

Missing the Target

Off target for 2010: How to avoid breaking the promise of universal access

Update to ITPC's AIDS treatment report from the frontlines



International Treatment Preparedness Coalition (ITPC)

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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 treatment activists and educators from over 60 countries. Since the Summit, ITPC has grown to include over 700 activists from around the world and has emerged as a leading civil society coalition on treatment preparedness and access issues.

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Executive Summary

Actions by governments and multilateral institutions over the last year helped lay the foundation for gradual expansion of AIDS treatment access. Yet the world is on a trajectory that will fall significantly short of the internationally endorsed universal access goal for 2010, leaving millions without lifesaving care and hundreds of thousands of people with HIV/AIDS facing the prospect of imminent death. In December 2005, the "3 by 5" initiative came to an end, having helped spur treatment expansion but falling 1.7 million people below its goal. In the wake of this failure the international community has made new promises, developed new plans, and is experimenting with new systems of operating.

Despite these positive developments, no one should be fooled that the current pace or magnitude of the response will come close to achieving the universal access pledge that will be solemnly reaffirmed at the UNGASS Review meeting in May 2006. According to the World Health Organization (WHO), about 600,000 more people gained treatment access in 2005. At that rate fewer than half of those who need AIDS treatment will have access in 2010.

An international alliance of civil society advocates has called for setting a new global AIDS treatment target of "10 by 10" – 10 million people accessing treatment by 2010. But the international community seems to have gone out of its way to avoid setting explicit global treatment targets that would focus attention on specific outcomes, acknowledge the responsibilities of global institutions as well as countries, and drive accountability.

The response to AIDS must be led at the country level, but this does not mean leaving countries on their own. Countries that sometimes fail in implementation of scale-up must not be abandoned, but instead receive intensive and ongoing international assistance to overcome impediments. The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), The Joint United Nations Programme on HIV/AIDS (UNAIDS), WHO, and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) should publicly challenge and call to account national leaders who are not doing enough to lead the fight to end the AIDS epidemic in their countries.

International and bilateral agencies will be judged on their ability to help countries set and achieve ambitious treatment and prevention goals. But major barriers to treatment scale-up remain on the country and international level, including inadequate financing, mismanagement, technical challenges, stigma, and human resources shortages. Are we moving forward or are we slipping backwards in the fight for access to treatment?

In November 2005, the International Treatment Preparedness Coalition (ITPC) issued *Missing the Target: A Report on HIV/AIDS Treatment Access from the*

Frontlines. The report detailed specific barriers and potential solutions to AIDS treatment delivery in six countries heavily affected by the epidemic, and it made recommendations for national governments and multilateral institutions. This bulletin is the first of the semi-annual updates ITPC will make on global and national progress on scale-up of AIDS treatment.

Six months after the publication of *Missing the Target*, ITPC has found progress on several of the barriers to scale-up identified in November. Still, deficient national leadership, and slow implementation of reforms remain critical roadblocks to treatment delivery and are costing lives every day in each of the six countries reviewed.

- In the **Dominican Republic**, treatment delivery is expanding but people in some of the poorest areas with the highest rates of HIV have seen little meaningful increase in treatment access. Government and donor agencies are still not collaborating efficiently. Scarce resources have been squandered even while there are ongoing concerns about sustainability of funding. Second-line drugs cost 10 to 20 times more than first-line generics.
- In **India**, the number of treatment centers has increased, but hundreds of thousands of people in need still do not have access to antiretroviral therapy (ART). National guidelines must be reformed and action is needed to reach children and ensure greater equity in care. A clear plan to achieve universal access has yet to be developed.
- In **Kenya**, AIDS treatment services have been undercut by growing food shortages in some areas. Stigma remains a serious issue and there is a critical health care worker shortage. Kenyan government delays in submitting audit reports held up the release of Global Fund monies.
- In **Nigeria**, more treatment centers have opened across the country. However, the Global Fund has suspended two grants because the country failed to meet targets on drug access and demonstrate transparency. This development could jeopardize the government's ability to meet its pledge to make free treatment more widely available. Also still lacking is improved collaboration among global agencies.
- In **Russia**, government funding has grown but these new resources have yet to translate into significant increases in treatment delivery. There is an urgent need for services appropriate for injection drug users (IDUs). Other top priorities include better health care worker training, more efficient drug procurement, and comprehensive anti-stigma efforts. Greater involvement of people living with HIV and AIDS (PLWHA) is essential.

- In **South Africa**, the number of people on treatment has increased, but scale-up efforts continue to lag due to inadequate national leadership, government efforts to inhibit civil society participation, pervasive AIDS denialism, and a virtually non-functional Global Fund Country Coordinating Mechanism (CCM). Among the greatest needs are improved treatment access for children and men and accelerated preparation for the implementation of second-line therapy.

The multilateral and bilateral response

To assess the work of international institutions, ITPC wrote to the Global Fund, UNAIDS, WHO, and PEPFAR to ask what they had done to tackle the challenges outlined in *Missing the Target*. The agencies' responses were hopeful in that they outline many of the building blocks of what an effective response would look like: a more coordinated, efficient global effort that is able to meet the needs of countries; build sustainable systems of care; and integrate HIV prevention, tuberculosis, and other services. There is evidence of hard work and noble intentions, but change is coming far too slowly. To move more quickly and effectively, each of these agencies needs increased and sustained financing from the global community. Other changes are needed as well:

- The **Global Fund** is providing resources to support treatment for steadily increasing numbers of people, but its ability to sustain and expand this work requires greatly increased financial support. The Fund must also identify new strategies to address failing grants and weak CCMs.
- **WHO** has made progress on providing technical assistance and guidance to countries and is expanding its in-country staff, but now needs to show tangible outcomes in terms of ambitious and workable national plans and resolution of barriers in countries. The late Director-General Dr Lee Jong-wook's leadership in spearheading the "3 x 5" initiative put WHO at the forefront of the global treatment response. His successor needs to be a visible advocate for universal access and aggressively seek funding to support WHO's AIDS-related work.
- **UNAIDS** has managed a universal access planning process and is helping some countries operationalize their national plans. However, the agency must also show faster progress on UN system collaboration and implement a true strategic plan for accomplishing universal access.
- **PEPFAR** has expanded the reach of its treatment delivery and has initiated a variety of activities to build health systems. While continuing these efforts it must, however, end counterproductive policy prescriptions that undermine service delivery and do more to build human resources capacity in countries.

There is little evidence that substantial progress has been made on the country or international level at integrating HIV and TB programming—another priority that will facilitate development of health care system capacity as part of AIDS treatment scale-up.

As an international group of PLWHA and their advocates, ITPC is committed to closely monitoring the action—and inaction—of governments and multilateral and bilateral institutions. It will continue to offer praise and encouragement, where appropriate, as well as criticism when leaders and organizations shirk their responsibilities to PLWHA. ITPC's goal is to focus attention on specific barriers to treatment access and to help drive progress on the goal of universal access.

