

This high early mortality rate has not decreased in subsequent treatment cohorts at GHESKIO, though all services are provided free of charge, and the clinicians have become highly experienced in the provision of ART. Six-month mortality has been approximately 12% among patients initiating ART in 2003, 2004, 2005, 2006, and 2007 at GHESKIO [46].

The etiologies of early mortality in resource-poor settings have not been systematically defined, but tuberculosis (TB) is likely a major contributor. A recent GHESKIO study found that AIDS patients who are diagnosed with TB in the 3 months after commencing ART had a mortality rate that was 3 times higher than that of other patients with AIDS and TB [47]. Many of these patients likely had sub-clinical TB at the time of ART initiation, and active disease was only diagnosed when TB was unmasked with reconstitution of the immune system. The high mortality rate is believed to be associated with the delay in diagnosis and treatment. Based on these findings, GHESKIO proposed a multi-country randomized control trial of empiric TB treatment for patients with advanced HIV/AIDS. This protocol, “Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens” has now been approved by the AIDS Clinical Trials Group Steering Committee of the NIH.

Economic Analyses of the Cost of HIV/AIDS Treatment

Multiple studies have been conducted to evaluate the cost and clinical impact of various HIV/AIDS treatment strategies in Haiti. A study found that the mean total cost of treatment per patient at GHESKIO sites was $US 982 including $US 846 in direct costs, $US 114 for overhead, and $US 22 for societal costs. The direct cost per patient included generic ART medications $US 355, lab tests $US 130, nutrition $US 117, hospitalizations $US 62, pre-ART evaluation $US 58, labor $US 51, non-ART medications $US 39, outside referrals $US 31, and telephone cards for patient retention $US 3.

ART Scale Up Nationwide

Eight years ago, PIH and GHESKIO were the only sites in Haiti with the capacity to test for HIV. By the end of 2008, there were 131 voluntary counseling and testing (VCT) centers in Haiti, and 98 of them had the capacity to provide mother-to-child prophylaxis. As of July 31, 2009, 1, 591, 580 patients had been tested for HIV in these VCT centers (PEPFAR Report 2009).

GHESKIO continues to provide ongoing training for health care workers in counseling, management of TB and HIV co-infection, treatment of opportunistic infections, provision of mother-to-child prevention, use of first and second-line ART, and other topics. In 2006, GHESKIO trained 630 laboratory technicians, 258 social workers, 2186 nurses, 785 physicians, 39 pharmacists, and 6478 community leaders [48]. In its two regional health centers, PIH trains close to 500 people each year. Approximately 300 are clinic-based staff, including physicians, nurses, nurse-midwives, nurse aides, pharmacists, social workers, and about 200 are community health workers.

Access to ART is now being expanded across the country. Forty-seven clinics are providing ART in Haiti, with 21,444 patients on ART. Two-thirds of patients on ART are still cared for in the PIH or GHESKIO networks in collaboration with Ministry of Health, but many other organizations are providing comprehensive HIV/AIDS treatment as well.

CONCLUSIONS

Haiti has mounted a successful response to the HIV/AIDS epidemic in spite of widespread poverty and limited infrastructure. The prevalence of HIV in Haiti is declining, the capacity for prevention and testing activities has been broadened, and ART is now available in every medical department – a remarkable achievement in the space of seven years. This was greatly facilitated by international funding. It would not have been possible without the presence of a strong foundation of dependable, high quality health programs that were Haitian, that were grounded by their experiences of providing HIV care before international funds were available, and that were willing to be nimble and to empower the Haitian state in its mandate to provide healthcare to all Haitians. Haiti's government has been critical to the success, demonstrating high-level political commitment and an openness to work in public-private partnerships with NGOs. Haiti's response to the HIV/AIDS epidemic is one of the most highly celebrated in the world, demonstrating that treatment outcomes rivaling those of developed countries can be attained even under adverse conditions in deeply impoverished settings.

