TREATMENT 2.0



IS THIS THE FUTURE OF TREATMENT?

IMAGINE TREATMENT 2.0

A radically simplified treatment platform that's good for HIV prevention too!

Imagine an easy to use pill—low in toxicity and doesn't lead to drug resistance.

Then imagine a drastically reduced need for costly labs—monitoring can be done at home.

Now imagine no stock-outs—a low-cost supply chain and the community ensure that pills are there when you need them.

Finally imagine that treatment is contributing greatly to the prevention effort.

One third reduction of new HIV infections globally

The latest studies show that a reduction in new HIV infections of up to a third could be achieved globally if there is a radical overhaul of the way that the world provides antiretroviral therapy and if global leaders meet their commitments of ensuring that all people in need of treatment are on it.

It's called treatment as prevention and it is one of the five pillars of the new Treatment 2.0 platform. In an effort to maximize the value of antiretroviral therapy, a radically simplified approach is needed. This includes the development of better combination treatment regimens, cheaper and simplified diagnostic tools, and a low-cost community-led approach to delivery.

Everyone wants to do things smarter, faster and better

But the reality is that treatment today is complicated. From starting HIV treatment to maintenance, the treatment process works, but each step is cumbersome and expensive.

Up to 80% of the cost of treatment isn't for the medication but for the systems to get it to a person and to keep him or her on it.

Globally, only one third of people who need treatment are on it. HIV testing is underutilized—most people still find out that they are HIV-positive when they develop clinical symptoms of AIDS. Antiretroviral therapy is not homogenous in cost, effectiveness or tolerability. And resistance can build up, making it necessary to maintain costly labs to monitor each person on treatment.

To get smarter, to get faster and to save more lives, the world will need to shift resources and thinking

Today, an estimated 5 million people living with HIV in low- and middle-income countries are receiving treatment, up from about 400 000 in 2003—a more than 12-fold increase in six years.

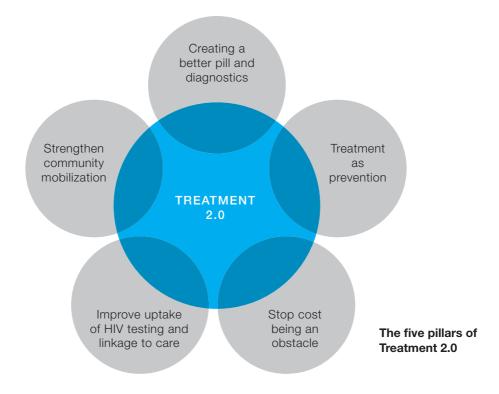
Despite progress, the global coverage of antiretroviral therapy remains low. For every two people newly on treatment, five more become newly infected. A majority of people living with HIV are unaware of their HIV status. And although easily preventable, rates of mother-to-child transmission of HIV in many countries remain high.

In many settings, HIV prevention and treatment are provided through a sophisticated delivery system requiring specialist doctors who tend to focus on HIV only. This system is often overstretched, due to an increasing number of patients, a shortage of trained medical personnel and financial constraints. Many in need of treatment live in rural settings, far from specialized care.

With competing global priorities and an economic crisis, a longer-term sustainable solution is needed to ensure that world leaders can keep their commitments to achieve the goal of universal access to HIV prevention, treatment, care and support.

The most recent World Health Organization (WHO) guidelines for antiretroviral therapy call for earlier initiation of treatment and the use of simpler, better drug regimens—recommendations that will further decrease morbidity and mortality as well as vertical and horizontal transmission. However, there is still a long way to go.

Treatment 2.0 opens a new door...



PILLAR 1

Creating a better pill and diagnostics

When treatment for HIV first came around in 1996, it was a tough pill to swallow—literally. It meant on average taking 18 pills a day, of varying shapes and sizes. Some were taken with food, others on an empty stomach, and rigorous monitoring of the time of day the pill was taken was needed in order to mitigate the risk of the virus becoming resistant to the drugs.

But it worked. People called it the Lazarus effect: people near death became healthy again.

Antiretroviral therapy works by suppressing the virus and stopping it from reproducing. If the active component of the drugs is not kept constant in the body, the virus can mutate, continue to multiply and become resistant to the drug. By adhering to a treatment regimen—for most combinations this means taking the medication at a given time of day, two to three times a day—drug levels are kept even.

The more different types of pills a person takes, the more substances the body has to accustom itself to, the higher the risk of developing side-effects. Many people living with HIV who have been on treatment can testify to the side-effects—from depression and fever to lipoatrophy (the loosing of fat from certain areas of the body).²

Developing resistance to a regimen is a well-founded fear—once a regimen is no longer effective, people living with HIV may have to move to a second-line of treatment.

Access to second-line treatment is still rare in most low- and low-middle income countries due to the high cost of the pills and the more complex monitoring systems and supply-chain management.