The Global Response

Since the end of WHO's "3 by 5" initiative in December 2005, global agencies and national governments have embarked on a variety of new efforts to advance AIDS treatment access. New systems, such as the Global Joint Problem Solving and Implementation Support Team (GIST) and Joint Teams (intended to coordinate in-country UN agency work), are being assembled to help countries address bottlenecks. The UN, the Global Fund, and PEPFAR are counting treatment numbers together and acknowledging double counting. African governments set bold new treatment targets at the May 2006 Abuja Summit. And access to AIDS treatment continues its steady, moderate climb: Some 1.3 million people now have access worldwide.

While an improvement, this number is still 1.7 million short of the "3 by 5" goal. The failure to reach this goal—or to even come close—indicates that changes are happening much too slowly and so far have had only limited impact on the global AIDS death rate.

In its November 2005 report, *Missing the Target*, ITPC urged UNAIDS, WHO, the Global Fund, and PEPFAR to do a much better job of working collaboratively to address implementation barriers and to advance country-specific strategies for treatment delivery. The evidence suggests that these agencies are lagging in their efforts to be more effective on the ground.

Prior to the preparation of this update bulletin, ITPC wrote the four agencies and asked whether they had taken action based on the recommendations from the November report. Each agency responded and reported progress; their responses are posted on the ITPC website: www.aidstreatmentaccess.org/responses0506.htm. In 2005, through the Global Task Team (GTT) process, international agencies acknowledged important shortfalls in coordination, provision of technical assistance, and several other aspects of the global AIDS response. In their responses to our inquiries agencies report follow-through in keeping with GTT recommendations, but at a frustratingly gradual pace. And two fundamental problems are clearly apparent.

First, a reality check on money: Current funding levels make it impossible to accomplish universal access. The Global Fund, which subsidizes nearly half of all people on AIDS treatment in less developed countries, does not have adequate resources to fund Round 6. Without significantly increased funding it will be impossible to sustain treatment for those currently receiving it, extend access to these life-saving medications to millions of others, and build adequate health care systems to deliver treatment in the long term.

The Pan American Health Organization (PAHO), WHO, UNAIDS, and other UN agencies also need increased funding if they are to provide the technical assistance

required to maximize the impact and success of treatment programmes and financing mechanisms such as the Global Fund. It is essential that WHO and UNAIDS are able to allocate appropriate resources to support countries. Financing this effort is too important to be left to the normal politics of UN budgeting processes. Therefore we call for: 1) more transparency in AIDS-related UN budget process and final budgets, 2) a management audit to assure that each UN agency is funded properly to accomplish measurable, non-redundant goals, and 3) an initiative to raise outside funds for supporting WHO and UNAIDS responsibilities for treatment scale-up and technical support.

Second, who is in charge here? The global multilaterals still have not defined clear and distinct roles and responsibilities for themselves and other major players. They have not stated plainly what universal access means and do not plan to articulate a new global treatment target based on adding up country targets. The unambiguous international target that “3 million on AIDS treatment by 2005” provided is missing in the universal access efforts. The world needs treatment goals that focus attention on specific, measurable outcomes; acknowledge the responsibilities of global institutions as well as governments; and drive accountability, funding, and advocacy.

UNAIDS, WHO, and other multilaterals have stated repeatedly that the universal access process must be country driven. This emphasis, while completely valid, must not be used to escape these agencies’ responsibility to lead the global charge to deliver antiretroviral treatment (ART) to three million people within the next year, and millions more before the decade is out. As ITPC stated in *Missing the Target*, what gets measured gets done. What is not measured simply gets talked about.

International and bilateral agencies will be judged on their ability to help countries set and achieve ambitious treatment and prevention goals. This means defining guidelines for planning, enabling implementation of national plans, providing effective technical assistance, establishing global systems to facilitate procurement where needed, and providing forceful leadership.

“Country-led” does not mean leaving countries on their own. Respect for the importance of country-driven responses must not lead to the abandonment of nations that sometimes fail in implementation of scale-up. Instead, the resources of the global community must be harnessed to overcome impediments at the national level.

Nigeria is a case in point. Universal access to AIDS treatment cannot possibly be achieved unless people in Nigeria, by far Africa’s most populous country, have access. As discussed in the Nigeria chapter in this report, the recent news that two Global Fund grants for that country have been cancelled imperils the goal of increased treatment delivery. (People already receiving treatment through the affected grants will continue to have their treatment financed by the Fund for up to two years while alternate treatment options are sought.)The international community must rapidly mobilize to provide the necessary resources, support, and new funding and delivery strategies to address challenges in Nigeria and other countries.

In *Missing the Target*, ITPC called for a global plan of action on AIDS treatment that has hard timelines and milestones and clear assignments of responsibility for specific tasks. Though global institutions are slowly and partially responding, a strategic and intensive mobilization has yet to be initiated. Who is in charge of ensuring that countries receive the technical assistance they need? Who is managing operations research so that lessons learned in scale-up reach programme managers rapidly and efficiently? Who makes sure that redundancy is minimized and that resources are focused on the most important priorities?

Unless multilateral and bilateral institutions radically reform their way of doing business, the pledge to provide universal access to treatment by 2010 will become a cruel joke for millions of PLWHA around the world. The reforms outlined in *Missing the Target* are challenging enough without being further compromised by failures in leadership and vision among governments and international institutions. Leaders must deliver now on all the grand plans and promises.

The Global Fund to Fight AIDS, Tuberculosis and Malaria

In its November 2005 report, ITPC called for increased funding for the Global Fund and more examples of the multilateral system working collaboratively to accelerate delivery of grants and supporting grant implementation. The Fund's response to ITPC's letter notes an increase in the number of people receiving treatment through Global Fund grants, full funding for Round 5 and the launch of Round 6, new fundraising strategies, fresh efforts at collaboration with other agencies, and measures to strengthen troubled Country Coordinating Mechanisms (CCMs).

Financial support for the Fund remains dangerously inadequate. It is irresponsible for the global community to commit to coming close to universal access and then not appropriately fund the major multilateral financing mechanism designed to increase access. All wealthy nations should increase their support for the Fund.

Delayed money flows and problem grants are an ongoing problem, including in several of the countries covered in this update. The case of Nigeria, noted above, is one of many examples of the need for the global community to find more effective ways of supporting local institutions to get vital programmes running appropriately. Grants with implementation problems should receive immediate attention from the Secretariat.

In some cases getting treatment to people will require changing the rules. The Global Fund should seek to identify other means of delivering services when a CCM or another national institution stands in the way of Global Fund grants being released and outside assistance fails to repair these entities' ability to function properly. For example, alternate organizations could be appointed on a temporary basis to implement a Global Fund grant while technical assistance and capacity building services are provided to failed CCMs and other institutions. Money should not sit in the bank for months on end while people wait for AIDS treatment and other services. The Fund needs to explore ways to ensure more on-the-ground

support for grantees from the beginning of a grant cycle. Also needed are incentives to encourage more full integration of HIV and TB services.

