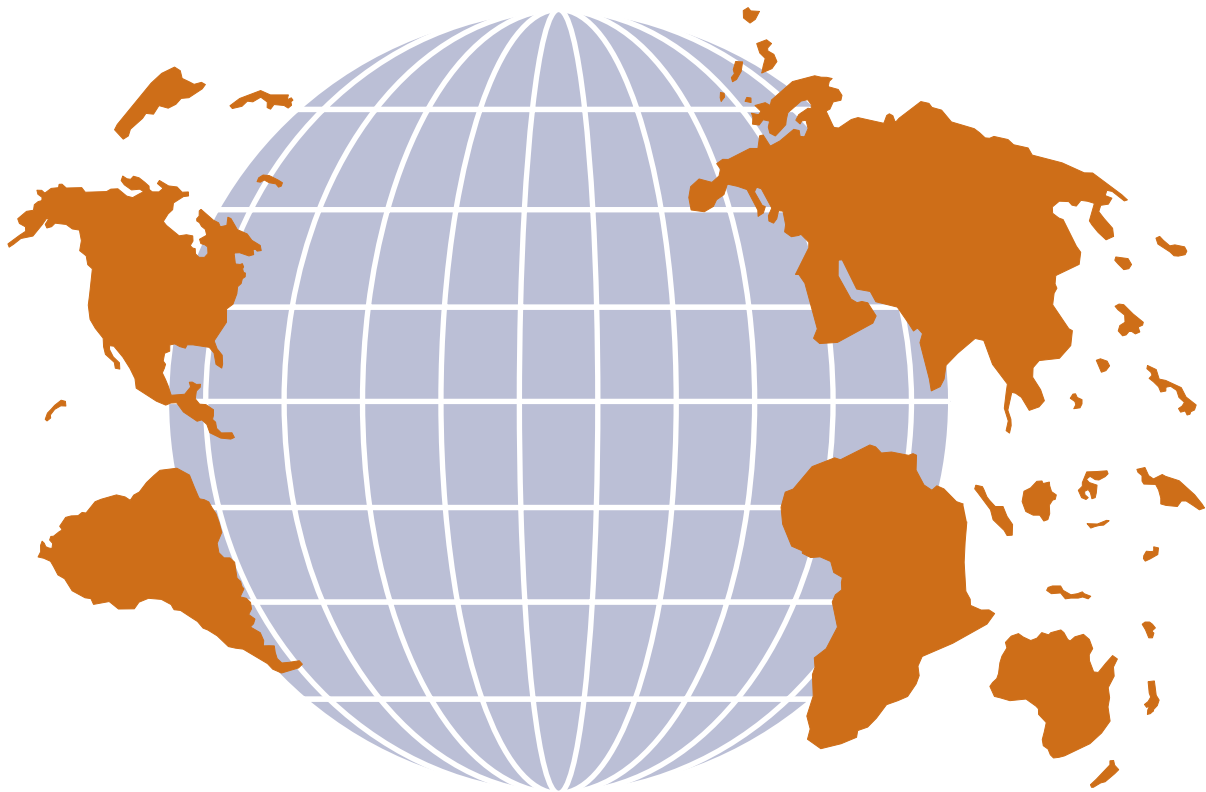


Missing the Target #3:

*Stagnation in AIDS treatment scale up
puts millions of lives at risk*

*Second six-month update to ITPC's
AIDS treatment report from the frontlines*



International Treatment Preparedness Coalition (ITPC)

28 November 2006

The International Treatment Preparedness Coalition (ITPC) was born at the International Treatment Preparedness Summit that took place in Cape Town, South Africa in March 2003. That meeting brought together for the first time community-based HIV treatment activists and educators from over 60 countries.

Since the Summit, ITPC has grown to include more than 800 activists from over 125 countries and has emerged as a leading civil society coalition on treatment preparedness and access issues.

All ITPC treatment reports are available online at
www.aidstreatmentaccess.org

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Acronyms

The following acronyms may be found in this report:

ARV = antiretroviral
ART = antiretroviral treatment
CDC = Centers for Disease Control and Prevention
GFATM = Global Fund to Fight AIDS, Tuberculosis and Malaria
HCW = health care worker
HR = human resources
IDU = injecting drug user
ITPC = International Treatment Preparedness Coalition
MDR-TB = multidrug-resistant tuberculosis
MSM = men who have sex with men
NGO = non-governmental organization
PCR = polymerase chain reaction
PEPFAR = U.S. President's Emergency Program for AIDS Relief
PLWHA = people living with HIV and AIDS
PMTCT = prevention of mother-to-child transmission
TB = tuberculosis
UNAIDS = Joint United Nations Programme on HIV/AIDS
USAID = U.S. Agency for International Development
VCT = voluntary counseling and testing
WHO = World Health Organization
XDR-TB = extreme drug-resistant tuberculosis

Executive Summary

This World AIDS Day, one year after the end of “3 by 5,” all of us engaged in the response to AIDS have a decision to make. Will we launch the full-scale, coordinated, deadline-driven mobilization envisioned just two years ago by such leaders as the late WHO Director-General Jong-wook Lee? Or are we willing to live with incremental gains that fall millions of lives short of the “universal access” goal?

This monitoring project from the International Treatment Preparedness Coalition (ITPC) has found that despite pockets of progress, efforts as a whole are stagnating.

The international community has reaffirmed the abstract goal of coming as close as possible to universal access to HIV treatment, but most major players have refused to define what this means. Imagine where the smallpox and polio immunization campaigns would have gotten had they focused on coming “as close as possible” rather than on bringing those diseases to an end. The May 2006 UNAIDS annual report¹ actually does quantify universal access as 9.8 million people on antiretroviral treatment (ART) by 2010. Yet at the current rate—600,000 more people receiving ART each year in addition to the 1.6 million on treatment as of June 2006—we are on course to miss that goal by over five million people.

With no clear targets to work against and diminishing public attention and accountability, urgency is being replaced by gradualism. Ultimately, we need to be building health systems that can deliver HIV treatment and prevention, as well as TB and other services. We need to reach people in rural as well as urban areas; the marginalized as well as the privileged; and children as well as adults. Yet we are at risk of forfeiting what is perhaps our best opportunity to build sustainable health systems through accelerated treatment delivery.

To ensure that stagnation in HIV treatment scale up does not become a permanent condition, this report calls for six specific action points by June 2007:

1. The incoming director-general of WHO, Dr. Margaret Chan, should reassert that agency’s profile and leadership in the fight for treatment access and declare a “3 by 5”-like campaign to reach universal access by 2010.
2. The Global Fund, PEPFAR and other agencies should put clear systems, lines of accountability and guidelines in place to avoid country-level failures to meet goals associated with their programs.
3. Multilateral agencies and country governments should agree on a consensus statement on what “universal access” to treatment means quantitatively for the world.
4. National governments should complete ambitious costed national plans in consultation with people living with HIV/AIDS with specific targets to reach universal access by 2010.

¹ UNAIDS, Report on the global AIDS epidemic, UNAIDS, Geneva, May 2006, pp. 227-228. Available online at www.unaids.org/en/HIV_data/2006GlobalReport/default.asp.

5. Donors should commit to specific year-over-year increases in funding for the Global Fund and other programs to finance the agreed-upon targets.
6. Governments, donors and multilaterals should negotiate lower prices for HIV treatments, particularly newer and second-line drugs.

This is ITPC's third report based on its monitoring of the state of AIDS treatment delivery in six heavily affected countries. As in previous reports, ITPC members based in each country used a standard questionnaire to interview and collect data from government officials, multilateral agency staff, health care providers, activists, and people living with HIV and AIDS (PLWHA) in their countries. For each country we have recommended specific areas where we want to see substantial progress by June 2007. This report finds that:

- In the **Dominican Republic**, treatment delivery has expanded by several thousand in two years and diagnostics are now more accessible. However, fewer than half of those who need ART have access; women and marginalized people receive substandard care; and a proposed new health insurance scheme explicitly excludes PLWHA and the disabled.
- In **India**, the increasing number of people receiving treatment represents only one in 14 of those in need; more treatment sites opened this year (though the number of sites is still insufficient); action is needed to secure access to second-line drugs; pediatric ARV formulations are not widely available; and marginalized groups face significant barriers in accessing ART at government-supported centers.
- In **Kenya**, although national treatment targets are said to be achievable and the PEPFAR program has been praised, the country is grappling with an acute shortage of health care workers, a Global Fund grant at risk, limited ART access for children, and an increasing need for expensive second-line drugs.
- In **Nigeria**, a free treatment policy is being implemented and more treatment centers are open. Yet costs associated with treatment are keeping many from care; the availability of treatment and voluntary testing is not well publicized; care centers remain concentrated in urban areas; and stigma is a significant barrier to access.
- In **Russia**, a rapidly expanding epidemic is being met with increasing government commitment. Yet major access barriers persist, such as a lack of support services for treatment uptake among vulnerable groups, including injecting drug users who represent the majority of those in need. Other barriers include lack of an approved national treatment protocol; poor coordination of provider training; and limited inclusion of civil society input.

- In **South Africa**, activists have persuaded the government to pledge dramatic improvements in its response to AIDS. Public-sector officials must now follow through with swift action to establish widely supported treatment targets; address severe human resources shortfalls; revise national pediatric and other treatment guidelines; and greatly accelerate the pace of treatment scale up.

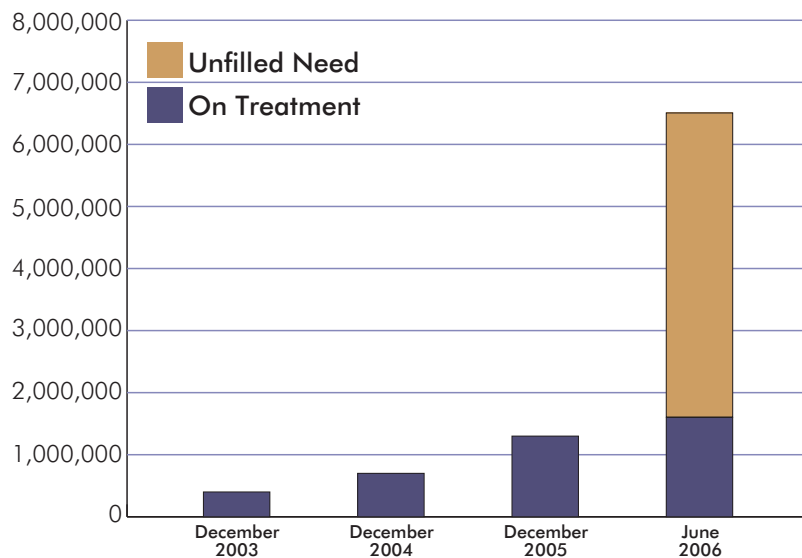
TB is the leading cause of death among PLWHA, yet in **every country** ITPC researchers found inadequate linkage of HIV and TB programs, with numerous reports of HIV and TB clinics that do not provide appropriate testing, treatment or referral for the other disease; limited awareness of TB/HIV drug interactions; and lackluster attention to the escalating epidemics of multidrug-resistant (MDR) and extreme drug-resistant (XDR) tuberculosis.

While each country profiled in this report is unique, their end stories are similar: treatment coverage is rising, yet the modest gains are dwarfed by the number of people who need ART, are not getting it, and thus face imminent death. Governments rich and poor and the global institutions they support must rediscover the urgency of addressing AIDS comprehensively. To do less is to lose a vast opportunity to advance humane systems of care and needlessly allow millions to perish.

The Global Response

The component parts of an international AIDS treatment delivery effort are gradually being assembled. There is evidence that multilaterals and bilaterals are collaborating more efficiently to meet country needs. The Global Fund and PEPFAR continue their lifesaving work, steadily increasing the numbers of people receiving AIDS treatment and other services. WHO is engaged in a range of valuable initiatives, including guidelines for treatment delivery and human resources development. UNAIDS is working on country planning and collaboration across agencies. The Global Fund's Round 6 is now adequately funded.

AIDS Treatment Access in Low & Middle Income Countries



Note: The total need number in the right hand bar is based on WHO data from March 2006

What is missing, however, is the deadline-driven urgency of the “3 by 5” campaign. The forward movement is happening on a timeline that cannot come anywhere close to the internationally affirmed and re-affirmed goal of universal access by 2010. A planning process that was to produce national targets and strategies by the end of the year is delayed in many countries. Connections between TB and HIV programming are not being made fast enough. The slow pace has deadly consequences: each day more than 7,600 people die of AIDS—more than five people every minute.

This fall the ITPC report team wrote the leaders of UNAIDS, WHO, the Global Fund and PEPFAR asking them to outline a vision of how global agencies could collaborate to accelerate ART delivery as part of overall health systems development. The agencies responded with a worthy list of projects that include doing more to help countries resolve bottlenecks; leveraging investments to drive down commodity prices; training and recruiting health care workers; developing needed policies and guidance; and working together more productively. (All responses are available online at www.aidstreatmentaccess.org/responses1106.)

Now it is time for UNAIDS and PEPFAR and the new leadership at WHO and the Global Fund to capitalize on this improving global architecture to get AIDS services to more people much more quickly. Here is ITPC's vision of what needs to happen:

First, global agencies must improve their ability and willingness to identify, diagnose and help address challenges in country programs. In its response to ITPC, UNAIDS has reported progress on implementation of technical support and global coordination mechanisms (such as Joint Teams in countries and the Joint Global Problem Solving and Implementation Support Team, or GIST). But significant improvements are still needed. Country governments are responsible for the underperformance of Global Fund grants. But implementation problems in Nigeria and Uganda are only the most visible recent examples of a global system that has to do a much better job of swiftly addressing problems on the ground.

