

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

**ACCESS TO ANTIRETROVIRAL
TREATMENT AND CARE :
THE EXPERIENCE OF THE HIV
EQUITY INITIATIVE, CANGE, HAITI**

CASE STUDY



World Health Organization



Partners In Health

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ACCESS TO ANTIRETROVIRAL TREATMENT AND CARE : THE EXPERIENCE OF THE HIV EQUITY INITIATIVE, CANGE, HAITI

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About This Series

With 42 million people now living with HIV/AIDS, expanding access to worldwide antiretroviral treatment for those who urgently need it is one of the most pressing challenges in international health. Providing treatment is essential to alleviate suffering and to mitigate the devastating impact of the epidemic. It also presents unprecedented opportunities for a more effective response by involving people living with HIV/AIDS, their families and communities in care and will strengthen HIV prevention by increasing awareness, creating a demand for testing and counselling and reducing stigma and discrimination.

The challenges are great. Sustainable financing is essential. Drug procurement and regulatory mechanisms must be established. Health care workers must be trained, infrastructure improved, communities educated, and diverse stakeholders mobilized to play their part. This series, *Perspectives and Practice in Antiretroviral Treatment*, provides examples of how such challenges are being overcome in the growing number of developing countries in which antiretroviral treatment programmes are underway. The case studies and analyses in this series show how governments, civil society organizations, private corporations, and others are successfully providing antiretroviral treatment and care to people with HIV/AIDS, even in the most resource-constrained settings. In documenting these pioneering programmes, WHO hopes that their experiences will both inform and inspire everyone who is working to make access to treatment a reality.

In most industrialized countries, the introduction of antiretroviral (ARV) therapy has led to a sharp decrease in AIDS-related mortality. However, most people infected with HIV lack access to such novel treatments. Haiti is the poorest country in the Western Hemisphere and the one most affected by HIV. It is but one example of the link between poverty, disease, and misery. For poor Haitians, contracting HIV has been a sentence of death since the advent of the epidemic in Haiti. The experience of the HIV Equity Initiative – an integrated HIV prevention and care project in rural Haiti – suggests that, despite widespread concerns, life-saving ARV therapy can be brought to the poorest and most vulnerable communities.

Background

In 1998, Partners in Health, a not-for-profit charity affiliated with Harvard Medical School, and its Haitian sister organization Zanmi Lasante (Creole for Partners in Health) launched the HIV Equity Initiative to deliver ARV therapy to some of the poorest people living with HIV/AIDS in the Western Hemisphere.

The HIV Equity Initiative is based on many years of experience in working in the poorest communities in rural Haiti. Over 15 years ago, Partners in Health and Zanmi Lasante began modest AIDS prevention efforts in the lower Central Plateau, where most people are peasant farmers and health indicators are well below the national estimates. The clinical facility, Clinique Bon Sauveur, is situated in a squatters' settlement of 3000 people displaced by a hydroelectric dam in a province that has no electricity and only a few roads that allow passage.

Political instability and a two-year economic crisis have further contributed to increasing poverty and deteriorating health and social care infrastructure for several years. Not surprisingly, Haiti faces the worst AIDS epidemic outside Africa: Haiti has the highest adult HIV prevalence rate in the Caribbean, with an estimated 6% of adults being infected annually, and more than 300 000 Haitians are living with HIV/AIDS. In 2001, the epidemic claimed about 30 000 lives, and HIV is now considered the leading cause of death among young adults. About 200 000 children have already lost one or both parents to the disease. Among women attending antenatal care, HIV seroprevalence was 5% at the national level in 1999 and twice as high in urban slums.

The Clinique Bon Sauveur documented the first case of HIV-related disease in Haiti's Central Plateau in 1986. Voluntary HIV counselling and testing has been offered free of charge since 1988, and provision of HIV education, condom promotion, and culturally appropriate prevention programmes were linked closely to access to HIV testing.

The introduction of zidovudine in 1995 to the prenatal clinic for the prevention of mother-to-child transmission decreased the rate of vertical HIV transmission and considerably

enhanced the uptake of voluntary counselling and testing among pregnant women. The acceptance of prenatal HIV testing rose from 30% to 90% once ARV drugs were available to reduce mother-to-child transmission and demonstrated how providing ARV drugs enhanced the utilization of prevention services. When voluntary HIV counselling and testing became part of routine prenatal care for pregnant women in Cange, over 97% of those offered the complete package for preventing the mother-to-child transmission of HIV accepted. This experience in Cange also demonstrated the feasibility of procuring, storing, and using ARV agents in a resource-limited setting.