WHO

WHO was lauded in *Missing the Target* for setting the "3 by 5" target and struggling to reorganize its bureaucracy. ITPC also called on the agency to be a more visible leader on implementation challenges in countries; be more of a treatment advocate on the country level; work more closely with civil society; and develop action plans for scale-up for all countries that were part of "3 by 5", with timelines and milestones for countries and WHO.

In its final report on "3 by 5" (issued in March 2006) and in response to ITPC's letter, WHO detailed important progress on technical support, expansion of in-country staff, drug resistance monitoring, and plans for a variety of forthcoming guidelines.

These steps are important. No other agency is in a better position to guide countries in development of national plans, help integrate TB, HIV prevention, and other services, share lessons from operations research, and promote a public health approach to AIDS treatment and prevention. WHO's regular interactions with health ministries around the world represent an enormous opportunity to push for the development of credible national plans, ambitious treatment and prevention targets, resolution of impediments, and involvement of multiple stakeholders. The agency has yet to take full advantage of these opportunities, however. In addition, greater efforts are needed to prepare for delivery of second-line therapy in many countries.

The AIDS division at WHO experienced a leadership vacuum for months after Jim Kim, who led the "3 by 5" initiative, stepped down in the fall of 2005. Chief among the challenges facing Kevin DeCock, new director of the AIDS division, is to demonstrate concrete progress on the ground. In its reporting to the world on the progress of AIDS treatment delivery, WHO needs to more clearly and specifically show how its guidance documents, technical assistance, and coordination efforts are translating into tangible results in countries.

The WHO HIV/AIDS programme currently faces a financial crunch and needs increased financing to accomplish its work. A relatively small share of the HIV/AIDS programme budget comes from the general WHO budget, forcing the programme to rely on voluntary contributions from donor sources and member states. This funding situation undermines the sustainability of WHO's work in the field. Dr. De Cock should call for member states to guarantee secure, sustained income for the WHO HIV/AIDS programme.

At the same time, regional WHO offices need to coordinate activities and programme plans more closely with the Secretariat in Geneva and must demonstrate the capacity to effectively utilize resources that become available. The resolution of this problem will require a pro-active effort by Dr. DeCock. As with the Global Fund, it is unacceptable to have resources allocated and then sit in the bank.

UNAIDS

In November 2005, ITPC applauded UNAIDS' work as a powerful global communicator and advocate and defender of marginalized groups. It also called for the agency to be much more visible in treatment advocacy at the national level and to place greater priority on acting as a problem solver to hasten the delivery of resources from throughout the entire UN system to address obstacles in countries. In response to our follow-up letter, UNAIDS pointed to a variety of initiatives intended to improve coordination of the UN system's efforts. The agency is now working with 20 countries to develop Road Maps—due by the end of 2006—for accelerated implementation of national AIDS strategic plans. To do this, UNAIDS needs to maximize the effectiveness of its country and regional staff.

In the first quarter of 2006, UNAIDS spearheaded (with the United Kingdom's Department for International Development) a series of meetings to develop a universal access plan. The final report lays out solid overarching principles, including a few well chosen specific measures for scale-up of services. Still, it is far from a global strategic plan—for one thing, it avoids specific global treatment and prevention targets—and is short on specific responsibilities for global agencies.

The various systems being put in place to assist countries and improve agency collaboration—notably, the Global Joint Problem Solving and Implementation Support Team (GIST) and Joint Teams—are promising concepts, but they have yet to prove their real effectiveness. Furthermore, although UNAIDS' work on the Road Map process is important, it is obvious that universal access is not attainable if only 20 countries are to be engaged in operationalizing their strategic plans. What is the action plan for these other countries not in the group of 20? ITPC will monitor the GTT and Road Map processes over the coming months.

Treatment does not work without food. One of the major themes to come from the ITPC country reports is the fundamental importance of access to food and nutrition. The World Food Programme needs far more support and resources to be able to expand targeted distribution to HIV-positive people.

In the hallways in Geneva one hears that UNAIDS "owns" prevention and WHO "owns" treatment. That bifurcation of responsibilities is counterproductive. Instead, truly integrated, strategic plans for service delivery must be increasingly promoted by both agencies, and each must maximize its resources and demonstrate increased collaboration on the ground.

PEPFAR

In November 2005, ITPC challenged the U.S. President's Emergency Plan for AIDS Research (PEPFAR) to show evidence that it is building sustainable health care systems, coordinating its medicines portfolio with country protocols and supply systems, focusing more intensely on capacity building in countries, and better integrating activities with partners. *Missing the Target* also raised serious concerns about misguided and dangerous policy prescriptions from PEPFAR. These policies include not allowing grantees to provide counseling on abortion; requiring grantees to adopt a policy specifically opposing sex work; and requiring a portion of prevention funds be used to promote abstinence-only programming.

The agency's response to ITPC's follow-up letter emphasizes the continued increase in the number of people receiving treatment through PEPFAR and its partners. It also lists a notable variety of capacity building efforts including health care worker training, technical support, infrastructure development, government institutional capacity, and improvement of health systems in public sector and rural areas. Yet the PEPFAR response did not address the policy issues raised by ITPC nor the evidence from a new U.S. General Accounting Office study that the abstinence spending requirement is limiting the ability of recipients to "design prevention programmes that are integrated and responsive to local prevention needs."

PEPFAR gets high marks for its organization and outcome orientation; it is undeniably getting treatment to people. Unfortunately, ideological biases and sluggishness on approving the use of generics keep PEPFAR from being as effective as it might otherwise be. In upcoming reports, ITPC will assess the work of several of the nearly 100 PEPFAR-supported treatment providers in the programme's 15 target countries.

PEPFAR needs to do more to strengthen health care workforce capacity in focus countries, particularly since PEPFAR and other bilateral AIDS programmes are hiring significant numbers of health care providers, thus draining human resources from the public sector. In particular the U.S. Government and PEPFAR should:

- invest in efforts to recruit pay, retain, and train health care workers in heavily impacted countries. These efforts should also concentrate on dramatically improving health care provider working conditions, supervision and support; and
- call for the International Monetary Fund (IMF) to state publicly that national budgets for the health sector are expected to greatly exceed health budget ceilings set in the recent past, particularly caps on public sector wage bills designed to control inflation. Such a statement would affirm the importance of countries increasing their funding allocations to address the human resources crisis.