Second, better linkage of TB and HIV programs is needed at the global level and in countries. The WHO TB and HIV programs have taken clear steps to improve collaboration but too often the response to both diseases still suffers from "silo" mentality. All the TB/HIV work outlined in the WHO paper *Interim Policy on Collaborative TB/HIV Activities*² must be operationalized with greater urgency. Countries should be required to include a TB component in their national plans. WHO's STOP TB program needs to be more ambitious and push for much more rapid scale up of services. GFATM Round 7 grant guidelines should encourage integrated HIV/TB programming.

An epidemic of extreme drug-resistant (XDR) TB is spreading rapidly in southern Africa and threatens the lives of both HIV-positive and HIV-negative people. The level of the response to this crisis has not been sufficient, however. Dr. Margaret Chan, the incoming WHO director-general, must bring the same leadership she demonstrated on avian flu to tackling XDR-TB.

Third, the human resources crisis remains a central barrier to providing HIV services. WHO must put its *Treat, Train and Retain* program into action, setting clear targets and producing more tangible results.

Fourth, free voluntary counseling and testing must be scaled up and more directly linked to care and services. Expanding routine access to testing in medical settings is only one part of what is needed. Since many people do not seek medical care on a regular basis, expanding testing in community-based settings is critical if we are to assist people in knowing their HIV status before they get sick. Furthermore, diagnosis of HIV infection is only useful if it is a trigger for additional interventions. A close linkage between testing and access to ART and other AIDS treatment is necessary. For those who are HIV-negative, knowledge of serostatus is only a

² World Health Organization, STOP TB Department and Department of HIV/AIDS, *Interim Policy on Collaborative TB/HIV Activities*, WHO, Geneva, 2004, www.who.int/hiv/pub/tb/tbhiv/en/.

weak agent of behavior change. Countries need to link testing to HIV prevention programmes and other services to reduce the vulnerability of women, drug users, sex workers, gay men and other populations at greatest risk of HIV infection.

Fifth, WHO and UNAIDS should call upon drug companies to drop prices on second-line medications. Less developed countries should be encouraged to use flexibility in international trade law to expand access to key drugs such as heat-stable lopinavir/ritonavir, other ritonavir-boosted protease inhibitors, and essential second-generation reverse transcriptase inhibitors such as tenofovir.

Sixth, although 380,000 children died of AIDS in 2005, many AIDS drugs are not yet available in pediatric form, the price of existing pediatric formulations of ARVs is still many times higher than for adults and the formulations in existence are difficult-to-measure syrups, often needed in large quantities for older children. In practice, this means that caregivers are forced to measure syrups and cut and crush adult formulations. UNICEF's Unite for Children, Unite against AIDS campaign needs targets, milestones and clear indicators on treatment in order for us to move forward with a real plan to save our children from what is a treatable illness.

Seventh, improvements are needed at the major players:

- ❖ The **Global Fund to Fight AIDS, Tuberculosis and Malaria** should develop new strategies and policies to address grants that are at risk of failure earlier in the grant cycle. If awardees do fail to deliver programmes, alternate means to get these services to people should be identified. We welcome the Global Fund's acknowledgement, in its response to ITPC, of the, "imperative of working closely with our partners such as WHO, UNAIDS, and many others, to ensure that struggling programmes are identified early and that appropriate technical assistance is mobilized... our contribution to this vital process, the Early Alert and Response System, must be strengthened."
- ❖ The new director-general of the **World Health Organization**, Dr. Chan, must carry on the leadership of Jong-wook Lee, her predecessor, who mobilized agency staff and member countries. A reinvigorated and better funded WHO AIDS effort would go far to realize Dr. Chan's priorities of helping women and Africans. WHO must also increase funding support for its drug prequalification program. The director of the HIV/AIDS Department, Dr. Kevin de Cock, should continue to build on his predecessor's commitment to AIDS treatment.
- ❖ **UNAIDS** must drive the country planning process with urgency and by May 2007 all national plans with targets should be delivered and posted on the agency website. UNAIDS must also marshal its staff on the ground to help resolve bottlenecks with program implementation in countries.

- ❖ The incoming **U.S. Congress** must change **PEPFAR** policy so that HIV prevention services are anchored in evidence of what is effective. Current Congressionally imposed mandates undermine access to comprehensive, non-stigmatizing HIV prevention services. Policies that require grant recipients to sign a pledge opposing commercial sex work and that limit condom distribution to high risk groups should also be removed by Congress. PEPFAR should place a premium on developing human resources and building sustainable health systems in focus countries. PEPFAR's reply to ITPC identifies several examples of welcome human resource capacity building efforts, yet the US government as a whole has not given the human resources crisis the attention and resources required. The US Congress must also increase funding for the Global Fund and United Nations agencies responding to the global AIDS epidemic.

In closing, we agree with the point many people have made: that a renewed emphasis on prevention is necessary to make universal access feasible. But scaling up prevention is not a prerequisite for treatment. The care of the sick cannot become reasonable only after we've gotten new HIV infections under control and mortality has driven the numbers of people in need of treatment radically downwards. Prevention and treatment must go hand in hand now as these are inextricably intertwined interventions with their success mutually dependent.

Country Updates

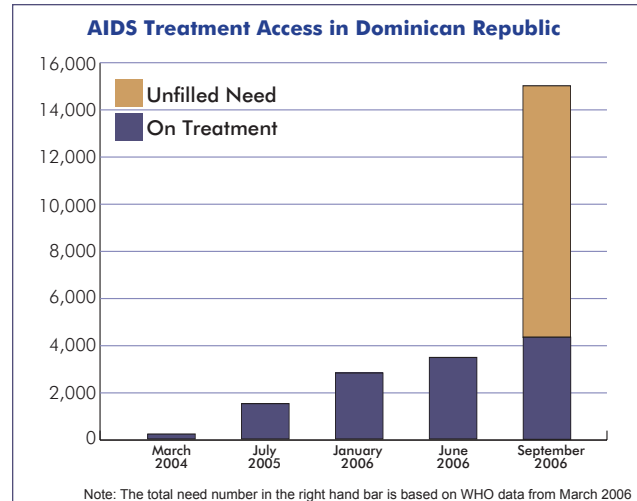
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By Eugene Schiff, , Agua Buena Human Rights Association

During the past two years, access to ART in the Dominican Republic has significantly improved. As late as March 2004, just 210 people were receiving medicines purchased through the public sector.³ It was only after years of delays, due mostly to a slow-moving bureaucracy and government and donor disinterest, that additional resources from GFATM were finally released in 2005 and allocated for the purchase of additional ARVs. This step resulted in no small part from considerable pressure from activists and PLWHA.

Encouragingly, the number of PLWHA accessing treatment increased to 1,500 in July 2005; 3,457 in June 2006; and 4,332 as of September 30, 2006. Even so, more than half of those needing ART remain without it. One important consideration is that ARVs in the national treatment program are currently procured exclusively with resources from GFATM. The grant provides temporary funds for limited treatment scale up, but sole reliance on the Fund exacerbates doubts as to the commitment of the government and donors to the sustainability of treatment scale up and delivery in the future.

The Dominican Ministry of Health and hundreds of local health care workers—physicians, nurses, adherence counselors and activists (many of whom are HIV-positive)—must be recognized for their important contributions in



Visible Progress Needed by June 2007

- Offer free confidential HIV tests and counseling nationwide
- Initiate monthly reporting on ART and diagnostic access and prices of medicines
- Set targets and action plans for treatment scale-up, including to vulnerable groups
- Advocate with drug companies for more affordable prices for first- and second-line treatment, fixed-dose combinations and diagnostics
- Greatly improve coordination between TB and HIV programs
- Improve quality of lab services in public health facilities
- Provide comprehensive HIV and TB services in all prisons, including prevention (i.e., condoms and counseling) and treatment
- Prepare detailed programmatic audits of the GFATM project

³ Most of the 210 PLWA obtained ART as result of a legal injunction initiated by activists against the Dominican government before the Washington, D.C.-based Inter American Human Rights Commission. The commission issued a decision requiring reluctant authorities to purchase ARVs for HIV-positive individuals who first signed onto the legal petition in 2002.

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enabling such progress and expanding treatment access. They have helped save and improve the lives of thousands. Since the last report update in May 2006, more than 1,000 additional people have entered the national treatment program, and the government lists more than 45 centers currently providing ART. For the first time, clinics now exist in most regions of the country, although close to half of the sites are concentrated in a small radius from the capital of Santo Domingo.

Visits to different treatment centers in September and October 2006 revealed that a steadily increasing number of people are able to obtain access to ART. However, several major problems can be identified in nearly every aspect of what the government euphemistically describes as *atencion integral*, or “comprehensive care,” that it strives to provide PLWHA. These challenges can only be addressed with the clear acknowledgement that they are a form of clinical and governmental negligence; as a result, they can all be corrected with better coordination and improved leadership and political will.

This case study discusses key issues that emerged during preparation of the update. Research included interviews; e-mail correspondence; site visits to prisons, hospitals, clinics, the homes of PLWHA, and the offices of community-based organizations; and responses to questionnaires provided to decision-makers at key national and international agencies. While a substantial amount of important information and observations were obtained, key government implementing agencies, notably COPRESIDA (the government agency serving as the GFATM Principal Recipient), were unwilling or incapable of responding to repeated requests for information. That is a serious concern for all involved in the HIV/AIDS response in the country because vital information—particularly that related to resource allocation, target setting, and drug pricing and procurement—is managed and manipulated by a small number of bureaucrats. Clearly there is a need for greater transparency and willingness on the part of government officials to dialogue with those engaged in independent civil society research, monitoring, and advocacy efforts. More thorough engagement would help ensure that serious, inclusive discussions are held and plans are subsequently developed to address the concerns and challenges raised below.

Critical issues affecting treatment access

This section highlights the most important issues regarding treatment availability and access in the Dominican Republic.

Haitians are often the last to access treatment programs

Field visits confirmed that Haitians living and working in the Dominican Republic struggle to receive the most basic health care for HIV infection and other diseases, and many die without treatment. There are almost no recent studies or reliable statistics regarding the number of Haitians living in the

Action points for Dominican Republic ITPC team

- Press for response from government and donors to recommendations
- Disseminate report findings widely among media and PLWHA, to encourage greater debate, monitoring and concrete actions.

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Dominican Republic or in need of HIV care. The Dominican government refuses to systematically collect such data, yet Haitians still serve as scapegoats for spreading HIV in the country. Meanwhile, many HIV-positive Haitians are marginalized and made vulnerable because they live in extreme poverty, are denied basic human rights, and are provided with some of the worst possible health care if they receive any care at all.

Substandard care for women and children

Authorities provide rapid HIV tests to hospitals and maternity clinics throughout the country and waive the cost of the test for pregnant mothers as part of a national PMTCT program. However, little effort is made to provide pregnant women with their test results in a timely fashion. During visits to a number of sites, this report's researchers found that test results are rarely returned on the same day.

In some sites processing the largest volume of tests, physicians and hospital officials claimed that more than half of the women never return for their test results. In many of these cases, some of the most impoverished expecting mothers cannot afford the recurring transport costs involved in traveling to the hospital numerous times. Services are often only available on certain days or during limited hours of the morning. HIV-positive women are then sent to seek follow-up care someplace else altogether, and they are later sent for CD4 tests at yet another separate facility (if they are lucky or persistent enough to even get a test).

One physician said that HIV-positive pregnant women probably receive the worst care of any group of PLWHA. She noted that women are neither offered CD4 tests after being diagnosed with HIV as part of the PMTCT program, nor are they offered ARVs through the program for themselves even if they need them. It appears that serious gaps still remain in every aspect of the PMTCT program.

Privately run specialized outpatient AIDS treatment clinics in Santo Domingo, La Romana and Puerto Plata are now treating thousands with ARVs purchased through GFATM. Yet many of the main public hospitals attending to pregnant women have barely begun to establish, let alone integrate, such programs into their facilities. In many of the largest and most important antenatal centers, even in the capital of Santo Domingo, it remains unclear when (if ever) authorities plan to fully link the two programs and begin providing full combination ART to HIV-positive mothers who need it.

"IDUs don't exist in the Dominican Republic"...or do they?

Research revealed that the prevention and treatment needs of most injecting drug users (IDUs) in the Dominican Republic continue to be ignored by government authorities, including those in the health sector. Officials who should be designing effective programs to reach this population prefer to cover their eyes and argue that drug use does not exist, clinging to their belief that "Caribbean people are scared of needles." Although needles can be purchased cheaply at private pharmacies, there

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are no clean needle exchange or distribution centers at or near the relatively few sites where heroin is bought and sold. They also do not exist in the neighborhoods—located in a handful of major cities—where drug use is already a major social problem.

Most drug users interviewed for this report noted that injecting drugs is a limited and relatively recent—but growing—phenomenon. It is both separate from and linked with other more common and widespread forms of substance abuse involving crack, cocaine, and alcohol. In the Dominican Republic, methadone pills can sometimes be bought and sold on the black market, but no official substitution treatment or harm reduction programs exist. Drug users in care and on the street expressed a wish for authorities to offer less punitive strategies that include harm reduction services; education and awareness raising; and treatment for HIV, hepatitis C, TB, drug addiction, mental health problems, STIs, and other diseases.