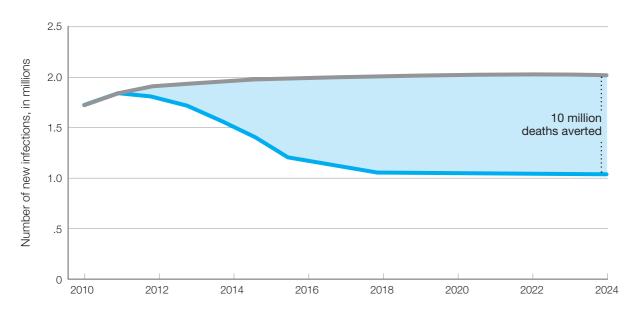
Improving effectiveness and ease of use, and lowering side-effects and resistance, need to be considered in the development of new treatment options. As a result of using such new and simplified treatment approaches, the number of HIV-related deaths could be reduced significantly. Compared with current treatment approaches, Treatment 2.0 would allow for an accelerated scale-up and has the potential of averting an additional 10 millions deaths by 2025.3

Some regimens already exist as fixed-dose combinations, in which multiple drugs are in one pill, but options that have fewer side-effects and have less potential for long-term toxicity (dose optimization, minimal requirements for laboratory monitoring) and that are more resilient and tolerant to treatment interruptions (to minimize the development of drug resistance) are needed. A one-pill, once-a-day antiretroviral therapy has been shown to improve both adherence and quality of life while maintaining the same efficacy.⁴ Antiretro-

Figure 1. Expected number of deaths under two hypothetical scenarios: compared with current antiretroviral therapy approaches an additional 10 million lives could be saved under Treatment 2.0.

Current

ART 2.0



What's it like being on treatment

Rodrigo Pascal

Partnerships Officer, UNAIDS

I was diagnosed with HIV in 1996 while living in Santiago, Chile. At the time, there was only limited access in the country to low-quality antiretroviral regimens.

Doctors connected me with a support group for people living with HIV that met weekly at a hospital on the outskirts of Santiago. I remember at my first session feeling amazed by the helplessness of others in the group—they were in a terrible condition, wasting away, skinny, eyes wide with fear, waiting to die.

As a middle-class Chilean citizen, I could access treatment immediately. Most of the people in my support group were unable to afford the medications and had been placed on a hospital waiting list. I was angry and enraged at these blatant inequalities in access to health.

When I first started antiretroviral therapy in 1997, I took 12 to 14 pills a day. Throughout the years, I have moved from one regimen to another. In all of my years of treatment, I have never developed resistance to any one drug, but I've had some very strong side-effects.

When taking Sustiva, for example, which is a commonly-used antiretroviral drug, I had vivid dreams, nightmares and other psychological issues. At one time, my head became noticeably swollen and disfigured—an allergic reaction to the medication. I had to stop the drug, go back to the hospital and try a new regimen.

Another antiretroviral drug, a protease inhibitor, left me with lipodystrophy, which is a loss of fat in some parts of the body and an accumulation of fat in other areas. I could barely look at myself in the mirror; it was very bad for my self-esteem.

In 2006, after almost ten years of antiretroviral therapy, all of my coronaries were completely blocked. I had to have four bypass surgeries to survive. Given my underlying heart condition, I probably would have had heart problems many years down the road—but not at the age of 50. I am actually taking more drugs now for my heart condition than for HIV.

My current antiretroviral regimen is pretty simple. I take three pills a day: one in the morning and two in the evening. I've had a few minor side-effects, but, on the whole, I feel good and the treatment is working.

Mrs Lineo Mafatle

(name has been changed) Mother of two, Lesotho

I first found out I was HIV-positive back in 2001. I didn't know that my husband had tested positive for HIV, but I started noticing changes in his behaviour—he started staying out late, started drinking a lot. One day he told me he needed to tell me something that would hurt me a lot, something that might even kill me. Then he said: "I'm HIV-positive."

First, I was very upset. I screamed and shouted at him. After a while, I started preparing my mind that I have to accept my test result if I get tested, so that I could live longer. We started talking about it and agreed that we would be there for each other, and we were ready to support each other, no matter what my test result was.

My husband came with me when I went for a test, and I tested positive. This was in 2001 and back then I didn't even think about treatment. It was so expensive, I didn't even try to find out how much it cost, as knew I would not be able to afford it.

In 2003, when the first antiretroviral therapy centre opened in Lesotho we went together to the clinic and my husband was initiated on treatment. But my CD4 count was 250—that was the first time I had my CD4 count checked—so I did not have to start my treatment yet.

At the centre they told me I had to go for check-ups every three months, which I did. It was not until 2005, when my CD4 count dropped below 200, that I started taking anti-

retroviral drugs. Even though I did not have any symptoms, I was what they called stage 1, I still started taking them.