However, the effect of these comprehensive prevention programmes was limited by political unrest, followed by migration for work and increasing poverty in central Haiti, and the magnitude of the suffering caused by HIV grew in Haiti's central plateau. An increasing number of young people returned to the area with HIV infection acquired far from their home villages. In the early 1990s, over 25% of the admissions to the Clinique Bon Sauveur were related to HIV. By 1995, about 40% of adults admitted were infected with HIV. As the efficacy of combination ARV therapy was not yet known, the focus of HIV care was the treatment of opportunistic infections. In Haiti, as in other parts of the developing world, half the people living with HIV/AIDS had tuberculosis co-infection. Death in such people can be postponed substantially by treating tuberculosis when HIV is not advanced. Thus, treatment of tuberculosis with the WHO strategy of directly observed therapy – short course (DOTS) became a critical component of HIV care, and the detection and treatment of every case of active tuberculosis was the first important programmatic link in developing the HIV care programme in Haiti.

However, as HIV infection surpassed tuberculosis and malaria as the leading cause of death among young adults in Haiti, Partners in Health had no choice but to move from preventing HIV infection to treating it. Starting in 1999, people living with HIV/AIDS who no longer responded to aggressive clinical treatment of opportunistic infections were offered highly active ARV therapy (HAART).

Objective

With the launch of the HIV Equity Initiative, Partners in Health set out to fortify the long-existing HIV prevention efforts, the programmatic success of the DOTS programme with expanding access to HAART, for the sickest people living with HIV/AIDS who were most likely to die in the short term. The HIV Equity Initiative sought:

- ▶ to use the methods of its successful community-based tuberculosis treatment and control programme, based on DOTS, using a cadre of community health workers (*accompagnateurs*) as the essential link between people living with HIV/AIDS and the clinic;
- ▶ to train this cadre of community health workers in the administration and daily follow-up of ARV therapy; and
- ▶ to prove that, in poor countries, HAART can be delivered by harnessing the capacity of the rich human infrastructure that exists and that the barriers to treatment in such settings are not so much a lack of infrastructure or the poor education of affected populations but the lack of will.

Clients served

Because of Haiti's economic and health crisis, the number of ambulatory visits at Zanmi Lasante's Clinique Bon Sauveur has risen from 30 000 to 200 000 in just 2 years. Patients selected for enrollment came from about 60 villages. Some of these villages are more than 5 hours away by foot, but each is served by *accompagnateurs*. The Clinique Bon Sauveur includes paediatric, infectious disease, general medicine and women's health clinics, adult and paediatric inpatient wards, two operating rooms, and a village school. In 2002, the Clinique Bon Sauveur followed more than 4000 HIV-positive people, and over 400 people living with HIV/AIDS have started directly observed therapy with HAART (DOT-HAART) based on laboratory and clinical criteria (Fig. 1).

Selection of people for therapy

From 1999 to 2002, people living with HIV/AIDS were selected for therapy based exclusively on clinical status. A set of guidelines that allows identification of patients for inclusion in the DOT-HAART project was developed by the team at the Clinique Bon Sauveur (Box 1). As a reflection of the local epidemic situation, these guidelines do not suggest ARV therapy for people diagnosed with active tuberculosis, which is the case for more than half of all people living with HIV/AIDS. For most people with active tuberculosis, effective anti-tuberculosis therapy alone results in symptom-free

periods that can last for years. Two physicians, one with training in infectious diseases, assess people living with HIV/AIDS. Community health workers (*accompagnateurs*) deliver most of the care. They close follow people living with HIV/AIDS, referring them back to the clinic for complications; those receiving ARV therapy receive daily visits from their *accompagnateur*.

Box 1. Criteria for inclusion of patients in DOT-HAART

- ▶ Absence of active tuberculosis
- ▶ Recurrent opportunistic infections that are difficult to manage with antibacterial or antifungal agents
- ▶ Chronic enteropathy with wasting
- ▶ Otherwise unexplained significant weight loss
- ▶ Severe nervous system complications attributable to HIV disease
- ▶ Severe leukopenia, anaemia or thrombocytopenia

Source: Farmer et al.¹

Initiating ARV therapy according to these criteria does not require any laboratory testing. In accordance with the 2002 WHO recommendations for scaling up access to ARV therapy in resource-limited settings, people who are HIV positive and have clinical AIDS are eligible for treatment, regardless of CD4 count.