Authorities still refuse to acknowledge growing drug use in the country or to launch interventions designed to reach the highly vulnerable and marginalized individuals using illicit substances in potentially dangerous ways. Many government officials and decision-makers shrug the issue aside, and a clinical expert speaking on behalf of National AIDS Program insisted that questions about IDUs be removed from research for this report due to the alleged irrelevance of injecting drug use in the Dominican Republic. Yet according to government data, the percentage of people with HIV who voluntarily report injecting drug use (which is likely an underestimate) has more than tripled in the last five years, from 1.8% in 2000 to 5.7% in 2005.

Lack of treatment access targets

There have been several consultations related to “universal access” organized this year by UNAIDS in the Dominican Republic, but it appears that no comprehensive national targets for treatment access beyond 2006 have been set. An estimated 10,000 to 15,000 PLWHA need access to ART in the Dominican Republic right now, and potentially as many more will need medicines each coming year. Ambitious treatment targets to meet this demand must be set immediately, both nationally and at local levels.

Discriminatory new social security system proposed

Even as it continues to accept GFATM resources for treatment, the Dominican government is designing and promoting a proposed new national social security plan and health insurance schemes that explicitly exclude the disabled, undocumented residents and PLWHA. This issue was highlighted in the May 2006 update report. Although the new social security laws are still being debated and have not been finalized, there has been little progress thus far in ensuring that PLWHA will be covered by the new social security system.

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Access to second-line drugs and salvage therapy exists in theory, but often not in practice

Many of the most effective single-source second-line and rescue therapies are unavailable (including nelfinavir, which is sold illegally through the black market and private sector); very expensive (atazanavir, which costs almost \$500 per month); or procured in very limited quantities in a few sites by government authorities despite lower access prices (such as Gilead's Truvada and Viread). One of the most important second-line drugs, Kaletra (a brand-name combination of lopinavir and ritonavir), costs more than \$200 per month, an unsustainable price five times the cost of the same drug in neighboring Haiti.

In another example of drug companies failing to respond appropriately to the needs of resource-limited countries, Abbott Pharmaceuticals has chosen to sell the remaining stock of an older formulation of Kaletra (which the government has bought and continues to use), and has not yet made available its new heat-resistant version of Kaletra, which does not require refrigeration or to be taken with food. This decision was made despite the country's persistent tropical heat, the limited diet of many PLWHA, and daily power outages nationwide that often render refrigerators useless.

Protease inhibitors usually need to be combined with a drug, ritonavir, which also is patented and manufactured by Abbott. Ritonavir alone costs close to \$2,000 per year in the Dominican Republic, according to government officials. These prices mean that the cost per patient for treatment with ritonavir-boosted combinations becomes 10-30 times more expensive than with first-line generic treatment, which costs as little as \$150 per year.

And finally, there is no resistance testing currently available in the Dominican Republic to scientifically analyze baseline and acquired levels of genotype and phenotype resistance of HIV to different ARVs and drug classes. Such tests are vital to help determine which drugs should be used during instances of treatment failure.

Accessing lab diagnostics: a logistical nightmare for the poorest living with HIV

Access to lab tests measuring CD4 and viral load has improved considerably but remains needlessly complicated for many PLWHA. The tests are also expensive for the government: authorities reported that each CD4 and viral load test costs as much as \$100 to \$200. Furthermore, in many regions, established protocols for lab tests are not being strictly followed. In a hospital in one of the most populous towns in a border region near Haiti, the treatment counselor observed without any apparent concern that only half of the HIV-positive individuals registered in clinical follow-up had received or were recommended for a CD4 test.

The government also claims that viral load tests have now been made available, but a visit to one of the oldest and largest treatment clinics, run by an NGO in Puerto Plata, revealed that none of the thousand or so PLWHA in follow-up have access

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to the tests. In the city of La Vega, hundreds of PLWHA must travel to Santiago en masse on selected dates to get their blood drawn for CD4 tests, an inefficient system that wastes time and money that could be saved if the government arranged for the tests to be done or blood drawn locally and transported to the lab. Access to simple and cheap rapid HIV tests, one of the most critical tools for effective prevention, surveillance, and treatment, has not been prioritized by the Dominican government (including the health ministry and COPRESIDA) or donors.

Lack of coordination between TB and HIV programs

In San Cristobal, a city just outside of Santo Domingo, a new hospital-based referral site for treating multidrug-resistant tuberculosis (MDR-TB) finally opened and began to provide treatment in the summer of 2006. This is a useful step forward, but already the specialized hospital ward is full to capacity, and fewer than 20 (none PLWHA) out of more than 100 culture-confirmed cases of MDR-TB nationwide are currently receiving second-line TB medicines. The others remain untreated, sick, and struggling to fight MDR-TB, a potentially deadly condition both to themselves and to others in close proximity.

Key donors, including USAID, claim that this small, expensive program is the best that can be done in the context of a resource-poor country with limited funds, yet such a program may be doing as much harm as good. A more ambitious approach is needed to reach those most in need, particularly people co-infected with HIV and TB. Interviewees revealed that there is still no coordination between the new MDR-TB referral hospital and prisons nationwide; that there are gaps in the availability of free, confidential HIV testing for all patients in the National TB Program; and that major gaps also persist in TB monitoring and treatment for PLWHA in clinical follow-up through the National AIDS Program. Almost daily there are reports of PLWHA being turned away from public hospitals, particularly if they are sick and poor. When PLWHA are admitted into hospitals, there is often limited space for complete isolation from others who may be sick with active TB. Therefore, PLWHA can become exposed and at considerable risk for developing TB merely by being in overcrowded hospitals.

Substandard lab facilities

Site visits revealed that several regional hospital-based lab facilities (most notably in the provincial cities La Vega and Dajabon) are shabby and neglected. Many lack air-conditioning, so lab workers have no choice but to use fans. This in turn circulates dust that can contaminate lab samples. Improved conditions and higher salaries are essential for effective scale up of these services.

Drastic USAID funding cut expected in near future

Several sources warned that the USAID budget for HIV/AIDS in the Dominican Republic is likely to be cut from the current level of nearly \$9 million to just \$3 million for 2007 and beyond. Furthermore, a significant percentage of U.S. funds that are allocated for prevention are required to be spent on abstinence and

DOMINICAN REPUBLIC

“be faithful” campaigns, as opposed to current projects that realistically focus on vulnerable populations including MSM and sex workers. As a result, important donor resources that for many years have gone to these programs—and ostensibly to strengthen the health system and national HIV, TB and reproductive health programs—will be lost or greatly reduced.

In comparison, meanwhile, the U.S. government is providing close to \$70 million per year for HIV/AIDS programs in neighboring Haiti, where HIV prevalence is comparable to many provinces in the Dominican Republic. These funds are of little benefit to Haitian PLWHA who leave Haiti out of desperation, stigma and poverty to work in the Dominican Republic. Corresponding USAID funding on the level provided to Haiti could go a long way in supporting scale up of treatment and prevention programs in the Dominican Republic.

Need for greater activism

Many individuals interviewed bemoaned the fact there is far less activism now that treatment access has improved in much of the country. Yet numerous new complex issues have arisen as treatment has been rolled out and they may require the close attention of activists. There is a pressing need to expand and improve the quality of a generally weak national ART program currently providing medicines to fewer than 5,000 PLWHA. Yet few PLWHA tend to see themselves as activists, and many are reluctant to challenge authorities and potentially cause problems for themselves, their families and their careers. The lack of PLWHA-driven advocacy means that little consistent pressure is placed on the increasingly large and complacent AIDS bureaucracy or the donors that support it.

Recommendations:

The following recommendations are designed to improve the availability and access of all HIV-related treatment services in the Dominican Republic:

- a presidential decree should mandate free confidential HIV tests and counseling nationwide, thus ending user fees for HIV tests;
- public reports on ARV and diagnostic prices, the number of people being tested, incidence/prevalence rates by site and region, and the total number receiving treatment and CD4 tests should be disseminated monthly;
- transparency should be enhanced regarding all HIV-related budgets, resource allocation, and decision-making processes;
- targets should be set and road maps created with the goal of scaling up treatment for all, including immigrant Haitians, prisoners, pregnant women, children and youth, the elderly, the disabled, sexual minorities, sex workers, people co-infected with HIV and TB, and even those accessing care in the unregulated private sector. Greater attention also should be paid to providing treatment to the unemployed and people living in rural areas, the border region and city slums;

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- solidarity campaigns and resource mobilization are needed to help transport PLWHA to and from clinics and provide food with which to take medicines, improve diets, and feed affected families;
- pressure must be placed on drug companies to provide more affordable access to first- and second-line treatment and the most appropriate lab diagnostics, including the newest and easiest to tolerate fixed-dose combinations such as Atripla (licensed by BMS, Gilead and Merck, and recently approved in the United States) and the protease inhibitor Kaletra (Abbott);
- community health workers should be more directly involved in helping improve infrastructure, logistics, staff hours, and compensation in public-sector hospitals and in laboratory testing facilities used for HIV and TB diagnostics;
- condoms are needed in prisons in tandem with greatly improved HIV/TB surveillance. These steps should be the cornerstones of specially designed prevention and treatment programs that address local needs in all prisons; and
- detailed programmatic audits are needed by GFATM, the largest current donor for HIV treatment in the Dominican Republic, to consider issues such as those raised in this report. GFATM should also seek to identify additional gaps above and beyond the current financial audits, which only measure if money is spent, how and if indicators (often conservative) are reported, and whether there are receipts for all budget items from the Principal Recipient.

INDIA

By Abraham KK, Dr. Venkatesan Chakrapani, M.D., Elango Ram, Alwin S, Ramesh VSG, Jacob John, Indian Network for People living with HIV/AIDS (INP+) Dr. Joe Thomas, FXB International

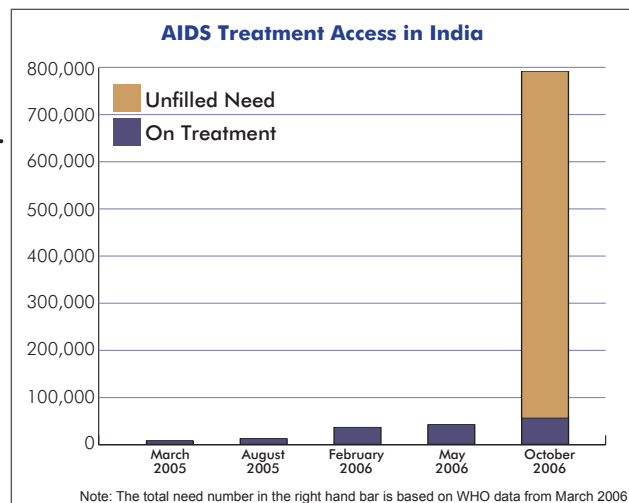
Nearly all international and national agencies agree that more than five million adults are living with HIV in India. There are a wide range of estimates, however, as to the number of people in need of ART. WHO estimated that 785,000 people required ART at the end of 2005.⁴ Yet an estimate provided in June 2006 by staff at India's National AIDS Control Organization (NACO) indicated that only some 380,000 PLWHA in India were in need of treatment, though the timepoint of this estimate was not mentioned.⁵ Though NACO once had a less ambitious target of providing ART to only 180,000 PLWHA by the end of 2010 through the government-supported ART centers,⁶ recently it has vowed to provide ART to 300,000 PLWHA (not including 40,000 children) by the end of 2011 in the third phase of the National AIDS Control Programme.⁷ In its recent global report (May 2006), UNAIDS mentions that coverage still remains well below 10%.

⁴ World Health Organization, Progress Report on Global Access to HIV Antiretroviral Therapy, Geneva, March 2006

⁵ As per a presentation made by Dr. N.S. Dharamshaktu, a project director at NACO, at a conference on treatment access and education and TB/HIV co-infection. The conference was held in New Delhi in June 2006.

⁶ ITPC November 2005 "Missing the Target" report, p. 27. Online: www.aidstreatmentaccess.org/itpcfina.pdf

⁷ Email communication from NACO to INP+ received on Nov 15, 2006 and NACO News (newsletter), Vol. II, Issue 2, March–May 2006. p. 4.



Visible Progress Needed by June 2007

- Establish drug quality assurance system to ensure the safest and most effective ARVs are available at all national ART centers
- Increase government resources for procurement of first- and second-line ARVs
- Negotiate with pharmaceutical companies to bring down prices of first- and second-line drugs
- Establish standardized packaging and labeling of ARVs to facilitate adherence
- Establish procurement and supply chain management plans to ensure uninterrupted drug supply in ART centers
- Develop back-up plans in the event of ARV shortages; for example, facilitate reimbursement to PLWHA who are forced to pay for their drugs out of pocket
- Routinely offer TB screening to all PLWHA and all those who receive HIV-positive test results
- Develop plan and take action to ensure equity in delivery of ARVs, including to members of vulnerable and marginalized groups
- Require state governments to contribute financial resources to ART access in their respective states.