In 2006, I experienced my first side-effect of one of the drugs, zidovudine. The fat on my body started redistributing itself and I got really thin on my backside, my legs and even my face. This meant I had to change one of the components of my treatment.

I take my three pills two times a day, every 12 hours. Apart from the fat distribution, I have also experienced a pain in my legs. I try to make sure that I massage them to make sure I don't feel it so much—I need to accept it as part of the treatment. I think at this point it is better for me to try to live through whatever minor side-effects, so I don't have to start on a second-line drug, which might have even worse side-effects than I am experiencing now.

The most difficult thing about being on treatment is adherence. Once you are on treatment and have been on treatment for some time, you get used to it, and you don't even remember if you have taken them or not, asking yourself "did I take them today?" Now I have a pill-minder where I put the pills for every day so I can check if I have taken them or not.

I think adherence is very challenging. But treatment has also given me hope. When I first found out I was HIV-positive I thought I was going to die, and that was very difficult. So for us to have antiretroviral drugs here in Lesotho, until we find a cure, treatment gives hope.

If I was allowed to dream of the future of treatment, for something like HIV where you have to take treatment for life, I think the main thing I would want would be for the number of doses to be reduced.

viral therapy simplicity favours adherence and may improve long-term success. In an ideal scenario, having such a pill could do away with the current need for secondand third-line treatments.

At the same time, simpler diagnostic tools and technologies are in short supply. Pregnancy tests can be used at home. People who have diabetes can check their blood glucose level nearly anywhere. And if a mother is worried that her child has a fever she has many choices on how to check her child's temperature. All of these diagnostics are easy to use, usually with-out the need for a doctor or a lab. But we do not at present have such tools for checking HIV status or CD4 and viral load testing. While robust rapid tests are more and more used for the first HIV test, monitoring CD4 counts and viral load requires expensive and time-consuming lab-based tests. We need tests that are inexpensive, that do not require laboratory expertise and that are heat stable, and the results should be available within a few hours (or at the time of a clinic visit). Hopefully, promising prototypes will reach the field in the next few years.5

Current WHO definitions of immunological failures show less than optimal diagnostic performance in resource-limited settings, leading to unnecessary switches to second-line treatment.⁶ Recent publications also show that good quality clinical monitoring could replace more complex and expensive lab monitoring, reducing costs and allowing a more decentralized delivery.⁷ CD4 count monitoring has been shown to be cost-effective as a targeted, rather than a routine, strategy.⁸

Treatment monitoring that is closer to the patient can lead to better treatment results. It can facilitate early detection and treatment of HIV and can ensure appropriate and rapid response to drug resistance, improving outcomes for people on treatment and reducing the development and spread of drug-resistant strains of the virus.

Innovation is needed to develop inexpensive point-of-care diagnostic tools like simple dip-stick tests to measure CD4 cell counts, viral load or tuberculosis infection.

PILLAR 2

Treatment as prevention

Since 1991, the world has known that effective antiretroviral therapy can help to prevent HIV transmission. This has been the case for vertical transmission, for example ensuring that pregnant women living

with HIV don't pass on the virus during pregnancy or childbirth. Although easily preventable at low cost, vertical transmission remains high. Better coverage of antiretroviral therapy at an earlier stage for women of child-bearing age could contribute to preventing mother-to-child transmission. Findings demonstrate that maternal triple drug antiretroviral therapy used throughout pregnancy and breastfeeding reduce vertical transmission to 1% (and lower the risk of prematurity, stillbirth and abortion).⁹

Recently, however, the dramatic impact of treatment on other forms of HIV transmission has become better understood. Evidence clearly shows that successful viral suppression through treatment can substantially reduce the risk of vertical, sexual and blood-borne HIV transmission.^{10, 11, 12, 13, 14}

A recent study supervised by the University of Washington and largely funded by the Bill & Melinda Gates Foundation looked at 3400 heterosexual couples—each with one HIV-positive and one HIV-negative person—from seven countries in sub-Saharan Africa. When the HIV-positive partner was on treatment, the researchers found the HIV transmission rate was 92% lower than among couples where the person living with HIV did not receive

Figure 2. Sketch of the evolution of viral load since seroconversion and associated cumulative risk of HIV transmission. The area in blue represents the share of infections averted through effective treatment of all people in need, according to latest treatment guidelines.