Country Updates

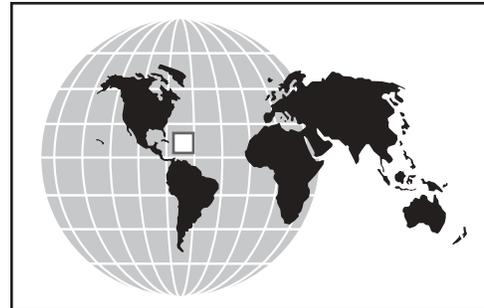


Delivery of AIDS treatment in the Dominican Republic and the Caribbean island of Hispaniola must be understood in the context of an HIV/AIDS epidemic that exploits gross inequalities which permeate nearly every aspect of economic and social life in the area. Despite important recent efforts and isolated projects, the vast majority of the hundreds of thousands of PLWHA in the Dominican Republic and neighboring Haiti have been deprived of access to lifesaving ART. They have also frequently been denied jobs, basic medical services, the confidentiality of their medical diagnoses, and optimal treatment for opportunistic infections.

In analyzing AIDS treatment delivery, it is also necessary to acknowledge the pressing broader inequalities that obstruct efforts to halt the spread of HIV and provide health care to all PLWHA. The hope is that the ongoing broad social movement to make AIDS treatment available in Hispaniola will also ultimately have a positive impact on related and urgent social priorities, including public health, primary care, and improved living conditions for the majority of the island's citizens.

This update on AIDS treatment access in the Dominican Republic is based on a series of follow-up interviews in April 2006 with key stakeholders including physicians, PLWHA, government and health officials, and staff of international agencies. The key findings and recommendations follow.

1. As of April 20, 2006, some 3,200 people in the Dominican Republic were receiving free combination ART, an increase of more than 500 people in five months. Over the same period, 10 new treatment sites were opened across the country, bringing the total number of such sites to 35. These impressive achievements represent a complete turn around from the



Update on treatment delivery

- Increase in treatment access and number of treatment sites.
- Improved but still inadequate access to CD4 and viral load testing
- Frequent charging for HIV tests
- PLWHA not covered in new social insurance plan
- No meaningful increase in access in bateyes
- Inadequate data collection
- Insufficient collaboration among primary agencies
- Concerns about sustainability of funding and access to second-line drugs

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situation two years ago. This expansion in access should be recognized, yet there is great need for closer monitoring by civil society, health workers, and policymakers as treatment scale-up continues.

2. Free, confidential HIV testing and counseling has not been prioritized. With the exception of a few small HIV programmes, fees for HIV testing often still remain the norm for many people—including sex workers, men who have sex with men (MSM), all men in general, TB patients, patients in rural health centers and provincial public hospitals, Haitian migrants, adolescents, and the elderly. Fees charged are usually five to ten times the actual cost of the test itself, which international agencies such as the Clinton Foundation claim they can secure for as little as 50 U.S. cents per test.

Currently only pregnant women receive free HIV tests, and even among this group there are reports that some are charged for testing. Moreover, major gaps in access and implementation exist at nearly every level of the mother-to-child transmission prevention programme. Reports indicate that substantial percentages of women—as many as half enrolled in PMTCT services—are not tested or given adequate follow-up. For those testing positive, many claim that the system misses an important opportunity by not adequately connecting women to long-term care and treatment programmes, providing CD4 testing, or securing ongoing access to ART for HIV-positive mothers and importantly, their children and their partners.

The health minister and highest political authorities must issue a decree eliminating user fees for HIV tests. The government should efficiently use national and donor resources to offer free counseling and testing to all Dominicans and foreign residents wishing to be tested.

3. Many of those interviewed expressed concern that planned reforms in the social security system will exclude PLWHA from being fully covered in new insurance schemes due to the lifelong nature and high costs of care and ART. Furthermore, a high percentage of residents will essentially be excluded from the new system because as many as one quarter of those living in the Dominican Republic lack legal documentation, including the rural poor, migrants from Haiti, and many people born to parents of Haitian ancestry. Donors currently funding relatively short-term HIV/AIDS projects and grants must work closely with governments to ensure that adequate resources are available to all people living in the Dominican Republic through improved and sustainable HIV/AIDS programmes.
4. The national laboratory in the capital, Santo Domingo, is now ready after a number of delays to perform CD4 and viral load tests at no cost to PLWHA. Some claim the lab is still not operating at full capacity, but

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problems with waiting lists for CD4 tests highlighted in the previous report appear to have been largely resolved. Coordination between clinics and central health authorities that approve these tests still needs to be strengthened. Other lingering challenges include delivering CD4 and viral load testing in rural areas and provincial hospitals, and to patients without ties to PLWHA advocacy networks. There is still no local capacity for resistance testing in the Dominican Republic, and sending samples off the island for such procedures remains extremely expensive.

5. There has been no meaningful improvement in access to treatment for people living in *bateyes*, where the highest rates of HIV in the country have been reported for more than a decade. *Bateyes* are typically tiny, impoverished communities located on the outskirts of major cities and sugar-growing areas throughout the island. These communities are intricately linked to historical migration patterns—most recently from neighboring Haiti—and slave-like working conditions. Little effective action has taken place to provide assistance to PLWHA and those at risk in *bateyes*. An abundance of NGO services, youth prevention and education strategies, and other health interventions have been initiated, but there is still no evidence of a coherent plan or genuine commitment to provide ART to people living with and dying from AIDS in these areas.
6. Surveillance estimates for adult HIV prevalence nationwide range from 1.1% to 2.6%, with rates in some communities being significantly higher. Official estimates are based on antenatal testing of pregnant women and 2002 census data; they may therefore be inaccurate and likely underestimate the extent of the HIV epidemic. In addition, it is difficult to assess the true level of treatment access and preparedness because, according to authorities from COPRESIDA, the presidential AIDS commission, there is no official data available or reports on the number of AIDS-related deaths in recent years. Even so, based on these prevalence rates an estimated 8,000 to 25,000 individuals need ART today. Currently treatment reaches only between 13% and 40% of those in need.
7. More than 60% of PLWHA needing medicines do not have them, yet the government will report to UNGASS and the Global Fund that it has met and surpassed indicators that were set for providing ART to 2,400 individuals by the end of 2005. Such indicators are the cornerstone of the Global Fund evaluation process, and important for portfolio managers and underperforming government bureaucracies, but they completely fail to engage in the real needs of communities on the ground. Most importantly, the indicators ignore and obscure the fact that the substantial majority of PLWHA in the Dominican Republic still lack access to lifesaving medicines. The indicators must therefore be challenged and revised by activists, PLWHA, the Global Fund board, and the international AIDS community.

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8. Coordination between officials at COPRESIDA, the Global Fund Principal Recipient, and the Ministry of Health's National AIDS Programme Coordinating unit remains strained and seems to have worsened, thereby creating ongoing challenges and competition rather than cooperation. This trend has adversely affected treatment preparedness and needs to be addressed and overcome at the highest political levels in order to strengthen the national response to the epidemic.
9. All ARV drugs available through the National AIDS Programme are currently purchased with Global Fund resources. This raises questions about the government's long-term commitment to ensuring the sustainability of the programme. It is chilling to hear even some PLWHA activists express fears about starting on ART themselves, given the uncertain future of Global Fund financing.
10. Second-line medicines are currently procured by the Clinton Foundation through secret tenders with prices that are not made public. Whatever the current prices, there must be greater transparency in the future in order for advocates and governments in the region to have information needed to secure more substantial price reductions for new drugs. All evidence indicates that second-line therapies are extremely expensive. For single-source patented ARVs such as Kaletra (and, to some extent Bristol-Myers Squibb's Reyataz, Roche's Nelfinavir and Fuzeon, and other drugs), the Dominican Republic and a number of other resource-poor countries in Latin America and the Caribbean currently pay eight to ten times the price paid by least developed countries, and 20 times the cost of the current first-line treatment combination therapy.