INDIA

At the end of October 2006, according to NACO, a total of 43,897 PLWHA were receiving ARVs in NACO-supported ART centers. A separate PMTCT program provides single-dose nevirapine to HIV-positive mothers and their newborn children.⁸

Number of PLWHA on ART In India (October 31, 2006)^{9*}

Sector	# on ART
NACO-supported ART centers (free ARVs)	43,897
State-supported ART centers (free ARVs)	217
NGO-supported ART centers (free or subsidized ARVs)	3,004
Intersectoral partners, including private-sector firms in the railway, steel, financial services, and defense industries (free or subsidized ARVs, often through insurance schemes)	2,327
GFATM Round II Centers	419 ¹⁰
Total	49,864¹¹

Children and ART

The internationally accepted definition of “child” is any individual below the age of 18. NACO’s reporting format considers children to be those younger than 14. Based on that criterion, NACO reported that 5,596 children had been diagnosed with HIV as of Aug 2006.¹² Yet according to some estimates, there are an estimated 200,000 children in India who are HIV-positive. NACO has yet to formally release the national pediatric HIV treatment guidelines that have been developed in collaboration with the Indian Association of Paediatricians.

NACO is in the process of establishing a trust for affected children and is also seeking to map the children who need care and treatment.¹³ Within the next five years, NACO hopes to reach 65,000 children living with HIV.¹⁴ During the third phase of the National AIDS Control Programme (2006–2011), NACO plans to provide pediatric-appropriate ART to 10,000 children with HIV. The agency has also recently announced that CD4 testing will now be free of cost for all HIV-positive children.¹⁵

⁸ WHO’s prevention and treatment guidelines recommend using multi-drug prophylaxis for PMTCT, but as of October 2006 the Indian government had not changed its policy from providing single-dose nevirapine.

⁹ Email communication from NACO to INP+ received on Nov 15, 2006

¹⁰ This data is provided by NACO. There is a significant discrepancy between this number and the total number receiving ARVs through GF funded sites as noted on the GF website. (http://www.theglobalfund.org/search/docs/2IDAH_59_140_gsc.pdf, page 11)

¹¹ This number differs from NACO’s estimate that a total of 50,000 to 60,000 PLWHA are on ART. The discrepancy exists because there are some undocumented PLWHA on ART, notably those who might be receiving treatment through private-sector hospitals.

¹² See www.nacoonline.org/facts_reportaug.htm.

¹³ Aarti Dhar, “Affected children missing from policymakers’ minds” The Hindu, August 19, 2006. Online: www.hinduonnet.com/thehindu/2006/08/19/stories/2006081900481300.htm.

¹⁴ Ibid.

¹⁵ Aditi Tandon, “HIV test price cut to half” Tribune News Service, November 2, 2006.

Methods used for this report update

1. E-mail communications to NACO and offices of WHO and UNAIDS in India.
2. Report and presentations made at a conference on treatment access and education and TB/HIV co-infection, held June 21–23, 2006 in New Delhi. The meeting was organized by the Indian Network for People Living with HIV (INP+).
3. Analysis of archives of postings in AIDS-India e-forum.
4. Analysis of website content of NACO and other Indian advocacy agencies.
5. Interviews with selected treatment activists in India including HIV-positive female sex workers, IDUs and MSM.

Action points for India ITPC team

- Advocate with NACO to:
 - introduce second-line ARVs in NACO-supported ART centers
 - develop efficient back-up operational plan to avoid shortages of ARVs
 - distribute treatment education materials (especially on ARVs) in local languages in ART centers
- Develop and distribute a plan, in partnership with NACO and other stakeholders, for ensuring equity in ART access in India
- INP+ to initiate a longitudinal study to examine the quality of life of PLWHA in India, including those who receive ART

Status of ITPC's November 2005 recommendations to NACO

1. Order public ART centers to enroll PLWHA even if the patient satisfies only one of the eligibility criteria.

Follow-up: At a national conference on treatment access and education and TB/HIV co-infection, held June 21–23, 2006 in New Delhi, PLWHA from across India stated that doctors at many national ART centers still refused to consider starting ART unless a patient's CD4 count was below 200 cells/mm³. One of the recommendations made at the conference was to "ensure that the current guidelines of NACO clearly indicate that clinical diagnosis of AIDS is sufficient to start ART at all national ART centers."¹⁶

2. Develop a plan to provide second-line regimens

Follow-up: Even though NACO has stated that access to affordable second-line ARVs will be a major problem in the near future,¹⁷ the agency has yet to take concrete steps to provide second-line drugs in national ART centers. Current options are extremely limited, meanwhile. Children's Investment Fund Foundation, a UK-based non profit organization in Tamil Nadu, has provided funds to the Tamil Nadu AIDS Control Society to expand ART to 1,000 people, some of whom will be able to obtain second-line regimens. Médecins Sans Frontières (MSF) is also providing free second-line ART to a limited number of PLWHA in India.

¹⁶ Copies of the June 2006 conference proceedings and additional information can be obtained directly from INP+. E-mail address: inppplus@eth.net.

¹⁷ "NACO wants to ensure adequate supply of second-line drugs for AIDS treatment". Online www.redribbon.org.in/news/april06/025040601.

3. Provide pediatric formulations for ART

Follow-up: NACO is planning to provide “emtri junior”, a pediatric formulation, to children living with HIV. Meanwhile, a majority of children on ART still continue to take adult tablets broken up into smaller pieces, an imprecise and potentially ineffective method. In general, no data exist as to how many children are currently receiving any kind of ART, substandard or not.

4. Develop a policy to ensure equity in ART access

Follow-up: No steps have been taken to ensure equity in ART access to members of vulnerable groups including women, children, MSM, *hijras* (transgendered women), and IDUs. Of the 32,744 people on ART in May 2006 through NACO-supported ART centers, about 64% were men, 31% were women and 5% were children.¹⁸ There is still no specific data as to how many MSM, sex workers or IDUs are on ART through the public sector, and there is no age or gender data for children on ART.

Interviews with HIV-positive sex workers, women, IDUs, and MSM indicate that there are significant barriers preventing them from seeking services from national ART centers. Among the obstacles are fear of discrimination by health care providers as well as by members of their own communities; limited knowledge about ARVs, including a belief among many that ARVs are dangerous and toxic; and, for IDUs, lack of availability of substitution therapies that might help them adhere to ART.

5. Establish enough ART centers across the country to help facilitate universal access

Follow-up: NACO is supporting 96 ART centers by the end of October 2006.¹⁹ NACO had a target to have at least one ART center in each state by “early 2006”, but as of May 2006 only 22 (out of 35) states and union territories had at least one ART center.²⁰ The latest NACO target is to have at least 188 centers by December 2007.

State governments need to contribute to ART access in their respective states

Local governments in only three states—in Jharkhand, Jammu and Kashmir, and Kerala—out of 35 states and union territories support ART centers independent of the NACO-supported ART centers in their states²¹. Because health is a state-level responsibility, the state governments are also accountable for the lack of ART access in their respective states. It is therefore crucial for state governments to provide the necessary resources to increase ART access in their territories.

¹⁸ As per a presentation made by Dr. N.S. Dharamshaktu, a project director at NACO, at a conference on treatment access and education and TB/HIV co-infection. The conference was held in New Delhi in June 2006.

¹⁹ Ibid.

²⁰ Ibid.

²¹ ITPC May 2006 “Missing the Target” update report, p. 16. Online: www.aidstreatmentaccess.org/itpcupdatefinal.pdf Also: email communication from NACO to INP+ received on Nov 15, 2006

PLWHA and TB

The joint action plan of NACO and RNTCP (Revised National Tuberculosis Control Programme) calls for screening HIV-positive individuals for TB infection. Yet according to activists and observations provided by participants at the June 2006 national conference on treatment access and education and TB/HIV co-infection, not all PLWHA are routinely screened or even offered screening for TB.

HIV-positive individuals co-infected with TB also do not always receive appropriate care. For example, government hospitals do not follow WHO's recommendation of providing INH prophylaxis to PLWHA who have latent TB. NACO says it has not implemented this recommendation because it is waiting for the results from a study on the efficacy of INH prophylaxis in preventing active TB among PLWHA. If a PLWHA is diagnosed with active TB, however, treatment is provided as per RNTCP guidelines.

KENYA

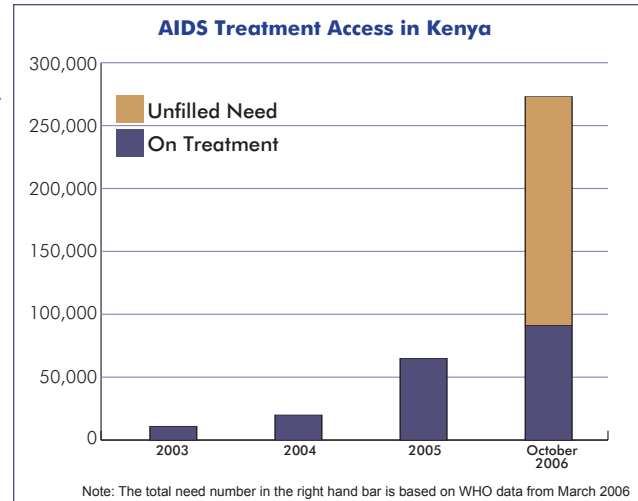
By Elizabeth Owiti, Healthpartners, Kenya
James Kamau, Kenya Treatment Access Movement

Overview

Treatment delivery is increasing in Kenya, though too slowly to reach all those in need. Currently some 263,000 adults and 39,000 children are estimated to be in need of ART yet only 90,000 are receiving it.²² This third treatment report provides a clear picture of Kenya's challenges in scaling up treatment, especially regarding pediatric ART, and offers recommendations to improve the situation. The last six months have seen some progress on treatment scale up, with almost 20,000 more people on ART; however, the inefficiencies and delays in releasing funds by the government remain major barriers to rolling out treatment comprehensively and efficiently.

Primary data for this report was collected using structured questionnaires. Ten people were interviewed, including key stakeholders (such as TB/HIV activists and doctors) and relevant employees from the following institutions involved in HIV/AIDS treatment scale up: WHO, Ministry of Health, National AIDS and STD Control Programme (NASCO), National TB and Leprosy Programme (NLTP), PEPFAR, and PLWHA organizations. Secondary data sources were also used in preparing this report.

Kenya's official goal is to have 190,000 persons on ART—which is assumed to constitute universal treatment—by 2010.



Visible Progress Needed by June 2007

- Expand pediatric treatment access with stepped-up provider training and development of national guidelines on pediatric treatment
- Provide TB screening for all those testing positive for HIV or receiving HIV care; improve linkages between HIV and TB programs
- Urgently address human resources shortfall through expanded staff recruitment and better compensation
- Promote task shifting in provision of AIDS treatment; recruit, train and support community members to provide basic treatment-related services
- Lift IMF and World Bank restrictions on hiring of health care workers
- Build linkages between PEPFAR and government programs
- Government to develop 10-year plan to sustain treatment delivery
- Government must more efficiently release funds already received

²² Kenya's HIV/AIDS Prevalence rate declines to 5.9 percent, People's Daily Online, October 13, 2006

The country is on track to meet this goal. But as noted above, the true number who need treatment today is over 300,000, so the treatment goal must be raised. The likelihood of success will be increased if treatment services are decentralized, more funding is secured, and the government's commitment increases.

Treatment access for children

HIV-related mortality rates among Kenyan children are very high, yet children's access to ART is still limited. In particular, the youngest HIV-positive children are least likely to be on ART—most of the children on treatment in Kenya are aged five years or older. The main reasons for limited treatment access for children are listed below.

- **Clinicians' lack of confidence, fear, and reluctance:** Treatment has been provided mainly to adults, or to children through research studies. Doctors are not well trained in pediatric treatment.
- **Conservatism and presumed complexity:** Pediatric ART is seen as a niche for specialists; as a result, lower-level health care workers are sometimes reluctant to start children on ARVs due to presumed complexity.
- **Inadequate health care worker training:** Initially, training programs on ART management for clinicians were largely theoretical and adult-focused. Recent scale up activities have included treatment training specifically for pediatric ART management, and private practitioners have also introduced practical trainings. Clinician training remains inadequate to meet the demand, however.
- **Failure to observe recognized treatment protocols:** WHO treatment standards and stages are sometimes not fully used. Based on past training and practices, some clinicians still insist on CD4 tests as a prerequisite for starting treatment even when the child is in stage three and is therefore clinically eligible for ART.
- **Limitations on diagnostic tests and procedures:** Diagnosis of HIV in children younger than 18 months old is not possible using the normal rapid tests. PCR tests can diagnose HIV in children younger than one month, but there are only five laboratories with PCRs in Kenya. They are primarily used for research purposes only.

Action points for Kenya ITPC team

- Advocate for improved efficiency and equity of HIV/AIDS spending to targeted groups
- Hold consultative meetings and seminars with representatives from the parliamentary health committee, the health ministry, the treasury, development partners and civil society
- Monitor progress and advocate for the allocation of 15% of the national budget to health, as per the Abuja Declaration.
- Hold press conferences to formally unveil the report and discuss its contents and recommendations with the media.
- Advocate for increased relevant theoretical and practical pediatric ART training of doctors, clinical officers and nurses. Push for increased donor funding for these trainings and for the government's involvement.