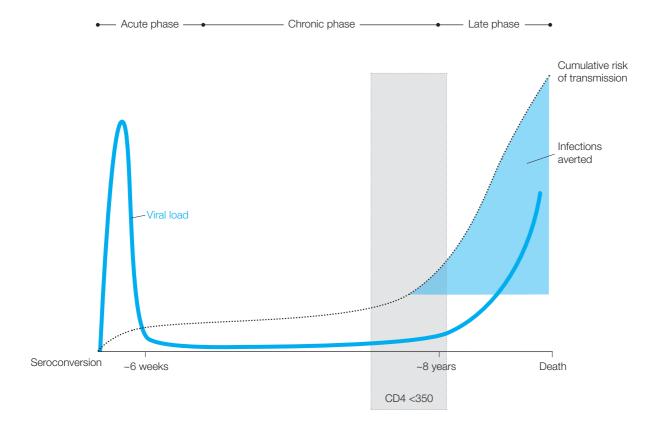
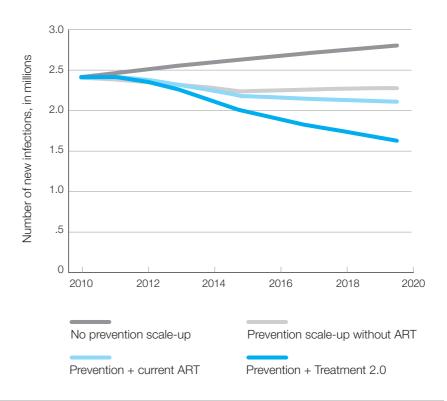


Figure 3. Incidence of new infections in four different scenarios.



treatment.¹⁵ This study also confirmed that a significant proportion of all HIV transmission happens during the phase when people living with HIV develop increasing immune impairment (which is marked with increasing viral load and decreasing levels of CD4 counts).

Treatment can become part of a combination prevention strategy. Optimizing treatment coverage will also result in other prevention benefits, including lower rates of tuberculosis. Thus, antiretroviral therapy confers huge individual and community benefits. In settings with a large burden of HIV and tuberculosis, studies show that antiretroviral therapy may contribute to tuberculosis control in both HIV-infected and HIV-uninfected individuals, suggesting that the community-wide benefit of antiretroviral therapy extends even to those without infection.¹⁶ By reducing mortality rates, ongoing antiretroviral therapy scale-up may accelerate progress toward the MDG tuberculosis control target of halving the 1990 mortality rate by 2015. Other studies show declining malaria incidence after antiretroviral therapy initiation. 17

Also, effective implementation of antiretroviral therapy reduces the incidence of pregnancy/childbirth-related deaths among women, who are at greater risk when their immune system is already low. A recent study estimated that AIDS is responsible for 61 000 of the 350 000 annual deaths of women worldwide during childbirth or pregnancy. The impact is harshest in Africa, where it is causing a rise in maternal deaths.¹⁸

Treating everyone in need of treatment according to the current treatment guide-lines could result in a one third reduction in new infections globally. As Figure 3 shows, Treatment 2.0 would avert a significant number of new infections as compared with the current approach or with doing nothing. Further research is urgently needed in order to better understand the possibilities and role of antiretroviral therapy in earlier asymptomatic phases of HIV infection.^{19, 20, 21}

Assuming a more effective treatment, it is anticipated that Treatment 2.0 could prevent millions of new infections, as compared with the current strategies, to social and behavioural factors such as coverage and retention rates.³

PILLAR 3

Stop cost being an obstacle

Despite drastic reductions in drug pricing over the past ten years, the costs of antiretroviral therapy programmes continue to rise.

In 2008, a vast majority of adults (98%) and children (97%) surveyed in 43 high-burden countries were receiving

first-line antiretroviral therapy regimens. The reported proportion of adults on second-line regimens remained low, amounting to no more than 2% of those on antiretroviral therapy.²²

In low- and middle-income countries the average annual cost of the most widely used first-line drug treatments was US\$ 143 per person in 2008, a price reduction of 48% since 2004. There was an even greater price reduction in paediatric formulations, from US\$ 436 per person per year in 2004 to US\$ 105 in 2008. This all helped to contribute to a wider availability of treatment. Second-line regimens continue to be more expensive.²³

Drugs can be even more affordable—however, potential gains are highest in the area of reducing the non-drug-related costs of providing treatment. Currently these costs significantly outweigh the cost of the drugs themselves.²⁴

Cost savings can be found in every step of the process. A better, singe-dose pill with decreased toxicity and that was resistant-proof would have fewer needs for treatment monitoring. This would lead to a reduced number of interactions with health-care providers—less health-care time spent on monitoring people enrolled on antiretroviral therapy programmes frees up resources to be devoted to other pressing health issues. A decreased frequency of interaction with health-care providers also lowers out-of-pocket costs, such as transport fees, for the care-seeker.

Although antiretroviral therapy costs could be considerably higher for a regimen that has better tolerability, safety and efficacy, if the monitoring and service delivery costs are less the total costs per patient would not be higher. For example, by using a simplified treatment requiring fewer visits to the doctor, we can pay for a more effective regimen costing double the current price without increasing the overall treatment delivery cost (Figure 4).

Antiretroviral therapy costs are expected to keep growing under the current approach, especially as the proportion of people on second-line treatment rises; in contrast, under Treatment 2.0 after a brief transition period and rise in costs the full cost of treatment will decrease, bringing down the long-term financial requirements and making the new approach sustainable in the long term. The introduction of more effective antiretroviral therapy would reduce the proportion of people requiring expensive second-line treatment by half.