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The “3 by 5” target for India was 355,000 people receiving ART by the end of 2005. Yet, according to the National AIDS Control Organization (NACO), a total of only 35,678 PLWHA in India were receiving ART by the end of February 2006.

Approximately 26,000 of them were receiving treatment through NACO-supported ART centers. In the states of Jammu and Kashmir, Jharkhand, and Kerala, state governments are supporting nine ART centers in which 766 PLWHA were receiving treatment as of February 2006.

For the ITPC follow-up effort, an INP+ research team met with NACO officials and also e-mailed them a list of questions. NACO provided the most recent information about ART to INP+ during the meeting.

The available data on ART access in India is shown in the table below. It includes both PLWHA who receive free ARVs and those who pay for treatment out of pocket.

Number of PLWHA on ART (free and out of pocket)

Sector	Number of PLWHA on ART-
NACO-supported ART centers (free ARVs)	26,485
State-supported ART centers (free ARVs)	768
NGO-supported ART centers (free or subsidized ARVs)	3,699
Intersectoral partners (Railways, , Employees State Insurance and Defense)	2,327
Private hospitals in Delhi (not free of cost)	2,398
Total	35,676

Source: NACO, as of the end of February 2006.



Update on treatment delivery

- Reforms to national guide lines allowing more people to receive treatment
- Action needed on paediatric formulations and equity provisions
- Clear plan for universal access by 2010 must be developed urgently

Status of November 2005 recommendations to NACO:

1. Direct public ART centers to enroll PLWHA even if they satisfy only one of the eligibility criteria.

Follow-up: Until recently in most of the ART centers only PLWHA with a CD4 count below 200 cells per cubic millimeter were enrolled in the government's ART programme. In December 2005, NACO set up a national ARV technical committee consisting of HIV/AIDS medical experts to look into issues related to the national ART programme. INP+ representatives had been participating in the meetings of this committee. The ARV technical subgroup of this committee recommended initiating ART for symptomatic patients whose CD4 count is between 200 and 350, and it advised clinicians not to wait for the CD4 count to fall below 200. However, these recommendations have not yet been formally accepted and announced by NACO.

2. Be flexible in eligibility criteria with regard to PLWHA who are already on first-line ART using their own money.

Follow-up: The ART technical subgroup recommended that ARVs should be provided to: "a) all persons with HIV infection who are eligible to receive ART medically, and, b) those who are on ART from outside the national programme and want to get enrolled into the national ART programme according to the available national ART regimen after written informed consent." Although this recommendation has not been formally accepted and announced by NACO, information gathered from PLWHA and doctors in government ART centers shows that PLWHA whose CD4 count is more than 200 and who can no longer afford to pay from their own pocket are being enrolled in the national ART programme.

3. Develop a plan to provide second-line regimens.

Follow-up: In November 2005, NACO organized a consultation meeting on the feasibility of introducing second-line regimens in the national programme. NACO has yet to take a decision on this issue. However, it has indicated that ensuring the availability of and access to affordable second-line ARV drugs will be one of the major problems in the near future¹.

4. Provide paediatric formulations for ART.

Follow-up: Paediatric formulations and dosages have yet to be distributed in government ART centers. However, NACO staff say they have consulted with the Indian Association of Paediatricians (IAP) to finalize national paediatric HIV treatment guidelines and drug procurement. Recently NACO's Director General Ms. Sujatha Rao announced that about 10,000 children living with HIV will be provided treatment, though no date was given. Further she mentioned "The [ARV] treatment will cost NACO Rs 8,000 per child. The

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[paediatric treatment] protocol will help us motivate pharma companies to produce ART drugs with specific formulations."² Currently, in the absence of paediatric formulations and dosages in government ART centres, adult tablets are often split or powdered and given to children. Recent studies have documented that dividing adult Triomune tablets for use by children may result in under-dosing. Even though generic manufacturers are producing paediatric formulations and children's tablets (like Pedimune baby and Pedimune junior, both made by Cipla), these are not yet available in government ART centers³.

5. Develop a policy to ensure equity in ART access.

Follow-up: There is no explicit policy regarding equity in ART access and also no plan for ensuring that marginalized groups (women, children, men who have sex with men, *hijras* [transgender women], sex workers, and injecting drug users) will have equitable access to ART. As of 28 February 2006 a total of 16,635 males were receiving ART in NACO-supported ART centers, compared with only 8,323 women, 1,215 children, and 58 *hijras* (transgender women). There is no specific data on how many MSM, sex workers, or IDUs are on ART through government centers, nor is there age or gender data for children on ART at all public ART centers.

6. Develop a plan for universal access to ART across the country.

Follow-up: INP+ has urged NACO to hold an urgent consultation meeting on universal access to treatment in India by 2010. However, NACO has not discussed developing such a plan. It is not known whether the India offices of UNAIDS and WHO are having discussions with NACO regarding universal access in India.

In its e-mail communication to INP+, NACO noted that "there is no change in the target of providing ART to 180,000 PLWHA by 2010. However if more persons come forward for ART, the targets can be scaled up." NACO also said that the number of government ART centers will be increased to 100 by the end of May 2006⁴. NACO does mention interim targets from 2006 to 2010, as noted in the table below.

NACO's proposed scale-up plan⁵:

Year	2006	2007	2008	2009	2010	2011
Target for ART through national programme	30,000	100,000	125,000	150,000	184,000	200,000

INP+ has been urging NACO to develop a plan for universal access in India by 2010 as soon as possible.

Other recent ART developments in India

Generic drugs

INP+ and the Lawyers' Collective HIV/AIDS Unit officially submitted their opposition to a patent application filed in the Kolkata patent office by Glaxo Group Limited for Combivir, a fixed-dose combination of two ARVs (zidovudine/lamivudine, or AZT/3TC). The opposition is based on technical and health grounds. If India grants a patent on this AIDS drug, it might set a precedent that will hamper access to affordable AIDS medicines worldwide⁶. K.K. Abraham, president of INP+, stated, "We are objecting to the patenting of Combivir because it is not a new invention but simply the combination of two existing drugs. More importantly, the granting of such a patent risks increasing the cost of antiretroviral treatment for many people living with HIV/AIDS, thereby further increasing the burden on developing countries already struggling to treat patients."⁷ A parallel legal opposition will also be filed by Cipla, a generic manufacturing pharma company.