Recommendations for improvement:

- **Provide practical training:** The government and donors should support short theoretical and practical training including internships during which clinicians learn to treat children and are supervised by specialists. This will build clinicians' confidence in providing pediatric services.
- **Decentralize and demystify pediatric ART:** Pediatric ART prescription and management should be decentralized from pediatricians to clinical officers and nurses. In Kenya, a majority of children do not see a pediatrician, a situation that makes pediatrician-directed treatment difficult to implement on a wide scale. Pediatricians should not be the sole providers of treatment.
- **Establish comprehensive laboratory network for infant diagnosis:** Following a country-wide mapping exercise, a network system for sending samples to clinics sites with PCRs should be established. At the same time, the number of PCRs nationally should be expanded.
- **Provide easy-to-take combination therapy:** Pediatric ARV formulations are abundant through projects supported by PEPFAR and the Clinton Foundation. In fact, existing supplies of syrups may expire because so many eligible children are not on treatment. Beyond the supply and demand issues is a larger problem, however. Current formulations, including syrups, are not optimal. For one thing, children must take several syrups, and ARV tablets intended for adults are often broken into smaller pieces for older children. Care providers therefore experience hygiene, dosing and administering problems that are compounded by a lack of policy as to the recommended age at which children should use syrups or tablets. These problems and complications would be greatly reduced if children-specific combination therapy was produced and made available.
- **Complete development of children-specific ART policy:** There is one comprehensive national ART policy in Kenya that addresses treatment for both adults and children. However, there are no specific national guidelines on access to treatment for children. Such a policy is currently in development and the government of Kenya should fast track its completion.

TB/HIV integration

As a policy, all persons who test HIV-positive should be screened for tuberculosis and provided treatment if needed. Since 2005, valiant efforts have been made to target HIV-positive individuals to be screened for pulmonary TB. Sixty-percent of all TB patients were offered HIV testing and the National TB and Leprosy Program (NTLP) was notified of all identified TB cases. NTLP has reported that as of October 2006, 30% of patients co-infected with HIV and TB were on ART.

However, appropriate linkage of TB and HIV services is not occurring in all health care centers. Rural areas fare worst due to high patient loads and lack of laboratory and X-ray facilities. When the government changed policies and scrapped user fees, 51 laboratories were closed down because they were no longer profitable. The poor quality of TB treatment provided by some health care institutions is another problem; in certain hospitals, for example, health care workers are deployed to TB clinics when these workers are being disciplined.

Recommendations for improvement

- **Greater commitment to coordinated services:** There is an urgent need for political commitment and increased resources for a variety of TB/HIV services, including staff salaries, drugs, reagents and equipment. Also needed is increased TB/HIV social mobilization to encourage individuals to seek and accept treatment. TB must be destigmatized within health care institutions. Moreover, the government should provide treatment and testing tools within sick people's walking distance.
- **Legislative changes are needed:** There is a need for TB-control legislation to compel private hospitals to offer proper treatment; ensure provision of the highest quality medicine; and direct the government to make TB drugs available to all sectors, including private providers, free of charge.

WHO and treatment scale up

Appreciation was voiced for the role of WHO in treatment scale up in Kenya. Most local observers agree that WHO's public health approach to treatment delivery is appropriate for resource-poor settings such as Kenya.

WHO is seen as a good technical resource to the country. It has supported the development of the national ART delivery plan, helped build the capacity of health workers in the rational use of ARVs, and assisted in monitoring and evaluating activities. Finally, WHO is supporting the development of procurement and supply management systems. Kenyans viewed the "3 by 5" initiative as an important effort that facilitated increased treatment scale up, even though the target was not achieved.

UNAIDS

UNAIDS helped create the National AIDS Control Council (NACC), the government's main body dedicated to facilitating access to treatment and prevention. Yet most respondents did not fully understand UNAIDS' role. It should be noted that the process for setting targets for universal treatment access, which was managed by UNAIDS, was consultative. The target has been set at 190,000 on ART by 2010. As noted above, this target is too low given the number of people who need treatment now.

Health care systems

One of the main bottlenecks to ART scale up in Kenya is the acute shortage of trained health workers, especially in rural areas. Kenya also has a substandard health system infrastructure in general and lacks adequate resources to improve it. Emphasis is now being placed on recruitment of additional health staff. In 2006, some 1,600 middle-level health care workers were recruited for the health sector by donors, mainly PEPFAR and the Clinton Foundation. Other efforts to build health workers' capacity are ongoing. Standard treatment guidelines have already been finalized and disseminated.

Sustainability

The health care sector in Kenya collapsed under “structural adjustment” programs initiated by multilateral lending agencies. Only recently has renewed attention been given to strengthening the health sector. Treatment scale up is occurring within the existing health facilities and has been an emergency approach to save lives. The sector is heavily dependent, however, on donor support and receives minimal resource allocations from the government.

Recommendations for improvement

- **Comprehensively build capacity:** The human resource challenges need to be addressed comprehensively, thereby including recruitment, deployment, training and retraining, mentorship and motivation. All clinical officers and nurses should be trained on ART management. Health systems infrastructure and training institutions should be improved. Pre-service as well as in-service training of health care workers should be strengthened.
- **Decentralize:** Some tasks related to ART, such as routine follow-ups and counseling, can be carried out by lay community workers, if properly trained and supported by referral systems. Decentralization should be two-fold: within health care institutions—i.e., task-shifting from specialists to clinical officers and nurses—and outside these institutions to include community workers to ease the burden on medical personnel.
- **Lift the IMF and World Bank ban on recruitment:** The government should prioritize its budgetary allocations to ensure that more health workers are hired and retained to ensure treatment scale up. At the same time, the International Monetary Fund (IMF) and the World Bank should remove all restrictions on the hiring of health care workers.

PEPFAR's impact

All respondents positively assessed PEPFAR's role in increasing treatment access in Kenya. PEPFAR is the single largest donor for treatment services. Those interviewed said it has made tremendous contributions, providing both technical and financial support for ART management, treatment guidelines, and training of health care workers. According to a WHO representative, "PEPFAR has done a commendable job and increased resources. The '3 by 5' initiative would have been meaningless without it." Similar praise was offered by a Kenyan treatment activist: "Without PEPFAR we would have not been where we are: over 60% of people on ART receive ART directly from PEPFAR and even those not on PEPFAR ART still receive other forms of PEPFAR support. It has invested a lot of resources in the country, has a comprehensive treatment set up and in fact the government is learning from it."

PEPFAR is structured to collaborate well with the government and local institutions, working within government systems and following the government's health sector plan and treatment guidelines where they exist. PEPFAR's decision-making process is consultative, involving NACC in the Office of the President, the National AIDS and STD Control Program (NAS COP) in the Ministry of Health, and their local partners. Although PEPFAR provides funds directly to its partners and for ARV procurement, all its treatment activities are in line with the government's guidelines, plans and priorities. It also supports government structures.

The evidence of PEPFAR's successful collaboration can be seen in the significant increase in access to treatment, greater availability of resources at the community level, improved health care capacity at all levels, and strengthened health care facilities. Several health care centers now have treatment and laboratory capacity for ART management. PEPFAR supports both public- and private-sector HIV/TB treatment initiatives and is efficient in funding disbursement—especially in comparison with the government's slow-moving bureaucracy.

PEPFAR largely supports its partners directly through a contractual system that is outside of the government. As a result, the government is only able to coordinate with the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID), and not with their implementing partners in-country. This sometimes leads to confusion because the government may not be able to identify the implementers.

Sustainability

The whole approach of ART in sub-Saharan Africa is financially not sustainable, although the current systems will continue so long as money continues to flow. AIDS services in many of the region's nations are basically donor-driven, just as many countries rely on external aid and loans to manage their economies. Currently, most of the funding for HIV/AIDS treatment and management comes from partners,

including PEPFAR, GFATM and the Clinton Foundation, and donors such as the Bill & Melinda Gates Foundation. In Kenya, the government's resource allocation is minimal. To make treatment more sustainable the government must take the leadership role by coordinating and negotiating with all donors and partners on both a medium- and long-term basis. The government must allocate its own resources and efficiently facilitate the implementation program.

"African governments are not financially sustainable and hence how do we expect systems under them to be sustainable?"

— One respondent

Recommendation for improvement

- **Plan for sustained treatment:** Once started, ART must to be provided for a patient's lifetime. The government and its partners must come up with a medium-term arrangement to support treatment for 10-15 years as the government devises a longer-term plan to ensure treatment sustainability.

GFATM grants

The GFATM-funded program is working rather slowly and is seen as dysfunctional, though there are signs of improvement. There is still lack of government accountability within the Kenya program. After funds are received in the country, their disbursement can take as long as one year, which translates into a major delay in delivery of services. The GFATM program in Kenya is at risk and the government should address the concern by improving accountability and the disbursement of funds.

The uncertainty with GFATM is a major issue. The poor quality and slow speed of the GFATM programs mean that the country risks not receiving expected payments on current grants. For example, in Phase 1 of the GFATM grant the Kenyan government planned to put 53,000 people on ART. But because the grant was reduced in the wake of its failure to meet grant goals and deadlines, the government had to reduce the target to 42,000. The Country Coordinating Mechanism (CCM) is functional and meets regularly. It needs to work with activists and push the government to release GFATM monies efficiently and to the target groups implementing treatment programs.

Second-line ART

Second-line ARVs are available in Kenya, but only the PEPFAR program has purchased these drugs. Second-line therapy is expensive, as noted in these prices from October 2006:

KENYA

- Kaletra (lopinavir/ritonavir) capsules = \$50 per patient per month
- Abacavir (diagen) tabs = \$80 per patient per month
- didanosine (DDI) 100g= \$15 per patient per month
- tenofovir 300 mg TQBS = \$20 per patient per month

The country is in the process of bringing its treatment protocols in line with the WHO essential package on ART delivery.

NIGERIA

by Bede Eziefule, Center for the Right to Health
Olayide Akanni, Journalists Against AIDS (JAAIDS) Nigeria

Overview

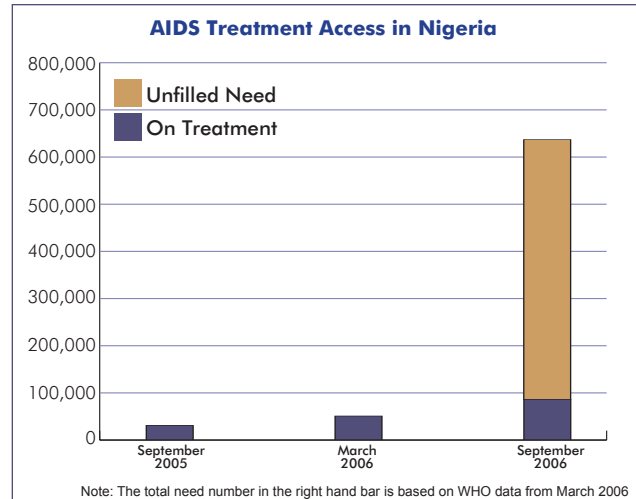
In 2005, Nigeria's goal was to place 250,000 people on ART by mid-2006. Yet by September 2006, it was only a little more than one third of the way toward that goal. Although the number of treatment centers has doubled over the past year, treatment uptake has lagged behind projections. Among the obstacles limiting uptake have been insufficient attention to opening centers outside of major urban areas; the negative impact of HIV-related stigma and discrimination on those who might otherwise seek treatment and care; poor linkage with VCT centers; and persistent limitations in human resource capacity.

About this report

The research process involved a literature review of existing reports, roundtable meetings and policy discussions as well as interviews with 13 individuals drawn from diverse backgrounds. Those interviewed included PLWHA and beneficiaries of care; care providers; representatives from multilateral organizations and international NGOs; and members of vulnerable groups, including sex workers and MSM.

Status of treatment

Adult HIV prevalence in Nigeria in 2005 was estimated at 4.4%, a slight reduction from the 2003 estimate of 5%.²³ In January



Visible Progress Needed by June 2007

- Greatly expand treatment access in rural areas by providing care at more rural health facilities and through NGOs
- Build capacity of health care workers at the various health facility levels on effective ART administration
- Make treatment affordable by providing free access to monitoring tests and other necessary services
- Scale up access to a comprehensive treatment package that includes treatment literacy, ARVs, lab monitoring, adherence counseling and psychological support
- Institute TB screening for all those testing HIV-positive or receiving HIV care
- Publicize availability of HIV testing and treatment sites

²³ Source: National AIDS and STIs Control Program (NASCAP)

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2006, an estimated 50,000 PLWHA were on treatment, but by September 2006 the number had increased to about 85,000. More specific data on treatment access, available as of June 2006, include the following:

- an estimated 100,000 people were accessing PMTCT (from 2002 through June 2006);
- 201,378 people had access to VCT²⁴ (from PEPFAR sites between 2005 and June 2006);
- 97,701 people were receiving palliative care services (from 2005 through June 2006); and
- 1,499 health personnel had been trained (from 2005 through June 2006).

Action points for Nigeria ITPC team

- Contribute to promoting awareness about existing treatment sites and VCT centers through the media, PLWHA networks, civil society groups and relevant stakeholders
- Partner with PLWHA support groups, treatment advocates and the Treatment Action Movement to promote treatment literacy

Steps toward universal access

Universal access consultations were held in February 2006. With the assistance of UNAIDS, the Nigerian government developed a road map toward achieving universal access by 2010.

Among Nigeria's major goals are to increase access (by 50% by 2009) to comprehensive gender-sensitive prevention, care, treatment and support services for the general population, PLWHA and orphans and vulnerable children, and to mitigate the impact of HIV and AIDS on the health sector.