In late 2002, the Clinique Bon Sauveur, with help from the Division of AIDS of Harvard Medical School, received a flow cytometer and can now measure CD4 counts on site. Although the sickest patients are still triaged directly into ARV therapy, some with fewer symptoms may now be screened to determine whether they meet immune criteria for HAART even before they develop advanced symptoms of AIDS. Based on initial review of the first 300 people living with HIV/AIDS followed at the Clinique Bon Sauveur at the time HAART was introduced, for a subset of those who appear well, death will occur within 2 years of diagnosis and is likely to be caused by subclinical immune suppression leading to aggressive opportunistic infections.

Laboratory monitoring

The programme uses a modest laboratory infrastructure to initiate and follow therapy. HIV serology, a haematocrit test, and a white blood cell count are prerequisites for starting treatment with ARV drugs. Liver function tests are performed in case of gastrointestinal side-effects, and complete blood count follows if symptoms of anaemia or thrombocytopenia develop. The patient's weight, which has shown to predict survival and disease progression, is one of the most important indicators in a simplified monitoring approach and is followed during the course of treatment. CD4 counts are not used to follow the response to therapy.

ARV regimens used

Once patients admitted to the programme were treated with a three-drug standard regimen. At the end of 2002, the Haitian government adopted new ARV therapy guidelines based on the WHO guidelines published that same year. People being treated at HIV Equity Initiative clinics therefore receive the drug combinations shown in Table 1.

The Government of Haiti further decided to procure drugs that have been approved by the WHO prequalification project. Clinical monitoring of treatment is foreseen at 1 week, 1 month, 3 months, and every 3 months thereafter. It should be noted, however, that patients treated through the HIV Equity Initiative were monitored daily by *accompagnateurs* and seen in clinic only once a month. For most people receiving DOT-

Adherence support strategies

DOT-HAART is based on experience from the tuberculosis programme at the clinic. DOT administered by community health workers had achieved outstanding tuberculosis cure rates. To ensure comparable adherence to ARV therapy, each person eligible for the programme is followed by an *accompagnateur*. During the daily visits, the *accompagnateur* observes the person in therapy taking one dose of HAART and may leave the second treatment dose at that time. In many cases – although this is not part of the protocol – the community health care worker visits people in therapy more than once a day to watch them take the second dose as well or to provide emotional and other types of social support. In addition, health care workers are trained to assess for common side-effects of the medication and signs of HIV-related illness.

New patients, in addition to the clinical and laboratory assessment, also undergo detailed social assessment to understand and address other barriers to good health and adherence to HAART. The interview with a social worker is followed by inspection of living quarters and the analysis of the financial situation and social support network of patient and their families. Based on the results of all three assessments, a management plan is elaborated. All medical consultations, drugs, social service, and social support are provided free of charge, as is the case with tuberculosis care.

The interaction between the community and the patient has been the cornerstone of the HIV Equity Initiative: meetings of commu-

nity outreach workers with people new to therapy, nutritional and family support (school, housing and financial), and monthly meetings of people living with HIV/AIDS that facilitate information exchange among them, have been popular and underpin the success of the programme.

Table 1. ARV drug combinations dispensed at HIV Equity Initiative clinics in Haiti

Regimen	Drug combination
Primary first-line regimen	Stavudine/lamivudine/nevirapine
Primary first line regimen for pregnant women	Zidovudine/lamivudine/nevirapine
Primary first-line regimen for people with tuberculosis/HIV	Stavudine/lamivudine/efavirenz
Second-line regimen	Zidovudine/didanosine protease inhibitor or stavudine/didanosine protease inhibitor (indinavir, nelfinavir or lopinavir boosted by ritonavir as options for protease inhibitors)

HAART, a physician or a nurse could easily manage clinic visits. Few patients had side-effects, and only one allergic reaction occurred among the first 350 patients. Thus, considerable clinic time could be dedicated to reinforcing prevention messages.