FUTURE PERSPECTIVE

Though the prevention and treatment of HIV/AIDS has improved dramatically over the past 7 years, many challenges remain. There is an urgent need to invest further in the health system as a whole, to improve maternal health services, including prenatal care (with HIV and syphilis testing), PMTCT, and treatment of obstetrical complications, and to improve access to primary healthcare services. It will also be critical to continue to reinforce prevention activities, including safer sexual behaviors, management of STIs, and improved education and gender equality for women. Social support must also be emphasized as treatment is rolled out, including strategies to improve nutritional and economic status, and to assist patients in adhering to therapy. HIV/AIDS and TB services must also be integrated as they are expanded, to preserve human resources, decrease overhead and transportation costs, and minimize financial and logistical challenges for patients. Throughout the scale-up process, it will also be essential to monitor quality of care, to ensure that all patients receive the same high quality of service that has been documented at established programs.

EXECUTIVE SUMMARY

History, epidemiology, and prevalence of HIV/AIDS in Haiti

- The HIV epidemic in Haiti became rapidly generalized; there are now more women than men who are infected with the virus (ratio of 2.3:2.0).
- Prevalence peaked in the late 1990s, and has since been dropping. The most recent household survey found a prevalence of 2.2% among adults.

HIV/AIDS prevention efforts

- The prevalence of syphilis in Haiti has declined from a peak of 7.6% in 1993, to 3.9% by 2006.

- Though significant progress has been made, further efforts will be necessary to improve safe sexual behaviors

Community-based care in rural Haiti - the Partners In Health Model

- Paid community health workers, called *accompagnateurs*, provide the backbone of all care delivered in the community by PIH.
- PIH developed one of the first ART programs in the world in a rural, resource-poor setting, demonstrating that ART could be successfully used in this setting.

HIV/AIDS treatment in Port-au-Prince - the GHESKIO model of integrated care

- GHESKIO started the world's first clinic devoted to treating patients with HIV/AIDS, and provides an integrated program for the diagnosis and treatment of HIV/AIDS, TB, and STIs. GHESKIO has also trained over 35,000 health workers in the management of these diseases.
- GHESKIO has conducted many landmark studies on HIV/AIDS, TB, and STIs that have improved the clinical care for these diseases across the globe.

Prevention of Mother-to-Child Transmission

- Haiti's national guidelines involve the use of triple drug ART for mother-to-child prevention when feasible; the transmission rate is < 2% with this therapy.
- There is an urgent need to expand access to prenatal care throughout Haiti.

HIV and Tuberculosis

- Haiti has one of the highest rates of TB in the hemisphere, and MDR-TB is a growing problem as well.
- PIH was one of the first organizations to treat MDR-TB in a resource-poor setting; outcomes are among the best in the world. GHESKIO has started a second MDR-TB treatment program in Haiti with the capacity to conduct first-line drug-susceptibility testing and rapid molecular testing for mutations.

Scale-up of Antiretroviral Therapy

- With the availability of funding from GFATM and PEPFAR, PIH has expanded services to provide comprehensive HIV/AIDS treatment to over 15,000 people. This funding has been used to strengthen the health system as a whole in the areas served, providing comprehensive health services.
- GHESKIO is supervising HIV/AIDS treatment at 16 sites throughout the country, providing care to about 50% of the patients on antiretroviral therapy nationwide.
- Survival and virologic outcomes for ART programs in Haiti are similar to those of industrialized countries.
- Early mortality after ART initiation remains high in Haiti, as in other resource-poor settings. TB is likely a major cause of morality.
- Comprehensive HIV/AIDS treatment is now being scaled-up across Haiti.

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Table 1

Prevalence of HIV by Gender and Characteristics*

	Females	Males	Total – Male and Female
Age Group (Years)			
15 to 19	0.9	0.1	0.5
20 to 24	2.3	1.1	1.7
25 to 29	3.5	3.0	3.3
30 to 34	4.1	2.4	3.3
35 to 38	2.2	3.7	2.9
40 to 44	3.1	4.4	3.7
45 to 49	1.6	3.3	2.4
Total ages 15 to 49	2.3	2.0	2.2
Education Level			
None	2.3	3.3	2.6
Primary	2.6	2.0	2.3
Secondary or More	2.1	1.6	1.8
Area of Residence			
Port-au-Prince	2.5	1.3	2.0
Other City	2.9	2.4	2.7
Town	2.7	1.8	2.3
Rural	2.0	2.1	2.0
Economic Status – Quintiles			
Poorest Quintile	2.4	1.7	2.1
Second Quintile	0.9	2.8	1.8
Third Quintile	2.4	2.4	2.4
Fourth Quintile	3.7	2.3	3.1
Wealthiest Quintile	1.9	0.9	1.5
Lifetime Sexual Partners			
1	1.3	0.6	1.2
2	2.8	0.1	2.2
3–4	5.4	1.1	3.4
5–9	8.0	2.1	2.9
10+	*	3.8	3.9