Nigeria also subscribes to the regional targets set by the African Union during the Abuja +5 Summit held in Abuja, Nigeria in May 2006. The regional targets aim to achieve universal access by 2010 as follows:

- by ensuring that at least 80% of pregnant women have access to PMTCT and ART services;
- by providing treatment access (particularly ARVs), care and support to at least 80% of those in need, including children; and
- by providing at least 80% of target populations with access to VCT.²⁵

The African Union at its May meeting had agreed that the regional targets are to form the basis of country-specific targets that need to be set by December 2006.

²⁴ This number refers only to those receiving VCT services through PEPFAR-supported projects.

²⁵ Abuja Common Position and Call to Action, May 2006.

Treatment protocols

The country's treatment protocols are currently being revised in line with WHO's PMTCT and ART-delivery guidelines. Over the last three months, WHO began collecting statistics from the various treatment sites in Nigeria as part of an ongoing treatment facility assessment.

Progress to date

Expansion of treatment services

By June 2006, more than 75 treatment centers had been established. That was more than double the number from the previous year. The expansion of treatment sites has also contributed to making treatment more accessible to PLWHA in other states across the nation. In particular, the free treatment policy announced by the president at the end of 2005 has contributed to an increase in uptake of treatment services.

Coordination of data collection

The National AIDS and STIs Control Program (NASCAP) has set up a treatment harmonization working group with a mandate of coordinating treatment activities in the country. The forum brings together the various partners providing treatment in Nigeria (including PEPFAR, GFATM and the government) to update one another on the number of clients receiving treatment services—such as ART, PMTCT and palliative care—as well as on plans for scaling up and challenges encountered so far.

The working group compiles the data and presents a report to stakeholders at a quarterly forum convened by the National Action Committee on AIDS (NACA).

TB/HIV coordination

A National Working Group on TB/HIV collaboration was set up in July 2006, and a few states are currently piloting TB/HIV integration at service-delivery level. Several ART centers are now located adjacent to or nearby centers providing DOTS services for TB patients.²⁶

Yet at the same time, screening for TB for all HIV-positive persons is not the norm. Often, PLWHA are referred to TB clinics for screening only on the basis of clinical evidence. Diagnosis of TB using sputum microscopy in PLWHA also remains a major challenge because these tests often are not sufficiently sensitive to detect TB in PLWHA.

²⁶ DOTS refers to "directly observed treatment, short course". It is WHO's recommended TB treatment strategy.

What needs to be done?

Nigeria fell far short of meeting its goal of placing 250,000 on treatment by mid-2006. As has been noted, some progress was indeed made, but the unmet goal indicates that efforts must be redoubled to address the obstacles to rapid scale-up.

Provision of a comprehensive, affordable treatment package

While ARVs are free in many treatment facilities in Nigeria, the costs of diagnostic tests often are not. Patients still have to pay for these services in government centers and many are unable to afford them. Patients sometimes interrupt treatment once they feel better, often because they are not aware that such a step is inadvisable and potentially dangerous. Clearly, a “pill approach” to treatment for PLWHA will not suffice. Measures need to be put in place to ensure that a comprehensive treatment package—including treatment literacy, provision of drugs, regular laboratory monitoring, follow up, adherence counseling, and psychosocial support—is provided to PLWHA free of charge.

Scaling up uptake of VCT services

In some states with several ART centers, uptake of ART services is still limited. This low demand for treatment stems in part from low demand for VCT services. Strengthening the uptake of VCT is one sure way of creating awareness and encouraging individuals to know their HIV status. VCT centers should also include a client-referral mechanism to create synergy between VCT and treatment services. Treatment scale-up must feed into a structured plan to increase access to and demand for VCT services.

Addressing stigma and discrimination

“I know of a company that provides free treatment for its staff living with HIV, but staff would rather go to government centers and other private care providers to access treatment. This adds great strain to the public sector even as the private firm’s own drugs waste away.”

— PLWHA

Stigma and discrimination remain major barriers to increased and consistent access to treatment. Several care providers noted that even in instances where care is readily available, PLWHA often choose not to access treatment at a nearby site and instead go to distant locations to avoid being recognized by colleagues, family members and friends.

There is great need for comprehensive and sustained awareness campaigns about HIV. These campaigns should include in-depth information about transmission, risks and treatment specifics—and they should seek to engage family members and other individuals in helping support PLWHA on treatment.

Inequitable distribution of treatment centers

Treatment centers are still largely concentrated in some regions in the country and expansion efforts have continued to focus on large cities. For instance, the Federal Capital Territory has 12 ART centers, yet some states only have one center. Even within a state, PLWHA living in rural communities often need to travel hundreds of kilometers to access treatment. ART services should be decentralized to secondary and primary health care facilities as well as community-based NGOs in order to make treatment more widely available. This would also help reduce the travel-associated costs of accessing treatment. The necessary infrastructure must be put in place to enable health care facilities at lower levels to deliver standardized care.

Lack of awareness about treatment services

Access to treatment for vulnerable groups is hindered mainly by lack of awareness. In some cases up to 60% of clients currently accessing care are women. Although some awareness-raising and prevention-outreach programs exist, sex workers and members of other vulnerable groups (including IDUs and MSM) have inconsistent knowledge and information about where to access HIV prevention and treatment services. They are also not normally targeted as part of treatment-awareness efforts. Specific programs aimed at creating awareness of existing treatment sites need to be developed.

Strengthening infrastructure and technical capacities

The infrastructure of secondary and primary health centers requires upgrading if they are to serve as points of delivery for ART. These centers also typically lack sufficient human resources and appropriately trained staff to meet such a challenge.

Currently there is a focus by HIV care implementers, including those supported by PEPFAR and GFATM, on capacity building, drug supply and laboratory support. However, the government's ability and inclination to address key human resources issues, particularly in the health sector, continue to lag. It should also be noted that shortfalls also affect individuals not directly involved in medical care. For example, the number of adequately trained counselors providing psychosocial support to HIV-positive patients is far lower than is needed.

Maximizing the effectiveness of existing staff and using resources that are already on the ground should be viewed as options for coping with the problem, as the answer does not always lie in hiring additional staff. Reallocation of staff to treatment centers and reconsidering where resources should be deployed more efficiently should also be top priorities for policy makers at the Ministry of Health. The application of decentralized nurse-based models, which have had demonstrated success in delivering treatment and care in many other countries, could also be a useful option to address the human resource needs at lower levels.

Limited access to pediatric ARVs and second-line treatment

The National HIV AIDS policy (2003) includes strategies for implementing a comprehensive and holistic approach to treatment care and support for children infected and affected (HIV orphans) by HIV. The pediatric arm of the ART program commenced in 2005, but access to pediatric treatment is still limited in some treatment centers.

A number of pediatric formulations (syrup form) are being produced by local pharmaceutical firms. Presently, there are no fixed-dose combinations available for children.

Access to second-line drugs is also limited. In July 2006, Médecins Sans Frontières (MSF) began offering the heat-resistant version of Kaletra (a brand-name combination of lopinavir and ritonavir) at its sites in Nigeria. Other treatment providers including PEPFAR and the federal government also offer drugs such as tenofovir and didanosine. However, these drugs are not readily available in all of the country's treatment centers.

In conclusion, though increasing availability of pediatric ARVs and second-line drugs is essential, it is also vital to provide appropriate guidelines for administering these drugs as well as building the capacity of providers responsible for ART delivery.

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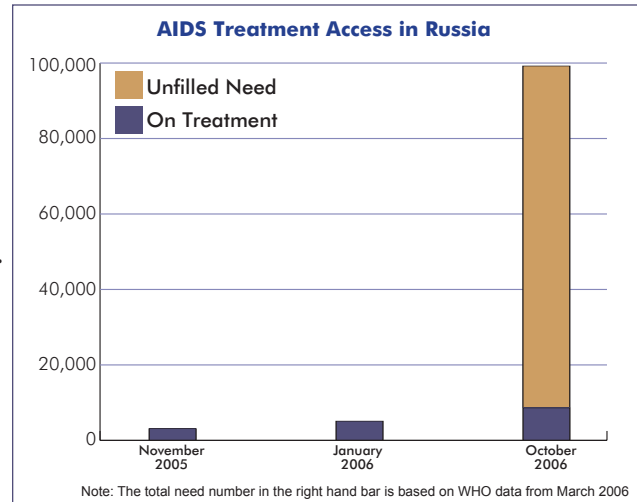
by Shona Schonning, Community of People Living with HIV/AIDS

Introduction

Russia is still home to Europe's largest epidemic and one of the fastest growing epidemics in the world. It is also home to Europe's lowest level of access to ART based on the percentage of those in need.

As of October 1, 2006, some 353,000 cases of HIV infection had been officially registered—although UNAIDS estimates that the true number of PLWHA in Russia is as high as 1.6 million. The Ministry of Health and Social Development (MoHSD) estimates that currently only 19,147 people are in need of treatment and that 100,000 will be by 2010. WHO, meanwhile, estimates that 100,000 people are already in need. As of October 2006, a total of 8,502 PLWHA were receiving treatment; which represents less than 10% of WHO's estimate of need.

The Russian government has expressed a commitment to achieve universal access, however, and it has embarked on an effort to scale up access to treatment. Currently the supply of drugs and lab equipment in Russia seems to be adequate at least in the short term, but there remain major challenges in making those supplies accessible. This report, based on a review of relevant documents and interviews with key figures from the governmental, non-governmental, business sectors as well as PLWHA, aims to highlight the key changes and challenges seen over the past year.



Visible Progress Needed by June 2007

- Notify the public of treatment availability through mass media and vulnerable groups through outreach and other client-centered services
- Strengthen harm reduction, drug addiction treatment and other services for vulnerable groups
- Establish credible baseline estimate for those who need treatment and national level universal access targets
- Finalize HIV treatment protocol
- Improve coordination of health care personnel training
- Significantly improve drug tendering process to end stock outs of AIDS medications
- Clarify customs procedures to avoid unnecessary hold up of drugs and other materials

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Moving from a problem of supply to a problem of demand

“Next year will be chaos—there will be a bunch of drugs in the AIDS centers and no patients.”

— Pharmaceutical company representative

Within the next year, Russia’s national program expects to treat 30,000 people, in addition to those to being treated by GFATM projects. The biggest problem may be a simple one: finding enough patients to take advantage of treatment services to be offered. In the regions where ART is available already, treatment uptake has been lower than expected. Observers report that doctors often ask, “What can we do if they don’t want to be treated?” The problem is not that PLWHA do not need or want to be treated but that services are not adapted to their needs and that people do not even know that treatment is available.

Action points for Russia ITPC team

- Push for national indicators and targets to be set
- Work with PLWHA activists to continue to monitor the scale up effort
- Promote the scale up of treatment literacy and peer support services

A representative of the Russian legislative assembly noted, “Many don’t know that treatment is available and is free...The state television channels should be doing it...we are not using them the way we should be.” Another respondent noted, “The potential role of NGOs in attracting new patients is underestimated.” Harm reduction outreach and client centered services for IDU which has proven successful in prevention of HIV transmission must begin to focus also on encouraging treatment uptake among IDU. Successful models for this must be studied and scaled-up. Attracting and retaining patients will also require reducing stigma among health professionals. When IDUs or representatives of other vulnerable groups are treated with respect in the medical setting they will be motivated to seek out necessary care and support.

Social services

“It was not too long ago that we heard the argument used against scaling up treatment in Africa—that Africans can’t tell time because they do not wear watches, but thankfully this theory was discounted. Of course adherence in Africa has not been perfected, but seeking and understanding the real barriers to implementation, instead of finding excuses for inaction, can lead us to solutions. The same is true for IDUs in Russia.”

— Jill Costello, Boston University

“Radical improvement in drug addiction treatment including access to substitution therapy is necessary to make universal access a reality in Russia.”

— PLWHA activist

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Provision of adequate social services to insure treatment uptake and adherence is one of the biggest challenges facing Russia. Drug addiction treatment services are antiquated and opiate substitution therapy is still illegal in Russia. Civil society does not appear to have a clear advocacy strategy to change this situation and should develop one immediately. The vertical nature of the AIDS center system limits referral services and integrated care. There are regions in Russia where integrated services have been piloted and these approaches must be rapidly scaled up. Also, some regions, especially those targeted by the GFATM round 3 project have developed client-oriented services incorporating work of multidisciplinary treatment teams, a case management approach, promotion of treatment literacy and peer support programs. These approaches must be advocated and scaled up rapidly

Commitment

The year 2006 marked dramatic change in Russia's approach to the epidemic. Even President Vladimir Putin publicly emphasized the need for change, remarking, "It [HIV] demands an adequate response—action rather than observation." At Putin's initiative, the issue of infectious diseases, including HIV, was put on the agenda of the 2006 Group of Eight (G8) summit, held in July in St. Petersburg. The government also created a high-level inter-ministerial and multisectoral Coordinating Commission on AIDS to help guide the response. Officials at the highest levels in the MoHSD have publicly embraced the drive to provide universal access. One of the most telling changes was that this year the MoHSD's budget for HIV was 20 times larger than last year.

Coordination

New challenges have accompanied the new budget and commitment from above. The national program aimed to provide ART to 15,000 people in 2006, but the initial tenders did not yield contracts for the purchase of a full first-line combination and drugs did not reach Russia's regions until November. As of this report's preparation the drugs had not yet reached many regions. As one respondent noted, "We saw this year a complete failure of the system. The money came in but the system was incapacitated. They tried to use existing procedures which weren't designed for a program this size."