Under the old approach, patients look for treatment when they are weak, very sick and their defences are low (with CD4 counts under 100 cells)—they present life-threatening infections and doctors treat them for days or weeks, exhausting hospital capacity. Under the new treatment approach, healthier patients start treatment when they are able to keep compliant with their treatment and incur less health-care utilization and costs. Figure 5 shows the average costs for a patient requiring multiple ambulatory visits, hospital days, diagnostic tests and expensive antibiotics during the advanced stage of the disease. 25, 26, 27 As compared with early treatment, late health-care utilization is so expensive that the hospital cost to treat severe opportunistic infections would pay for three years of antiretroviral therapy. Early therapy not only saves money but reduces hospital utilization and has social benefits in addition to individual benefits.

Treatment 2.0 is cost-effective and saves money in the mid and longer term.³ With higher coverage, lower morbidity and mortality, and the additional secondary benefit of prevention, Treatment 2.0 is a smart investment.

Figure 4. On average, the largest share of treatment costs in low- and middle-income countries is not drug-related.

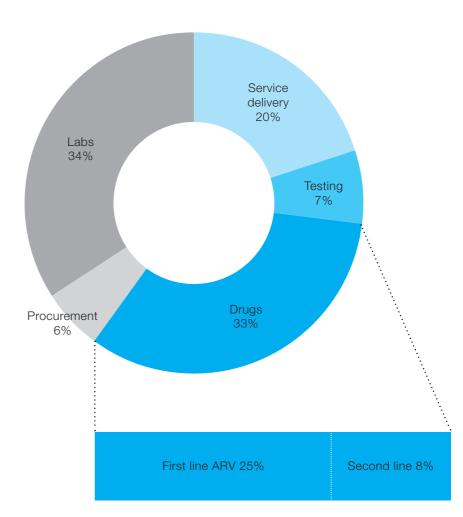
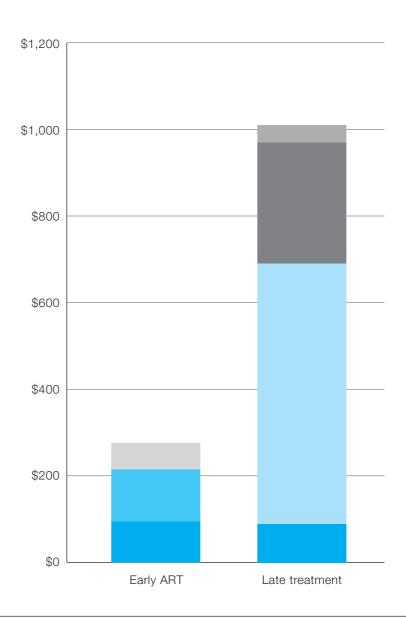


Figure 5. Comparison of antiretroviral therapy costs per person-year for early and late treatment initiation. Late treatment initiation for patients with often severe clinical conditions requires significant levels of clinical care. This is avoidable through treatment initiation prior to the development of severe HIV-related disease.





Decentralizing HIV treatment in Malawi

According to government sources, nearly 200 000 people living with HIV in Malawi were accessing antiretroviral therapy in 2009, up from about 10 000 in 2004. Between 2003 and 2009, the number of sites in Malawi providing antiretroviral therapy increased from nine to 377. A decentralized approach to HIV treatment and care was critical to this national success in antiretroviral therapy scale-up.

Under Malawi's first national antiretroviral therapy guidelines of 2003,
only doctors and clinical officers—
based primarily at larger health facilities in urban settings—were empowered to start patients on antiretroviral
therapy. Medical assistants and
nurses could monitor and follow up
on a patient's progress, but were not
able to prescribe treatment.

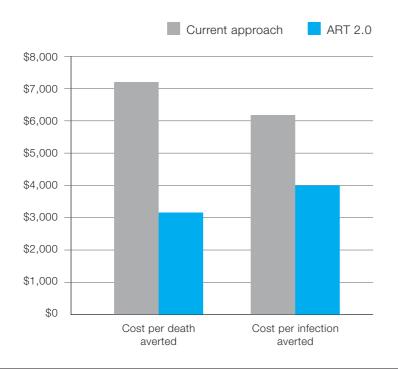
With about 85% of the population in Malawi living in rural areas, treatment access became an important issue. "Some people had to travel 100 kilometres to be assessed if they were eligible for antiretroviral therapy," says Professor Anthony Harries, an adviser to the Malawian government's HIV programme from 2003 to 2008. "Though this was a free service, it meant time away from work. Those who did manage to access antiretroviral therapy had great difficulty continuing treatment because of the cost of transport."

Malawi's new antiretroviral therapy scale-up plan (2006–2010) included a number of strategies to bring HIV treatment closer to the primary point of care, where the majority of the population lives. Under the new guidelines, medical assistants and nurses were empowered to initiate antiretroviral therapy—from 2006 and 2008, respectively.