* EMMUS-IV Haiti 2005–2006

Table 2

Number of Pregnant Women Receiving Prenatal Care in Haiti*

Category	2005	2006	2007	2008
Number of Pregnant Women Tested for HIV per Year	54,704	80,555	106,087	138,775
Number of Pregnant Women Testing HIV Positive	1839	2621	3437	5021
Percentage of Pregnant Women Testing Positive for HIV	3.36	3.25	3.24	3.62
Pregnant Women Enrolled in HIV/AIDS Care	1770	2498	2685	3642
Number of Pregnant Women Tested for Syphilis	45,280	69,819	90,542	105,429
Number of Pregnant Women Testing Positive for Syphilis	2468	3337	3710	5246
Percentage of Pregnant Women Testing Positive for Syphilis	5.45	4.78	4.10	4.98

* PEPFAR Report 2008

Table 3

Percentage of Pregnant Women Receiving Prenatal Care in Haiti*

Age Group	Received HIV counseling	Counseled, tested, and received test results	Number of women in the study who were pregnant in the prior two years
15 to 19	34.6	19.8	245
20 to 24	33.0	18.1	582
25 to 29	38.6	23.6	586
30 to 39	31.8	18.3	734
40 to 49	29.6	15.6	171

* EMMUS-IV 2005–2006

Table 4

Knowledge of Mother-to-Child Transmission by Characteristic*:

	FEMALES		MALES	
Characteristic	**HIV can be vertically transmitted**	**Risk of vertical transmission can be reduced with medication**	**HIV can be vertically transmitted**	**Risk of vertical transmission can be reduced with medication**
Ages				
15–19	80	38	88	28
20–24	83	39	87	39
25–29	83	40	90	33
30–39	83	33	89	27
40–49	82	28	91	27
Marital Status				
Single	80	39	88	33
In long-term union	83	35	90	28
Divorced/Separated/Widowed	82	31	87	29
Pregnancy Status				
Currently Pregnant	85	35	n/a	n/a
Not pregnant/unsure	82	36	n/a	n/a
Urban vs. Rural				
Port-au-Prince	82	49	86	40
Other City	83	36	88	36
Town	83	43	87	38
Rural	82	30	90	25
Education Level				
None	77	25	92	17
Primary	84	32	89	25
Secondary or More	82	46	88	40
Economic Status – Quintile				
Poorest Quintile	77	27	91	18
Second Quintile	81	27	92	23
Third Quintile	83	32	91	30
Fourth Quintile	85	36	85	31
Wealthiest Quintile	82	49	87	45

* EMMUS-IV 2005–2006

Table 5

GHESKIO Outcomes, Stratified by ART Initiation Year*

Year of ART Initiation	No. Enrolled	No. (%)Active	No. (%)Lost to Follow-Up	No. (%)Died	No. (%)Transferred	Median Follow- up (Months)
2003	743	462 (62)	59 (8)	165 (22)	57 (8)	66
2004	735	473 (64)	58 (8)	129 (18)	74 (10)	53
2005	481	336 (70)	57 (12)	56 (11)	32 (7)	40
2006	676	486 (72)	101 (15)	71 (10)	18 (3)	31
2007	1028	750 (73)	119 (12)	93 (9)	66 (6)	19
2008	1156	1014 (88)	52 (5)	52 (5)	38 (3)	7
Total	**4819**	**3521 (73)**	**447 (9)**	**566 (12)**	**285 (6)**	**20**

*ART-naïve at GHESKIO presentation