The management structure within the ministry remains diffuse, without a clear locus of responsibility. Lines of command between the regions and center remain unclear. AIDS care is still managed through a vertical system that is not only problematic in terms of providing comprehensive care at the service delivery level but limits the degree to which the scale-up effort contributes to the strengthening of sustainable health systems capacity.

According to Dr. Ruslan Khalfin, a deputy minister at the MoHSD, “The need to provide universal access to services requires improved coordination and harmonization of our efforts...the ‘Three Ones’ principles on coordination are essential.” Attempts to meet these principles have yielded some significant progress, but there are still hurdles to be overcome. In October, the government established the Governmental Commission on Prevention, Diagnostics and Treatment of the Disease Caused by HIV-infection as a high-level multisectoral coordinating body. This was a big step forward, but the civil society representatives on the committee were not chosen by civil society; instead, they were selected by the government. Moreover, there is not an official PLWHA representative on the committee. It will be vital for the nation’s civil society and PLWHA networks to hold representatives accountable and to push for the meaningful involvement of PLWHA and vulnerable group representatives.

Targets and monitoring and evaluation (M&E)

Some significant progress has been made in developing a unified M&E (monitoring and evaluation) system. In the national program, progress has been made by creating a national MI Information system for gathering information on new registered cases, the effectiveness of treatment, and the extent and effectiveness of prevention activities. Some of the work done through the GFATM Round 4 project on monitoring is likely to be integrated into this system, which would be a positive development because it captures information about ART access among vulnerable groups. Existing methodologies for civil society monitoring of drug pricing, equity in access, and national budgets are rarely used in Russia. Civil society capacity to engage in the monitoring process should be increased.

Preliminary universal access targets for 2010 were set during a national consortium in December 2005. Civil society representatives including PLWHA were present, although they were not briefed about the target-setting process ahead of time. In November, 2006, during a meeting of representatives of the Commonwealth of Independent States, regional targets were set but national targets for many countries in the region including Russia have not been established. Civil society should push governments to set targets and should participate in the process. In Russia where equitable access by stigmatized vulnerable groups like IDUs is problematic, indicators and targets for access by these groups should be established. It will also be vital to establish a clear baseline—as noted in the introduction, the MoHSD claims that 19,147 need treatment while WHO estimates that 100,000 need treatment.

Equity

In Russia, access to PMTCT is over 90% for newborns and over 85% during labor. Treatment access for children is also relatively good. In fact, children were generally not affected by the series of treatment interruptions experienced throughout the

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country in 2006. This is of course good news, but access for Russia's vulnerable populations is disproportionately low. Access for IDU and for prisoners is lower than average. Russia does not have a policy on equity. Such a policy would facilitate the development and promotion of targeted interventions to promote access among vulnerable groups. The lack of a policy means that information on equitable access is not available. Estimates of the proportion of those on ART who are IDUs range from 5% to 50%. Given that they account for a considerable proportion of PLWHA, their access to treatment services is obviously not equitable.

Treatment protocols

Russia still does not have a treatment protocol for HIV. A total of 51 normative documents that were developed in cooperation with WHO and UNAIDS are either waiting approval or being re-worked by the MoHSD. "Everyone's waiting for these documents" said one respondent. Review and approval of the documents are delayed largely because of insufficient human resources capacity within the MoHSD. Once approved, these documents must be distributed to Russia's regions and the true human resources capacity building will begin. "It will take years," said one respondent.

Human resources

A major challenge centers on ensuring adequate numbers of personnel to provide HIV-related services, including treatment. "They recommend that each doctor should treat not more than one hundred patients. Our AIDS center will need to provide treatment to 1,300 people and we don't have enough manpower," said one regional AIDS Center doctor. Human resources are not funded by the new National Program, so while AIDS Centers will receive drugs and new obligations to provide services they will have to seek funding for human resource from regional governments. This is likely to slow the scale up effort and decrease equitable access as poorer regions will be less able to support the work needed.

AIDS centers across the country have little experience administering ART; as a result, staff at all levels of the system will require training. Training initiatives so far have been very poorly coordinated. "There are regions where doctors have already been through their fifth training on the same subject and others where they have had none at all." said one respondent. It will also be important to take measures to prevent burnout among AIDS center staff and to provide "care for carers" because they are likely to experience significant stress associated with changing management structures and increased patient loads.

Civil society's role

The national program has engaged civil society in its prevention components but engagement has been weaker in program components focused on treatment.

NGOs continue to be largely dependent on foreign funding; for their input to be brought to scale, local or governmental funding of NGOs must be developed. The capacity of NGOs to apply for governmental tenders must be increased and likewise the governmental tender system requires revisions to make it possible for regional NGOs to apply for funding. Russia's three national civil society networks, the NGO Forum, the Union of PLHIV and the Russian Harm Reduction Network are growing in strength and increasingly involved in decision making processes. The controversial new law tightening registration requirements for NGOs gives the government broad powers to limit the activities of NGOs. Some organizations focused on human rights have been closed.

GFATM

The GFATM Round 3 project, Globus, was given the highest possible rating status for its work in Phase 1, and its Phase 2 proposal subsequently was approved. The project, run by a consortium of NGOs, providing ART to 1,700 patients, has achieved high rates of patient retention with a less than 9% drop-out rate in its first 18 months of providing service using an evidence based approach that hinges on the work of multidisciplinary treatment teams composed of doctors, nurses, social workers and peer educators.

Nonetheless some problems are apparent. Patient demand has been lower than estimated need. Additional resources have not been allocated in phase 2 to increasing outreach among vulnerable groups or increasing work with mass media to inform the general population that treatment is available. It appears that the focus on preset indicators has limited flexibility in this respect. The vertical nature of the AIDS center system and of GFATM disbursement procedures limits the project's ability to strengthen peripheral services such as provision of treatment for drug use. There is not yet a clear plan for advocating the use of models that were successful in the Round 3 grant within the Round 4 project and the national program.

The GFATM Round 4 project, run by the Russian Healthcare Foundation, could become an important link between the government and civil society approaches. The project seems to be on target for meeting key project indicators except for one: the number of people on treatment. The ARVs ordered for the project were held in customs for over 4 months. The drugs arrived in the regions giving the project only two months to attract the targeted 7000 patients in the first year

Creating adequate patient demand among those in need is generally problematic in the region and is expected to be a challenge during the Round 4 project. As its treatment program gets started, of particular interest is its pilot program called "100% social support." This program seeks to engage a broad spectrum of governmental and non-governmental organizations to support PLWHA at the regional level.

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Russia's Round 5 project, run by the Russian Harm Reduction Network to provide harm reduction services to IDUs, started up in October. It contains a component designed to enable outreach workers to engage in treatment literacy activities to promote treatment uptake and adherence among IDUs which may prove to make an important contribution to access to treatment for vulnerable groups.

Treatment interruption: The road to resistance

"I was certain a year ago that the national program would have problems providing drugs. My doubts were based on the fact that there isn't any kind of logistical system for delivering large quantities of drugs to regions and there never has been one. I don't know if it is possible in a country as big as ours."

— Pharmaceutical company representative

Russia is one of the world's major producers and exporters of multidrug-resistant tuberculosis (MDR-TB). Unfortunately, it is well on its way playing the same role regarding HIV. Russia's Union of PLHIV still reports cases of frequently changed treatment regimens and prescribing of mono- and bi-therapy. In 2006, as many as 954 people stopped receiving ART "for various reasons" according to the MoHSD. Though some of these treatment interruptions were likely attributable to legitimate medical reasons, many are due to inadequate psychosocial support or the fact that pharmacies ran out of the drugs.

As the new National Program began, regional authorities were ordered not to purchase drugs from regional budgets. The first tender for the National Program did not produce contracts for the purchase of a valid first-line combination. And then when the national project drugs did not arrive, the regions ran out of drugs and patients who had already started therapy were told there were no drugs in stock. It will be vital for Russia to improve the logistics of its pharmaceutical delivery and storage systems and to reexamine its tendering and customs procedures.

Drug pricing, purchasing and management

Within the last two years pharmaceutical prices have declined significantly in Russia. However, the current price of around \$1,500 per patient per year for a first-line regimen is still too high. GFATM's purchase price for nevirapine is significantly higher in Russia than in other countries. Generics are not used by GFATM projects or by the national program, and no action has been taken to further develop

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local production of either branded drugs or generic versions. The World Bank recently re-classified Russia's gross national income as "upper-middle-level" and pharmaceutical companies have used this to justify charging Russia higher prices for ARVs. Such decisions do not take into account the special characteristics of Russia and its epidemic. Each dollar spent on excessive pharmaceutical prices is a dollar not spent on building the infrastructure or developing adequate social services. On a positive note, a system for gathering and compiling drug orders from regions has been developed and drug purchases for the National Program are made through central tenders. Drugs purchased federally are several times cheaper than drugs purchased by the regions. Civil society organizations as well as governmental structures should actively monitor drug prices, advocate for continued price reductions, and continue to increase the drug management capacity of medical institutions.

In 2006 Russia experienced significant delays in delivery of pharmaceuticals due to the ministry's inability to successfully carry out tenders for the purchase of pharmaceuticals. Further delays were experienced due to drugs and equipment being held up in customs. To ensure sustainable access to ARV and prevent further treatment interruptions, tendering and customs practices must be improved.

SOUTH AFRICA

by Fatima Hassan, AIDS Law Project

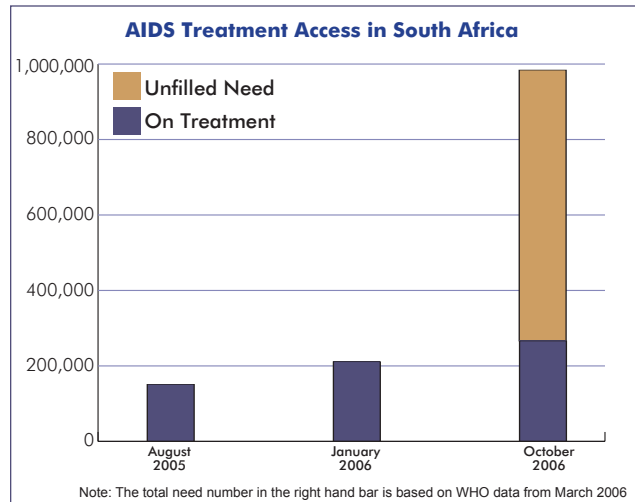
Introduction

In its previous reports, from November 2005 and May 2006, the ITPC reported that the lack of leadership on the part of Health Minister Manto Tshabalala-Msimang—in particular her denialist views on HIV/AIDS as well as her confusing and ambiguous messages—were undermining the country's response to AIDS. Since September 2006, however, the South African government has committed itself to a major policy reversal. The deputy health minister²⁷ and deputy president have recently been given control over the country's HIV/AIDS program.²⁸

This development may be a lasting political solution to the growing national and international criticism of the government's response to AIDS. It means that the health minister is no longer the political head of the HIV/AIDS program in South Africa. As chair of the South African National AIDS Council (SANAC), which is also

²⁷ The deputy minister, Nozizwe Madlala-Routledge, described South Africa's stall—at which beetroot, garlic and lemons were promoted as AIDS treatments—at the XVI International AIDS Conference in Toronto (held August 2006) as "an embarrassment" to the government. "Toronto was a catalyst and a turning point," she said. "It galvanized government to be on a new footing and to recognize that the atmosphere of perpetual conflict with civil society is not helping the fight against HIV."

²⁸ The deputy president, Phumzile Mlambo-Ngcuka, has met on two separate occasions with civil society organizations, including the Treatment Action Campaign (TAC), to discuss a coordinated and comprehensive response to AIDS in South Africa.



Visible Progress Needed by June 2007

- Increase the pace of treatment rollout so that at least 500 000 are receiving ART
- Revise national pediatric guidelines so that they are in line with WHO Pediatric and MTCT Treatment Guidelines
- Significantly increase voluntary HIV counseling and testing at TB sites, and provision of TB testing and services to HIV-positive individuals at health clinics
- Significantly increase the number of nurses trained in post-basic health assessment, increase nurse salaries, and allow foreign-registered medical personnel to work in South Africa
- Establish treatment targets agreed to by both the government and civil society
- Increase PEPFAR's focus on strengthening sustainable public-sector services
- Reduce delays in drug registration

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the Country Coordinating Mechanism (CCM) for the Global Fund for AIDS, Tuberculosis and Malaria (GFATM) inside South Africa, the deputy president has already undertaken a review of the structure of SANAC to make it more transparent, representative, efficient and accountable.

Through SANAC, the government is also reviewing South Africa's National Strategic Plan (NSP) on HIV/AIDS and developing a new plan for 2006–2011. However, sector representatives at SANAC are concerned that inputs made by civil society into this process may be ignored and that genuine consultation is not taking place. As one interviewee said, "It appears as if these efforts are cosmetic" and may not in fact lead to a "consultative and technically sound NSP and SANAC."

Action points for South Africa ITPC team

- Ensure that civil society fully participates in the processes set up to restructure SANAC with a view to strategically influencing the new NSP 2007–2011

It is hoped that the NSP will include all aspects of the response to HIV, notably HIV prevention, treatment and care. As one journalist commented in a widely circulated South African newspaper, "The plain language of the moment suggests the government is ready to act resolutely and unequivocally."²⁹ Hopefully the shift in political mood will mean that the pace of the rollout will improve.