In partnership with the Ministry of Health and district-level medical facilities, many community-based health centres were accredited as antiretroviral therapy delivery clinics. About 88 000 people started antiretroviral therapy in 2009 alone. Of the 377 sites in Malawi in which antiretroviral therapy is now offered, more than 50% are simple health centres.

"Through this decentralized approach, we were able to reach out into the communities, where people otherwise could not access treatment," says Dr Frank Chimbwandira, Director of the HIV/AIDS Department in Malawi's Ministry of Health. "We were also able to improve treatment follow-up, as more people could come back and forth from the health centres to access their medication."

Figure 6. Annual cost of Treatment 2.0 as compared with the current antiretroviral therapy delivery approach. The cost differential between the two approaches reflects the savings achieved in health care delivery for Treatment 2.0. This analysis does not include the full benefits derived through indirect cost savings as a result of healthy life years gained.



PILLAR 4

Improve uptake of HIV testing and linkage to care

The uptake of HIV testing and counselling and linkage to care will need to be improved drastically if the promise of treatment and treatment-centred HIV prevention approaches are to be realized.

Globally only about 40% of people living with HIV know their HIV status— the large majority of whom find out they have HIV by developing clinical AIDS, with their immune system already seriously weakened.

Stigma and discrimination remain as the foremost impediment to HIV testing utilization. For many people even seeking out HIV testing can lead to serious, even life-threatening, exposure to violence, legal action and loss of family, employment and property. And where care, treatment and support services are unavailable, there is little incentive to take an HIV test.

However, progress is being made. South Africa is scheduled to reach 15 million people in two years. In the United Republic of Tanzania, three million people received HIV tests in six months; in Malawi 200 000 people took HIV tests in one week.

Community-based organizations, often led by people living with HIV, provide an important and effective bridge into HIV testing and a link to treatment and prevention services. Peer-based services are often more trusted than governmentled services, especially by populations at higher risk, which can be fearful of government-run health-care approaches. The results of programmes from countries as diverse as Bolivia, Botswana, China, India, the Russian Federation, Rwanda and Uganda all show the positive impact that individual engagement with community-based services has on increased HIV testing rates and increased use of HIV prevention and treatment services, as well as improved treatment adherence and prevention practices and a reduction in stigma.

We need to learn from and scale up successful models of partnership between health service providers and community-based service providers in order to assist in stigma reduction and increased utilization of services by populations at higher risk. Many examples exist in countries, including programmes that receive support from the United States President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

PILLAR 5

Strengthen community mobilization

Drug users, men who have sex with men, sex workers and poor women often have little reason to trust government-provided health services. Fear of exposure of their HIV status keeps many people from seeking HIV testing and health services.

Community-based approaches to build trust, protect human rights and provide opportunities for socialization directly improve the ability of people to use HIV services and to benefit from antiretroviral therapy and prevent new infections. In fact, much of the success to date in the AIDS response is due to the unprecedented engagement of affected communities as advocates, educators and service providers.

In the late 1980s, TASO (the AIDS Support Organization) developed models for community-based support services in Uganda that were duplicated all over the world.

Grupo Pela Veda in Brazil successfully helped to advocate for full antiretroviral therapy coverage in the country, which led to a 50% drop in AIDS-related deaths in one year.

Work by AIDS activists in the United States of America helped to cut the time its takes to approve new drugs for life-threatening illnesses in half, leading to the early approval and availability of highly active antiretroviral therapy in 1996, saving millions of lives.

The All-Ukrainian Network of People Living with HIV managed a Global Fund grant to provide treatment access and prevention services in response to one of the world's fastest growing HIV epidemics.

The Treatment Action Campaign in South Africa successfully confronted a government that failed to address the most destructive HIV epidemic in the world, leading to the development of treatment access programmes throughout the country and an increased commitment to HIV testing and prevention.

Simplified approaches to treatment offer unique opportunities to increase community-based delivery of outreach and support services, with direct positive effects for prevention and for lower-cost treatment.

For example, in Nepal the National Association of People Living with HIV has been supporting eight community-based organizations by providing counselling for discordant couples, condom promotion and referral for treatment, care and support services.

In China, an independent evaluation of 26 community-based organizations, all run by people living with HIV and supported by the International Treatment Preparedness Coalition (ITPC) HIV Collaborative Fund, showed that participation in support services provided by these organizations increased treatment adherence rates, brought more people into HIV testing and health services and increased CD4 cell responses to antiretroviral therapy.