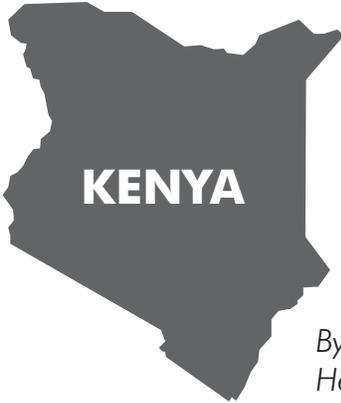
Also, in the first week of May 2006, the INP+ and the Delhi Network of Positive People registered a pre-grant opposition to the patenting of Viread (Tenofovir disoproxil fumarate), an important second-line ARV. Doctors Without Borders (DWB) is providing technical support to the groups in their legal fight. The group's statement said if Gilead gets the patent, Indian production of the generic version would be forced to halt. "This will not only increase the price of the drug, but it would also lead to its unavailability in many developing countries," DWB said.⁸ Cipla had also filed a pre-grant opposition to the patent application, arguing that tenofovir was "known" prior to 1995, the cutoff date for patent protection under the new Indian patent law.⁹

Union budget 2006–2007 and HIV/AIDS¹⁰:

The Indian government appears to have recognized the need to give adequate attention to HIV/AIDS in the most recent national budget. Earlier this year, INP+ also sent a briefing note and recommendations to the Indian finance ministry on the issues related to HIV/AIDS that need to be considered when finalising the union budget 2006-2007.

The highlights in relation to HIV/AIDS are:

- the customs duty on 10 antiretroviral drugs has been slashed from 15% to 5%;
- ARVs and test kits have been exempted from excise duty and countervailing duty (CVD);
- the National AIDS Control Programme budget has been raised from Rs 476 crore (US\$ 108 million) to Rs 636 crore (US\$ 144 million); which is 35% higher than last year; and
- special diagnostic kits (including CD4/CD8 and viral load tests) are exempted from customs duty and CVD.



By Elizabeth Owiti,
Healthpartners, Kenya

In Kenya, HIV prevalence is 7% and more than 220,000 people are thought to be in need of ART. By the end of December 2005, approximately 39,000 people—30% of the 130,000 patients receiving HIV/AIDS care—had begun ART. By 31 March 2006, however, data from the country's 218 ART sites indicated that a total of 73,528 patients had at one point started on ART, and that 69,384 were currently receiving it¹¹.

This was below the government's "3 by 5" target of having 95,000 on ART by end 2005, and makes it unlikely that the target for the end of 2006—140,000 on treatment—will be met.

ART taskforce results

A taskforce of experts from health and academic institutions as well as stakeholders including the Ministry of Health, the National AIDS Control Council, the National Leprosy and TB programme, WHO, PEPFAR, civil society organizations, and PLWHA was formed to deliberate on ART-related issues and advise the national government. This taskforce operates through several subcommittees that focus on training, systems, communication, laboratory, opportunistic infections, drugs, operations research, and paediatric care. The following is their progress report:

Treatment literacy

A substantial number of people still do not have access to treatment because they do not have adequate treatment information. In one promising development, the government, through the ART taskforce and in partnership with funding initiatives like PEPFAR, has increased media coverage of HIV/AIDS by airing programmes on prevention, ART, care and support. One television programme, "Mending the Ribbon," also offers treatment education. However, since only 22% and 3% of Kenyans have access to radio and television, respectively, the majority of HIV-



Update on treatment delivery

- Famine is a growing problem
- Insufficient access to treatment information
- Delays in release of Global Fund monies and concerns about management of the national programme
- Inadequate number of health workers to provide necessary services
- TB remains critical issue
- Integrated TB/HIV reporting system launched
- Weak drug supply chain
- Well functioning PEPFAR programme

infected and -affected people do not receive this information. The programmes are not aired in local languages, which also limits their effectiveness. The government, technical assistance organizations and the ART taskforce need to implement new ways of getting timely and accurate treatment information to the people who need it.

Poverty, food, and nutrition issues

Famine and drought in many regions of Kenya during the last six months have further complicated treatment delivery. Even in facilities providing HIV/AIDS comprehensive care, nutritional support is still minimal except for nutritional education.

"I am too weak to work for food. The [provincial] chief gives us food, and I eat about one meal per day...It is taking very long for me to recover because I do not have enough food."

— Kenyan PLWHA

Problems with Global Fund grants

The Global Fund Country Coordinating Mechanism (CCM) remains weak. It has long been criticized for shortcomings in its management of the country's Global Fund grants, including in areas involving planning, accounting, transparency, and documentation.

In May 2006 the Global Fund approved a US\$70 million, three-year second-phase grant for programmes in Kenya even though the government had not submitted an audit of the previous grant by the agreed upon deadline. Though there were no indications of fund mismanagement, the second-phase grant has been approved conditionally. The conditions have not been made public by the Global Fund.

Though the Global Fund did not ultimately withhold the approved grant, the slowness and lack of transparency in the government's auditing policies may cause more problems in the future. The National Community-Based Organizations Council has called on the Global Fund to revise its funding policy to allow for the direct application of multisectoral principal recipients, thereby bypassing the government.

In addition, significant resource delays within Kenya continue, both in funding from the government and in financial transfers among individual agencies, such as from the Finance Ministry to the Health Ministry.

Health care workers

Kenya is facing a human resource crisis. As in other African countries, the brain drain of medical personnel has become a major constraint to development and health systems improvement.

KENYA

The human resource crisis continues even as the government says it is training and employing more health workers. Since June 2005, the government has released several statements saying that some 4,000 nurses would be hired—but that has still not happened. The government's inability to respond to (or perhaps even fully understand) the crisis was characterized by a comment in April 2006 by an assistant health minister. He reportedly applauded the migration of Kenyan nurses to the United Kingdom and the United States, saying that it was a positive health development since the government was unable to absorb all Kenyan health care workers. The government has also made no effort to improve working conditions for existing health care workers, who frequently are overwhelmed and inadequately trained in crucial things such as how to administer ART.

Other funding initiatives, including PEPFAR, are funding HIV/AIDS technical health workers who provide treatment, monitoring, and evaluation in public health facilities. However, much more needs to be done to boost the size and quality of health care personnel if scale-up is to be successfully achieved.

TB/HIV

Currently TB is killing 200 people a day in Kenya. In 2005 alone, 108,000 TB cases were reported in the country, and an estimated 70,000 people died of the disease. TB has become a major entry point to ART when the TB patient is also HIV-positive. Though TB treatment is free in Kenya, many patients die from TB due to the lack of treatment education, ill-equipped laboratories and poor infrastructure, a paucity of trained health care workers, and stigma. Furthermore, many Kenyans are suffering from multi-drug resistant tuberculosis (MDR-TB), which is extremely difficult and expensive to treat. In March 2006, the government declared TB a national emergency.