Benefits resulting from the programme

The active community support offered to patients was key to the dramatic clinical responses visible to everyone, including neighbours, *accompagnateurs*, physicians, and nurses. Patients for whom therapy resulted in full viral suppression became known as HIV-treatment successes in these communities and proved to be valuable human resources for HIV prevention activities. In addition, Partners in Health believes that «... the stigma associated with AIDS has diminished as a result of the dramatic responses to therapy. Decreased stigma is reflected in an increased willingness of patients to discuss their diagnosis openly, an increased demand for HIV testing, and a reduced number of patients' complaints regarding abusive behaviour of family members or neighbours ...»². For example, within the first² years of the programme's existence, utilization of the clinic's free HIV counselling and testing services increased by more than 300%. Moreover – in contrast to reported emotional problems among health care workers in areas without available AIDS treatment – staff morale in the HIV Equity Initiative was significantly boosted by the provision of the life-saving treatment.

According to Farmer, «Small victories that are thought to be big miracles by patients are more rewarding than one could ever deserve.»³

Results

An interim assessment of the programme prior to 2001² suggested that DOT-HAART was very effective (Box 2):

- ▶ The clinical response to therapy was beneficial in 59 of the first 60 people receiving therapy (not including the more than 40 people who started therapy in 2001).
- ▶ In a subset of patients in whom viral load testing was performed, 86% had no detectable virus in peripheral blood.
- ▶ A weight increase of more than 2 kg within the first three months of therapy was observed in 58 patients.
- ▶ An estimated 48 patients resumed working and caring for their children.

Box 2. Successful treatment with ARV drugs shows results within weeks

Adeline contracted HIV far from home, in Port-au-Prince, when she was only 18 years old. She attended the clinic just a few years later when she had an episode of pneumonia. The additional diagnosis of herpes zoster and HIV infection resulted in treatment of opportunistic infections for almost 10 years. By 1999, her chronic diarrhoea no longer responded to the treatment, and her weight had dropped to 36 kg (Fig. 2). Within the first five weeks of treatment with zidovudine, lamivudine, and indinavir, she gained 12 kg (Fig. 3).



Fig. 2. Adeline before ARV therapy



Fig. 3. Adeline after ARV therapy was initiated

Source: Farmer et al.¹

A more recent review in 2003⁴ of key clinical and laboratory parameters compared outcomes between a group of 100 people living with HIV/AIDS who received DOT-HAART based on the clinical criteria of advanced disease (generally bed-bound with significant weight loss) and two other groups, each with 100 HIV-positive patients in whom ARV drugs were deferred because they 1) were deemed less sick (generally ambulatory without significant weight loss) or 2) because they lived too far from the clinic to arrange an *accompagnateur* (Table 1). Even though the patients in the first group were far sicker than those in the two groups in whom HAART was deferred, the first group improved significantly in terms of fewer hospitalizations, opportunistic infections, tuberculosis, and mortality. In addition to the outcomes listed below, the assessment confirmed the reduction

Table 2. Comparison of outcomes among three different intervention groups

OUTCOME	GROUP A	GROUP B/C
n	100	200 (100 each in group B and C)
Mortality at end of study period (number of deaths)	0	43 (14 and 29 in groups B and C respectively)
Tuberculosis incidence	2/100	21 out of 100, groups B data only
Number of opportunistic infections from start of interventions	0.24	3.3
Average weight change	10.3 kg increase	6.0 kg decrease
Number of days in hospital from start of intervention to end of study period or death	0	23.4
Activities of daily living score for people surviving 1 year after the intervention	At beginning of study period: 2 At end of study period: 3.8	At beginning of study period: 2.7 At end of study period: 2.3

Group A: the first people receiving DOT-HAART from a community health worker for more than 1 month (n = 100).

Group B: people diagnosed with HIV infection at the same time and from the same catchment area as those in group A, receiving regular care (such as prophylaxis for opportunistic infections) but no DOT-HAART (n = 100).

Group C: people diagnosed with HIV infection during the same time period but living outside the area served by the community health worker (n = 100) who thus received only clinic-based care.

Source: adapted from Farmer et al.⁴

of stigma and increased staff morale as favourable results of the programme. The drop-out rate from the programme was remarkably low – less than 2 % since 1999. Side-effects of the treatment have been rare, and only a few people required a change in drug regimen.

Prevention versus care: a false dichotomy

The HIV Equity Initiative was designed as an integrated prevention and care programme. The treatment component, from the prevention of opportunistic infections to ARV therapy, was grafted onto an existing DOTS programme and was linked to clinic- and community-based prevention efforts from the outset. Nevertheless, one unexpected benefit of improving the quality of care was the positive effects on the quality and results of activities to prevent HIV/AIDS⁵. Seven effects are noted here.