Integration of HIV with other health services and using a variety of service delivery approaches (including deploying trained community or lay workers) can exponentially expand health system capacity without compromising standards of care or treatment outcome. Experience from Malawi shows that a variety of measures, including task shifting, decentralization of care to health centres and community involvement can help countries meet universal access targets while controlling the cost of the antiretroviral therapy programme due to economies of scale.28 A home-based HIV-care strategy, which has been shown to be as effective as a clinic-based strategy, could also enable improved and equitable access to HIV treatment, especially in areas with poor infrastructure and access to clinic care.29

A WHO evaluation of 186 community-based mobilization and service delivery projects in eastern Europe, South-East Asia and Latin America found that local-level community-based organizations led by people living with HIV are often best able to reach populations at higher risk of HIV and to get people to utilize health services effectively.³⁰

Community organizations can lead and manage access to HIV prevention, treatment, care and support, especially for populations at higher risk.

Strengthening community mobilization efforts can increase demand for HIV prevention, treatment and testing, ensure protection of human rights, advocate for equitable care, and provide community-based prevention and care support services.

Community buy-in

David Barr

Director of Development and Special Projects, International Treatment Preparedness Coalition and UNAIDS consultant

What is different?

This is a major shift in thinking. Up until now, treatment and prevention programmes have been relatively siloed. We used to think about treatment primarily as a way to reduce morbidity and mortality. Recognizing that treatment also prevents new infections provides us with new opportunities to better integrate prevention and care efforts. It requires that we recalculate the cost-effectiveness of providing treatment.



Young people need access to information about HIV.

Why is community engagement critical to the success of a decentralized approach to HIV treatment and care?

Without the engagement of affected communities, it's impossible to get the people who are most at risk into care, and to get them to utilize care effectively. Global utilization of HIV testing and counselling is dismal. Without a greater investment in community mobilization, it will be impossible to improve uptake of HIV testing and prevention and care services. This is true across the board and most poignantly true for populations at higher risk, who experience severe discrimination when they seek out health services-the rural poor, men who have sex with men, drug users, sex workers. These groups have a very good reason not to trust public health officials and public health services that their governments run.

What are some of the risks of such an approach (human rights, quality of care, etc.)?

All HIV testing and care has to be provided within a framework of human rights protection. There's nothing in the Treatment 2.0 approach that changes that. The only way people can engage in these services is if they're not at risk of having their human rights violated. The Treatment 2.0 initiative will improve quality of care by bringing more people into the realm of care providers and making treatment and diagnostics easier to use.

References

- WHO (2009). Rapid advice: antiretroviral therapy for HIV infection in adults and adolescents. Geneva, WHO. Available at: http:// www.who.int/hiv/pub/arv/advice/en/index. html [accessed 10 June 2010]
- Murphy RA, Sunpath H, Kuritzkes DR et al (2007). Antiretroviral Therapy – Associated Toxicities in the Resource-Poor World: The Challenge of a Limited Formulary. J Infect Dis, 196 (Suppl 3):S449-56.
- Stover J and Bollinger L. Personal communication. Futures Institute 2010.
- van Oosterhout JJ, Brown L, Weigel R, et al.: Diagnosis of antiretroviral therapy failure in Malawi: poor performance of clinical and immunological WHO criteria. *Trop Med Int Health* 2009, 14:856–861.
- DART trial team. Routine versus clinically driven laboratory monitoring of HIV antiretroviral therapy in Africa (DART): a randomized non-inferiority trial. *Lancet* 2010; 375: 123-31
- Keiser P, Ojoo S, Mwangi I, Smith N: Cost effective model for reduced sampling of viral loads for monitoring anti-retroviral therapy in resource limited settings. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention. 2009 (MOPDD106).
- Airoldi M, Zaccarelli M, Bisi L, Bini T, Antinori A, Mussini C, Bai F, Orofino G, Sighinolfi L, Gori A, Suter F, Maggiolo F. One-pill oncea-day HAART: a simplification strategy that improves adherence and quality of life of HIVinfected subjects. *Patient Prefer Adherence*. 2010; 13:115-25.
- Fiscus SA, Cheng B, Crowe SM, et al.: HIV-1 viral load assays for resource-limited settings. PLoS Med 2006, 3:e417.
- Marazzi MC, Palombi L, Nielsen-Saines K, Haswell J, Zimba I, Maulidi M, Abdul Magid N, Richard L, Buonomo E, Scarcella P, Ceffa S, Paturzo G, Narciso P, Liotta G: Favorable pregnancy outcomes with reduction of abortion, stillbirth, and prematurity rates in a large cohort of HIV+ women in Southern Africa receiving highly active antiretroviral therapy (HAART) for prevention of mother-child-transmission (PMTCT). 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention 2009 (TUAC102)
- Myron S. Cohen and Cynthia L. Gay. Treatment to Prevent Transmission of HIV-1. Clinical Infectious Diseases 2010; 50(S3):S85–S95
- Dieffenbach CW, Fauci AS. Universal voluntary testing and treatment. for prevention of HIV transmission. *JAMA* 2009; 301:2380–2382.