Country-wide integrated TB/HIV recording and reporting tools, introduced during the third quarter of 2005, should greatly increase the availability of accurate and updated information on TB and HIV. In addition to the existing TB data collection system, HIV-related data are now being recorded/reported on CD4 counts, HIV testing, partner HIV testing, cotrimoxazole preventive therapy, ART, and referrals to and from other TB clinics, antenatal clinics, and VCT units.

During the third quarter of 2005, a total of 39 districts used the new tools and 16,470 (58%) out of 28,269 TB cases reported using the new system. In the fourth quarter, 60 districts used the new tools and 23,033 (84%) of TB cases reported using the new system.

PEPFAR

The PEPFAR-funded collaboration of the government of Kenya, WHO, UNAIDS, UNICEF, PEPFAR, and local institutions has been useful and effective. The consultative process and joint planning enriches the treatment plans, and treatment-related

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decisions such as ART procurement and types and quantities of ARVs to procure are usually discussed by these stakeholders. Treatment guidelines from WHO and the government are used by the group.

Overall, PEPFAR is focused and results oriented. There is continuous monitoring and evaluation of its projects and also ongoing efforts to ensure that targets are met. PEPFAR has a well coordinated and efficient ARV procurement and distribution process through Mission for Essential Drugs, a faith-based organization that has been involved in the training of health care workers on ART and distribution of ART throughout the country for several years. The ARVs are ordered directly by treatment sites.

PEPFAR also procured 3,000 doses of AZT (tablet form) and 3,000 doses of syrups for its PMTCT projects, which are currently being implemented at five PEPFAR-funded sites in Kenya. In 2006, PEPFAR plans to reach 25,000 mothers and children with appropriate PMTCT and related therapies.

Persistent challenges

PEPFAR aside, there is a weak supply chain for critical commodities throughout Kenya, especially for HIV test kits, reagents, and Global Fund ARVs. The efficiency of the government's National AIDS Control Council also suffers from inadequate staffing and frequent personnel changes.



By Olayide Akanni,
Journalists Against AIDS Nigeria

The November 2005 ITPC report identified several barriers to treatment delivery in Nigeria:

- Inequitable distribution of treatment centers in the country
- Lack of financial, human, and infrastructure resources
- High cost of treatment and CD4 and viral load tests
- Inadequate coordination among providers, the government, donor agencies, and TB programmes
- Bureaucratic delays
- Stigma against PLWHA
- Lack of treatment literacy programmes

The report made the following recommendations to accelerate scale-up of ART access:

1. Expand geographic reach of services beyond cluster zones
2. Include more NGOs in service provision
3. Increase government funding consistent with commitments
4. Make treatment and CD4 and viral load testing free
5. Work with donors to strengthen overall health system

Progress report update

A number of initiatives have taken place in Nigeria over the last six months as part of the government's stated goal of expanding ART access to 250,000 Nigerians by the end of 2006. Some of these developments—the good news and the bad news—are chronicled below:



Update on treatment delivery

- Cancellation (in May 2006) of two GFATM grants jeopardizes further expansion of treatment access
- Government pledges free treatment availability, but not free access to testing
- Increased number of treatment centers throughout the country
- Modest increase in treatment access
- Continued need for harmonization of GFATM, PEPFAR, and government programmes
- Need for greater involvement of civil society in planning and implementation

The good news:***The pledge of free treatment***

1. **December 2005**¹²: The president announced the provision of free treatment and free antenatal care and delivery services to PLWHA accessing treatment in government-owned ART centers across the country. The programme started in some facilities in January 2006 and is gradually spreading to other government sites. However, patients still face the challenge of having to pay for testing services such as CD4 count and viral load testing. There has been no definite commitment to free monitoring tests by the government programme.
2. **January 2006**¹³: The Federal Ministry of Health brought together all chief medical directors (CMDs) of government-run ART programmes and a few civil society representatives to discuss plans for ensuring successful implementation, monitoring, and sustainability of the free treatment policy and free antenatal care services. Attendees also discussed their roles and responsibilities and pledged their full commitment to the programme's implementation.

This meeting also identified poor coordination and collaboration between partners as a major factor limiting treatment scale-up efforts. Issues raised at the meeting were quite similar to those noted in the November 2005 ITPC report.

During the meeting, a report from the Federal Ministry of Health based on monitoring/supervisory site visits to 29 government ART centers in 2005 was presented¹⁴. Among the key challenges observed from the site visits are the following:

- Parallel ART programmes were operating at the sites, a situation that contributed to the lack of harmonization among ART programmes funded by different organizations. Findings from the supervisory visits showed that programmes were labelled specifically as a federal government, Global Fund, or PEPFAR programme instead of self-identifying as part of the federal government's overall treatment programme.
- Complaints were raised by site personnel as to the different yardsticks being applied under the ART programmes. While incentives—including overtime allowances and travel grants to participate in international conferences—were provided to some site personnel working with some "partner" programmes, personnel working with the government programme did not receive such additional benefits.

NIGERIA

During discussions at the meeting, CMDs also raised several other concerns, including:

- the feasibility of achieving the presidential mandate to place 250,000 PLWHA on ART by the end of 2006;
- the need for civil society involvement, particularly in areas of treatment literacy and patient follow-up;
- the need to reduce stigma in order to promote uptake of services;
- providers' non-alignment with national programme requirements and the need to develop clear cut, patient-centered harmonization of all existing treatment programmes; and
- the need to view all treatment programmes as one unified programme—rather than as separate, parallel structures divided according to whether they are funded by the federal government, PEPFAR, or the Global Fund.

Increasing harmonization of services

At the end of the January 2006 meeting, a Harmonization Committee was set up. The committee was given the task of developing the Nigerian government's strategy for its ART programme. Several side meetings have also been held with PEPFAR partners to discuss the issues raised and to seek agreement on a joint position.

Next Steps: The Nigerian government needs to speed up the process and obtain agreement from its partners on a harmonization plan for the treatment programme as soon as possible.

Toward universal access

3. **February 2006:** A consultation on the development of a road map for scaling up universal access to HIV prevention, treatment and care by 2010 was held in Abuja¹⁵.

The new road map identified next steps to be taken to attain universal treatment access in Nigeria, with assignments of individuals and organizations responsible for particular tasks. The road map was presented at a meeting in Congo-Brazzaville in March.

A separate meeting was convened in March 2006 by civil society groups working on HIV/AIDS in Nigeria to discuss their position on universal access, Abuja+ 5, and UNGASS. Concerns raised at the meeting about the road map process included the limited engagement of civil society representatives and the limitations of the country reporting format developed by UNAIDS, which makes it difficult to adequately reflect grassroots perspectives about challenges to treatment scale-up.

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Next Steps: Outcomes of the consultation meeting need to be translated into action, starting immediately. National goals and targets need to be broken down into measurable tasks and followed through with commitment: Who does what, when, and how should be clearly articulated and resources made available to implement the road map.