First and most significant was the sharply increased uptake of voluntary counselling and testing. Free voluntary counselling and testing was made available in the Clinique Bon Sauveur beginning in 1988, but the demand for such services was limited. Staff clinicians initiated almost all HIV testing and thus voluntary counselling and testing, and an estimated 60 % of those offered these services before 1995 declined the offer. This

meant that 60–75 % of all serological tests were positive. After 1995, requests for voluntary counselling and testing by people living with HIV/AIDS and a high rate of acceptance were registered largely in the prenatal clinic, when zidovudine was introduced to prevent mother-to-child transmission. By 1999, voluntary counselling and testing was considered part of routine prenatal care, but an increase in voluntary counselling and testing in the general ambulatory clinic was temporally associated with the introduction of DOT-HAART.

In the first year of the HIV Equity Initiative, demand for voluntary counselling and testing increased by more than 300%, and demand soon surpassed the capacity to offer these services. By 2000, most HIV serological tests were negative; in 2002, only 11% of more than 4500 serologies were reactive. Clinic- and community-based staff agree that improved care has driven increased demand for voluntary counselling and testing.

Second, the introduction of ARV agents has changed the nature of clinic exchanges considerably. Before the HIV Equity Initiative, most HIV clinic visits were devoted to managing chronic diarrhoea, thrush, weight loss, and fatigue. People receiving ARV therapy do not often have such problems, however, and physicians and nurses can now spend more time reinforcing safe-sex messages (secondary prevention).

Third, the decreased viral loads associated with ARV therapy render people living with HIV/AIDS less infectious when they do have unprotected sex.

Other means by which improved care may reinforce prevention activities are less well documented but no less important. A fourth benefit encountered in rural Haiti is the decreased stigma associated with AIDS. Prior to the advent of ARV agents, a diagnosis of HIV infection was regarded locally as a death sentence. There are now so many stories of dramatic improvement on ARV agents that most villagers in the Zanmi Lasante catchment area know someone who has responded to therapy. Decreased stigma improves the quality of life of people living with HIV/AIDS and their families but also leads to increased willingness to be tested and to discuss AIDS prevention more openly.

Fifth, the lack of ARV agents before 1998 meant that physicians, nurses and community health workers had to stand by helplessly as people wasted away from AIDS. ARV agents have permitted health care workers to offer people living with HIV/AIDS hope of survival, thereby improving morale among the staff.

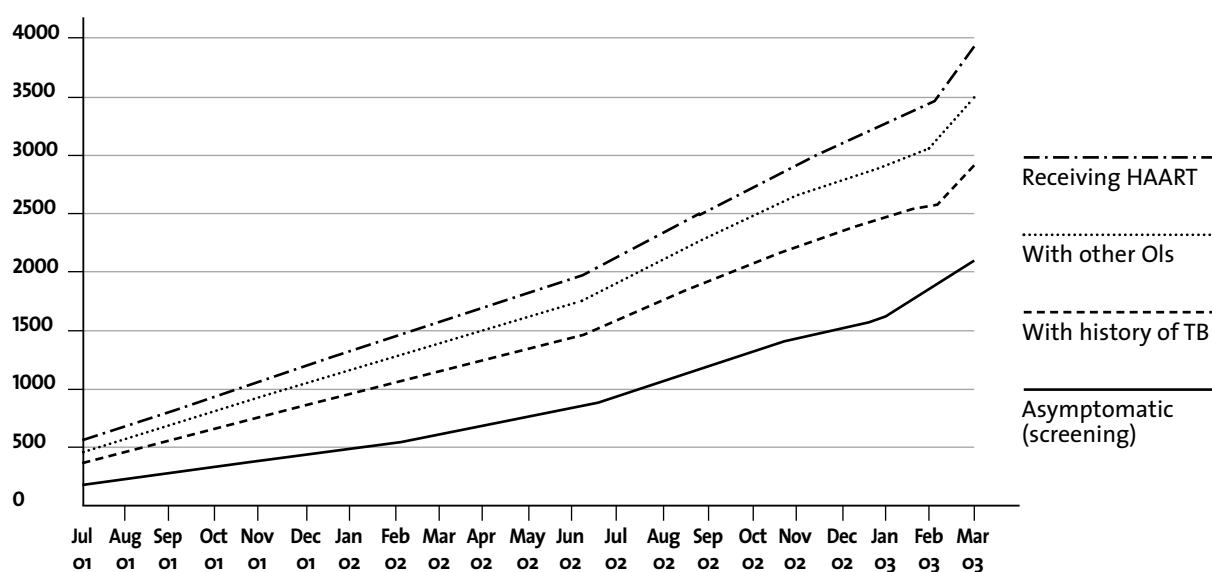
Sixth, people receiving ARV therapy are unlikely to require hospitalization, and decreased expenditure for hospital care means that more resources may be devoted to prevention activities. A similar experience has been well-documented in Brazil. Seventh, the incidence of tuberculosis has declined sharply among people receiving ARV therapy.