Action point for South Africa ITPC team

Quickening the pace is necessary even though great strides have been made. By October 2006, three years after the South African government agreed to provide ART directly, a combined total of about 265,000 people were on treatment in the public and private sectors. About 165,000 to 175,000 people were accessing ART in the public sector, with some 100,000 to 110,000 receiving it in the private and not-for-profit sectors. During that month, the government itself estimated that about 177,000 people were on treatment in the public sector and that 31,000 were on waiting lists. Health care workers (HCWs) in some provinces report that waiting lists could be cut down if patients were not required to undergo lengthy adherence counseling sessions— a process that, in some parts of the country, takes as long as two months.

Overall, however, the need for treatment remains far greater than what is available. Recent UNAIDS estimates indicate that some 600,000 people in South Africa are in need of treatment but do not yet have access. Newer data suggests 800,000 people urgently need treatment and are not receiving it.³⁰

²⁹ Brendan Boyle, "Government joins the real war on AIDS," Sunday Times, 5 November 2006.

³⁰ Comment on the HIV and AIDS, STIs National Strategic Plan for South Africa 2007-2011 (draft 2, October 2006)

Treating children

Interviewees agreed that there is no comprehensive national policy regarding access to treatment for children. Pediatricians estimate that the approximately 17,000 children currently receiving ART represent only 10% of those in need and that the figure masks inequitable patient distribution across provinces. HCWs report that some treatment sites have not even commenced to treat children. One of the challenges to improving pediatric ART is the sub-standard capacity of NGO and private-sector providers to prioritize children and enroll them in HIV care and treatment programs. This shortcoming is mainly related to human capacity constraints and the lack of experience in these programs.

According to doctors at sites, there are “inadequate pediatric formulations generally” for treating children—and not just in South Africa. This has prompted WHO to create a priority list of 12 ARV formulations that need to be developed for children. Currently a handful of formulations are now available in tablet or capsule form in South Africa. Yet other crucial ones are not. For example, it has been reported that only one province (Western Cape) has been able to procure and use 15 mg stavudine (also known as d4T); the other eight provinces, meanwhile, are still waiting for this formulation to be put on the national drug tender in 2007. HCWs report that at some treatment sites, registered pediatric formulations are not available and in many cases have not even been procured. While there are reports of stock outs of d4t suspension, it appears that this has been resolved at an operational level.

Most of the children on treatment are found at a handful of urban children’s hospitals. Even so, the percentage of needy children with access to ART varies considerably among the nine provinces as well as among health care centers within provinces. Activists and HCWs also contend that the national PMTCT program is not being managed, monitored or implemented properly. Although the program exists on paper, in practice it is non-existent in many parts of the country. In addition, most treatment messaging still targets adults and often ignores children.

According to diagnostic and laboratory experts, about 300,000 infants a year should be tested for HIV.³¹ But they are worried that the laboratory capacity to do PCR (polymerase chain reaction) tests on such a scale does not exist because “there does not seem to be any urgency to provide this capacity” given the delays in introducing dried blood spot testing. In addition, HCWs report that mothers are reluctant to test their children because they do not understand the benefits. They report that there is no coordinated or monitored effort to increase pediatric testing or a uniform and consistent national policy on where and when testing should take place. HCWs advocate that HIV PCR testing, at four weeks, should be included as

³¹ This estimate is based on national antenatal HIV prevalence of 30% and a birth rate of about one million per year.

part of Integrated Management of Childhood Illnesses (IMCI) and linked to immunization coverage.³² All interviewees recommended that the national pediatric guidelines should be revised and brought in line with WHO's Revised 2006 Pediatric and MTCT Treatment Guidelines.

Tuberculosis

As with previous reports, there are no uniform outcomes on TB screening and treatment. Provincial variations therefore continue.

Some HCWs agreed that one of the major barriers to scaling up TB screening and treatment is that the "NGO and private sector does not provide TB treatment and refers patients to the public sector for treatment." Again, it was reported that newly diagnosed pulmonary TB cases are not routinely offered VCT for HIV and that opt-out approaches for HIV testing are not widely applied.

Although integration of HIV and TB care has ostensibly occurred at a programmatic level (with the establishment of the HAST directorates in each province),³³ HCWs warn that "silo" programs continue to operate under the new structure. They recommend that HIV-positive individuals be asked about symptoms of TB at each visit. It was also reported that symptomatic patients are not referred but that sputum samples were taken instead. Significantly, the increased availability of HIV testing in all settings—not just health settings—could assist with identifying TB/HIV patients much sooner than currently used models. Given the recent outbreak of extreme drug-resistant TB (XDR-TB) in KwaZulu-Natal province, it is vital that testing include both active TB screening and HIV testing.

In the wake of the recent outbreak of XDR-TB, clinicians have warned that second-line TB drugs for patients identified with XDR-TB are now urgently required. For example, over half of the 183 patients identified with XDR-TB in KwaZulu-Natal are resistant to one or two first-line drugs. TB specialists say that even though the South African government was aware of an imminent XDR-TB outbreak as early as the beginning of 2005, when the first two cases were reported, health officials took no urgent action. So far none of the seven points on WHO's Emergency Plan for TB address the issue of getting treatment to these patients quickly. It has been reported by HCWs that they are aware that the South African government is negotiating with the WHO GLC (Green Light Committee); however, these negotiations are still under way, thus leaving patients without access to second-line drugs.

³² PCR tests for early pediatric diagnosis are not widely used in all provinces even though it is part of the national protocol.

³³ The term "HAST" refers to "HIV and AIDS, STIs and TB."

Human resources shortfall

The shortage of HCWs continues to be a significant barrier to increasing the pace of ART rollout, with many sites still reporting understaffing. Patients living with HIV report that at some urban sites they must wait in the hospital queue for up to seven hours. In some areas where new posts have been created, only a minority have been filled, even after extensive and expensive advertising (e.g., in Gauteng province).

These shortcomings are among the main reasons why health activists argue that the national HR plan released in April 2006 does not go far enough in addressing the crisis. For example, it does not address the short-term needs of the health system. HCWs provided examples of district hospitals that have not had a pharmacist for four months, which resulted in difficulties with pharmaceutical procurement. They also argued that nurses should be allowed to manage uncomplicated patients with HIV, including initiating therapy and monitoring of treatment. At the same time, however, HCWs recognize that there is a massive nursing shortage in the country. Nurses interviewed recommended that more nurses should be trained in post-basic health assessment (PHC) to manage patients in the communities where they already live and that salaries should be substantially increased so that they will be encouraged to work in rural areas. They also suggested that the government should help facilitate permits for foreign-registered doctors and nurses to work in South Africa and that bursaries should be offered to matriculants to encourage them to study to become laboratory technologists, pharmacists, nurses and doctors. HCWs themselves have also warned that a plan for addressing HIV/AIDS within the health workforce is urgently needed, given the prevalence and incidence of HIV amongst HCWs in South Africa.

Target-setting processes

In May 2006 the African Union, of which South Africa is a member, agreed that by December 2006 its countries would include "revised, quantified national targets for prevention, PMTCT, AIDS treatment and care and support that are consistent with and contribute to the Africa wide targets." In June 2006, South Africa also signed the UNGASS Declaration.

The process of setting national targets, however, has been subsumed by SANAC through its review of the NSP. That is, the Department of Health has stated that the targets in the NSP will be in line with the commitments made at UNGASS. The targets that have been proposed by the department in the draft NSP released in November 2006 have been rejected by civil society because there has been no proper consultation and because they are regarded as "inappropriate" (i.e. far too low). According to activists, the department has since said that it will revise these targets. It is unclear to what extent, if at all, the submissions made by civil society on targets for prevention, care and treatment will be incorporated.

PEPFAR, GFATM, UNAIDS and WHO

Again, interviewees felt that multilateral agencies have little direct impact in South Africa, in either the public or private sectors. HCWs said they “do not see any impact of WHO on the ground,” particularly because WHO’s recommendations are not necessarily adopted and adapted by the government. Participants stated that PEPFAR is providing considerable resources to NGOs and research structures that either provide services directly (e.g., CAPRISA) or provide scarce human resources to state facilities (e.g., ARK). But health academics are worried that PEPFAR resources are also being used to fund “consultancy” arrangements that may not have as direct a bearing on the total number of people treated, as opposed to “strengthening” the public sector through indirect means. Patients living with HIV stated that PEPFAR-funded institutions “need to develop a better strategy and not stick to the ‘abstain’ methodology.” According to them there is little knowledge on the ground about what PEPFAR is doing in terms of scaling up access to treatment.

Some observers suggested that the GFATM grants have to be considered “at risk” to the extent that all follow-on grants submitted by South Africa (until Round 6) have been unsuccessful. The reasons subsequent grants have been rejected are related primarily to economic status, lack of international faith in the leadership of the national Department of Health and slow progress on implementing South Africa’s current TB/HIV grant.

The KwaZulu-Natal grant has been taken over by the provincial government and therefore it has not delivered the intended tripartite (province, university, business) alliance, and possibly not the range of outcomes that were initially intended. However, as with PEPFAR the number of personnel trained is regarded as impressive; on the other hand, whether such outputs are translating into markedly different outcomes is unknown. HCWs working for PEPFAR-funded projects stated that they “work very closely with the Department of Health at provincial, district and local level.” The majority of support they provide is directed towards training/mentoring, service integration, infrastructure provision (in the past), and monitoring and evaluation activities. Again, concerns were raised that the CCM is not yet functional—although this may change if SANAC’s restructuring is comprehensive. Recommendations regarding the role of the CCM included exercising constant supervision over grants and the compilation of implementation reports, as per its fiduciary responsibilities.

According to HCWs familiar with grant implementation, the Western Cape AIDS treatment grant is doing very well. On this basis there has been a request to extend on an exceptional basis the Phase 2 renewal to four years (instead of the usual three); in any case, the Western Cape provincial government will take over the funding responsibilities after the grant terminates. The status of the KwaZulu-Natal grant remains unclear. Some interviewees said that it “never really got off the ground” even though it did get Phase 2 renewal. An important recent development

was the approval, in early November 2006, of South Africa's proposal for GFATM's Round 6. The total amount of that grant is \$103 million; of that, \$55.8 million is expected to be disbursed in Phase 1 (the first two years).

Second-line drugs

Second-line drugs are available in South Africa. Because Kaletra (a brand-name combination of lopinavir and ritonavir) is available at a fixed low price, the overall cost of a second-line regimen is not considered excessive, at least when compared to international prices. Beyond prices, the issues of sustainability, availability and affordability continue to surface. At the time of the drug tender award in 2005, only five of the ten ARVs used in the public sector could be procured from generic companies.³⁴ Since then, no generic company has managed to secure a voluntary license to import and/or produce any of four of the remaining medicines.³⁵ In regard to the fifth ARV, efavirenz, only Aspen Pharmacare has been licensed,³⁶ but its product has yet to be registered for use.

Finally, the slow pace of drug registration by the Medicines Control Council effectively blocks access to new ARVs (many of which have better efficacy and side effect profiles) and generic versions of existing ones (thus limiting competitive pressure and ensuring sustainability of supply). For example, tenofovir has still not been registered for use in South Africa. In regard to drug supplies, nurses reported that attempts to establish public-private efforts for sustainable medicine distribution have been hampered by competing interests of key role players.

Vulnerable groups

There is little qualitative or quantitative data on vulnerable groups. Clinicians suggest that ART access by MSM, sex workers and refugees is unlikely to be extensive given high levels of stigma and the lack of targeted interventions and services for members of such groups.

In general, treatment access is limited among prisoners already sentenced or awaiting trial. A recent landmark court judgment against prison authorities has placed a much-needed spotlight on the issue of prisoners' access to prevention, care and treatment services. However with only four prison facilities accredited in the whole

³⁴ The medicines are abacavir (syrup), didanosine (25 mg, 50 mg and 100 mg tablets), efavirenz (50 mg and 200 mg capsules and 600 mg tablets), indinavir (400 mg capsules), lamivudine (solution and 150 mg tablets), lopinavir/ritonavir (solution and 133/33 mg capsules), nevirapine (solution and 200 mg tablets), ritonavir (solution and 100 mg capsules), stavudine (solution and 20 mg, 30 mg and 40 mg capsules) and zidovudine (syrup, 100 mg capsules and 300 mg tablets).

³⁵ These four are GlaxoSmithKline's abacavir, MSD's indinavir and Abbott Laboratories' lopinavir/ritonavir and ritonavir.

³⁶ Prior to licensing Aspen, MSD licensed Thembalami Pharmaceuticals, a joint venture between an Indian and a South African company. When Thembalami collapsed (as did its license), Aspen was licensed. MSD has stated that it is only prepared to license a single company at this stage.

country to provide treatment, prisoners are heavily dependent on accessing treatment through hospitals that are outside of prison facilities. They must therefore rely on prison officials to make arrangements for them to be admitted to these hospitals.

Financial resources

The national government allocated 1 billion rand (\$136 million) for the ART program for 2006. (Provinces also allocate additional resources from their own provincial budgets.) In the medium term (2006–2008), the government has allocated about 9.5 billion rand (\$1.3 billion) for AIDS, and close to 50% will purportedly be spent on the ART program. However, figures from the National Treasury do not indicate spending on specific priority areas, such as treatment and prevention, care and support. It is therefore difficult to ascertain specific allocations for ARVs and other treatment-related spending areas such as laboratory services. Determining actual levels of spending is also difficult due to problems with reporting and poor information sharing between the provincial and national government and with civil society.