- Montaner Julio S G et al (2006) The case for expanding access to highly active antiretroviral therapy to curb the growth of the HIV epidemic. *Lancet* 368: 531–36
- Moupali Das-Douglas, Chu P, Santos G-M, Scheer S, McFarland W, Vittinghoff E, and Colfax G (2010) Decreases in Community Viral Load Are Associated with a Reduction in New HIV Diagnoses in San Francisco. 17th Conference on Retroviruses and Opportunistic Infections. Available: http://retroconference.org/2010/Abstracts/38232.htm. Accessed 2 May 2010.
- Attia S, Egger M, Müller M, et al. Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. AIDS. 2009; 23(11):1397-1404.
- Donnell D, Baeten JM, Kiarie J, Thomas KK, Stevens W, Cohen CR, McIntyre J, Lingappa JR, Celum C. Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. Lancet, Published online May 27, 2010 DOI:10.1016/ S0140-6736(10)60705-2.
- Badri M, Wilson D, Wood R (2002). Effect of highly active antiretroviral therapy on incidence of tuberculosis in South Africa: a cohort study. *Lancet*, 359 (9323): 2059-64.
- Lawn SD, Badri M, Wood R (2005).
 Tuberculosis among HIV-infected patients receiving HAART: long term incidence and risk factors in a South African cohort. AIDS, 19 (18): 2109-16.
- Hogan MC, Foreman KJ, Naghavi M et al (2010). Maternal mortality for 181 countries, 1980—2008: a systematic analysis of progress towards Millennium Development Goal 5. Lancet, 375(9726): 1609 - 1623.
- Del Romero J, Castilla J, Hernando V, Rodriguez C, Garcia S, Combined antiretroviral treatment and heterosexual transmission of HIV-1: cross sectional and prospective cohort study. BMJ 2010;340:c2205. doi:10.1136/bmj.c2205
- Peter J. Dodd, Geoff P. Garnett and Timothy B. Hallett. Examining the promise of HIV elimination by 'test and treat' in hyperendemic settings. AIDS 2010, 24:729–735.
- Boily MC, Baggaley RF. HIV transmission in serodiscordant heterosexual couples: Risk is not zero but is low if the infected partner takes antiretrovirals BMJ 2010;340:c2449. doi:10.1136/bmj.c2449.
- Renaud Théry F, Nguimfack BD, Vitoria M, et al (2007). Use of antiretroviral therapy in resource limited countries in 2006: distribution and uptake of first and second-line regimens. AIDS, 21: S89-S95.

- 23. WHO (2009). Transaction prices for Antiretroviral Medicines and HIV Diagnostics from 2008 to October 2009 A summary report from the Global Price Reporting Mechanism. Geneva, WHO. Available at: www.who.int/hiv/amds/GPRMsummaryReportNov2009. pdf [accessed 1 June 2010]
- 24. Resource needs for AIDS in low- and middle-income countries: estimation process and methods. Methodological Annex III. Methodology for Care and Treatment Interventions. Available at: http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2007/20070925_Resource_needs_methodology.asp
- Cleary SM, McIntyre D, Boulle AM. The cost-Effectiveness of Antiretroviral Treatment in Khayelitsha, South Africa – a primary data analysis. Cost effectiveness and Resource allocation 2006; 4
- Badri M, Maartens G, Mandalia S, Bekker LG, Penrod JR, Plat RW, Wood R, Beck EJ. Cost effectiveness of highly active antiretroviral therapy in South Africa. *Plos medicine* 2006, 348-56
- 27. Goldie SJ, Yazdanpanah Y, Losina E, Weinstein MC, Anglaret X, Walensky RP, et al. Cost-effectiveness of HIV treatment in resource-poor settings—the case of Cote d'Ivoire. N Engl J Med. 2006;355:1141-53.
- 28. Jouquet G, Bemelmans M, Massaquoi M, Arnould L, Mwagomba B, Bauernfeind A, Philips M: Cost analysis of and HIV programme reaching district-wide access to ART in Thyolo, Malawi. 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention 2009 (TUAD105).
- 29. Jaffar S, Amuron B, Foster S, Birungi J, Levin J, Namara G, Nabiryo C, Ndembi N, Kyomuhangi R, Opio A, Bunnell R, Tappero JW, Mermin J, Coutinho A, Grosskurth H; Jinja Trial Team. Rates of virological failure in patients treated in a home-based versus a facility-based HIV-care model in Jinja, southeast Uganda: a cluster-randomised equivalence trial. *Lancet.* 2009; 374: 2080-9.
- Barbara A. Israel, Amy J. Schulz, Edith A. Parker, Adam B. Becker. Review of community-based research: Assessing Partnership Approaches to Improve Public Health. *Annual Review of Public Health*, May 1998, Vol. 19, Pages 173-202.

20 Avenue Appia CH-1211 Geneva 27 Switzerland

T (+41) 22 791 36 66 F (+41) 22 791 48 35

unaids.org