Scaling up

Partners in Health believes that the programme has already proven the efficacy of community-based care including ARV therapy. In contrast to claims that expansion will divert resources from other health priorities, the increased attention to AIDS has resulted in new attention to primary health care and drug procurement.

At the end of 2002, the Global Fund to Fight AIDS, Tuberculosis, and Malaria granted Haiti US\$ 67 million for programmes to battle the current HIV/AIDS epidemic in the country. With some of the funds awarded to Partners in Health, the comprehensive HIV/tuberculosis programme has

Progression of HIV+ Patient Enrollment Partners In Health, Rural Haiti



been launched at four new sites in Lascahobas, Belladère, Boucan Carré and Thomonde. The expanded services and an additional number of newly-trained community health workers resulted in a 10-fold increase in ambulatory visits in six months at each of these facilities. With a growing demand for HIV testing, the case load is expected to double in the next year, bringing life-sustaining drugs free of charge to an increasing number of patient who qualify for DOT-HAART according to treatment criteria.

Further, drug costs have fallen dramatically with the introduction of generics into the market. Partners in Health is a

Box 3. Excerpt from the Cange Declaration

«We, the patients of Partners in Health, are fortunate to receive medication and health care even if we do not have the money. Many of our problems have been resolved with the medications. Given how bad off we used to be, we have greatly benefited. But while we feel fortunate to receive the medications, we feel sad for others who don't receive the same treatment we do.»

Source: Cange Declaration⁷

founder of the Green Light Committee, which reduced the price of antituberculosis medication by 90% by using multiple sources for drug purchases⁶. A similar success was achieved for ARV drugs: concessional pricing agreements with pharmaceutical companies, purchase of drugs from WHO-prequalified manufacturers, and collaboration with the International Dispensary Association, a wholesale distributor of essential drugs based in the Netherlands, have driven prices in Haiti from US\$ 10 000 per patients per year in 1999 to below US\$ 300 per patients per year in 2003. Thus, drugs as a proportion of programme costs declined from about 80% to below 15%, allowing an estimated 10 000 rural Haitians to benefit from the Global Fund grant.

The expectation that the programme will be scaled up district-wide within the next five years has created the need for improved information management. In response to that need, Partners in Health has built a system with three components: a Web-based medical record system, an application that allows off-line data entry and a drug inventory system. The system is now operational and medical records are being entered.

The introduction of advanced diagnostic methods, such as flow cytometry, improves local capacity to identify those who need ARV therapy and further illustrates the broad spectrum of new developments in the care of people living with HIV/AIDS in resource-limited countries.

Feasibility of replication

With the sole help of a start-up fund of US\$ 100 000 from a small Haiti-based foundation, the HIV Equity Initiative was piloted in one of the poorest areas of the world, where health infrastructure has been seriously compromised by years of conflict and extreme poverty. Partners in Health believes that, with minor adjustments to the existing public health infrastructure, many district hospitals in developing countries would have the capacity to provide HAART to patients advanced HIV diseases. Hence, the central concept of the HIV Equity Initiative in applying the lessons learned from a tuberculosis control programme to an AIDS treatment programme has not only been taken to more sites in Haiti but is now being further exported to health facilities in Peru (Lima), the Russian Federation (Siberia) and the United States (Massachusetts).

The example of the HIV Equity Initiative offers hope that the voices of people living with HIV/AIDS – as expressed in the Cange Declaration (Box 3) – may be heard. With more national and international support and an environment responsive to the increasing demand for effective AIDS treatment among people in resource-limited countries, there should be no barriers to access to life-saving HAART for those who need it most.

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