Expansion of ART centers

4. **March 2006:** Health Minister Eytayo Lambo announced that there were 74 treatment centers in the country; they were operating in the capital, Abuja, and in 35 of the country's 36 states. The last state is expected to have a treatment center by the middle of this year¹⁶. In March, an estimated 50,000¹⁷ PLWHA were on treatment, an improvement from the over 30,000 recorded in September 2005.

The bad news: Global Fund grant cancellation¹⁸

A serious financing gap for the expansion of treatment access in Nigeria has been created as a result of the Global Fund termination, in May 2006, of two grants to Nigeria on the grounds that performance on these two grants has been inadequate. The two terminated Nigerian grants were a Round 1 award for provision of ART, and a Round 1 grant for PMTCT services. The grant termination suggests that Nigeria will lose an estimated US\$81 million which could have been used to further expand access to much needed ARV and PMTCT services.

However, the Board has decided that individuals who are currently receiving ARV treatment under these grants will continue to have their treatment financed by the Fund for up to two years while alternative options are pursued.

According to AIDSpan¹⁹, numerous reasons for the grants' cancellation were indicated in documentation provided by the Secretariat to Board members. For one thing, the grant agreement specified that 14,000 people would be on treatment by the end of the grant's fourth quarter, but the actual number was zero. At least 24,000 should have been on treatment by the end of the seventh quarter, but the actual number was 6,865.

Multiple other targets specified in the grants also were not met, and funds were spent at a much lower rate than they should have been.

Questionable data was provided to the Global Fund by the Principal Recipient (PR), the NACA (National Action Committee on AIDS). In particular, at one point the number of people that the PR reported as being on treatment turned out instead to be the number of people who could have been treated if all the drugs sent to health facilities had been used.

NIGERIA

Funds were spent on inappropriate activities: For instance, US\$50,000 was spent to send 14 people on information missions to Botswana at a time when the grant was not performing.

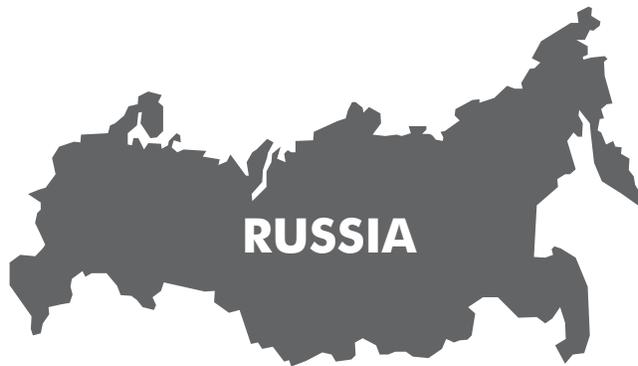
The CCM rated these grants as "B1: Adequate" when this clearly was not the case. The CCM failed to acknowledge or report many of the problems. Promised reforms to the CCM itself had not taken place either.

The PR has made remarkable efforts to improve the implementation of the grants in the last six months, but the Global Fund did not take these into account since its assessment was based on the first two years of performance.

What needs to be done?

An orientation/proper briefing on Global Fund grantmaking and grant assessment procedures need to be provided to potential PRs, SRs, CCM members, and treatment advocates to forestall a similar occurrence again.

CCM restructuring is currently underway. The new CCM needs to discharge its oversight functions more effectively, particularly in regard to ensuring that PRs and SRs with adequate capacity to deliver are selected and that grant implementation is conducted in a timely manner.



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

By May 2006, only slightly more than 5,000 people of the estimated 50,000 in need were receiving ART. This woeful situation will hopefully change as a result of an ongoing massive campaign to scale up access with the financial support of donors including the GFATM and, more recently, the Russian government. The Russian Health Ministry has announced that it plans to provide ART to 15,000 people by the end of 2006 and to 30,000 by the end of 2007. Some progress toward these goals has been made within the last six months, but major reforms and increased capacity building are needed to make the government's goals a reality.

Follow-up to recommendations from the November 2005 ITPC report

Develop treatment protocols. Follow-up: The Federal Scientific Methodological Center for Prevention and Combating HIV/AIDS is in the process of developing a set of protocols related to the treatment of HIV. Some of them are projected to be completed by September 2006. WHO has been involved in the development of the protocols, but civil society involvement has been weak. PLWHA have been involved neither in the review nor in the development of the protocols.

Build collaborations between civil society and the government. Follow-up: Foreign-funded civil society organizations are under increasing scrutiny in Russia in the wake of a new law—which took effect in early 2006—that tightens state control of NGO activities. There has been growing suspicion and pressure on NGOs. In



Update on treatment delivery

- Increased government financial support for treatment and distribution of new GFATM funding
- Limited increase in treatment access
- Treatment protocols under development
- Tighter controls on civil society organizations, including NGOs providing HIV/AIDS prevention and treatment services
- Continued urgent need for harm reduction and substitution therapy services for IDUs
- Need for training and other measures to expand human resource capacity
- Need for improved drug procurement, better monitoring, and more adherence support, anti-stigma campaigns, and involvement of PLWHA.

RUSSIA

Moscow, for example, a member of the municipal legislature publicly appealed to President Putin to close down the NGO consortium administering the Round 3 Global Fund grant because, he said, the project approach was antithetical to Russian values. The appeal was not upheld and Ministry of Health officials publicly defended the NGO consortium, whose GFATM project is based on international best practice. One positive outcome of this controversy is that despite growing suspicion of NGOs throughout much of the government, the Ministry of Health is becoming more supportive of them, especially regarding HIV/AIDS service delivery.

At the same time, communication and cooperation between civil society and government have been encouraged through the UNAIDS “Three Ones” initiative at the federal level, but local level cooperation remains weak. There is a need to increase the capacity of NGOs and PLWHA groups to more strategically take advantage of the opportunities to participate.

Provide training and support for human resources. Follow-up: A colossal amount of training for a wide range of health personnel is necessary to ensure the success and effectiveness of Russia’s scale-up effort. Difficulties include a lack of training modules adequately adapted to the Russian setting and an insufficient quantity of qualified trainers. There is increasing recognition that some HIV-related services should be integrated into primary care facilities instead of being relegated only to the soon-to-be-overwhelmed AIDS centers.

Promote treatment uptake. Follow-up: One of the most serious barriers to access to ART in Russia is a lack of awareness among PLWHA and the general population as to the existence and availability of treatment for HIV infection. In the regions covered by the Round 3 Global Fund grant—where ART availability is reasonably adequate—patients are not coming forward. ART access is not advertised publicly, and outreach efforts among vulnerable populations are of inadequate scale to bring in new patients.

Tap the expertise of people living with HIV/AIDS and vulnerable communities. Follow-up: There is a limited but growing recognition among governmental structures of the important role of PLWHA in decision making and service provision. However, considerable work still needs to be done to encourage PLWHA involvement and make it effective. There is also an urgent need to increase the capacity of PLWHA to take full advantage of and to create opportunities for participation in the decision-making process.

Use monitoring to improve programmes. Follow-up: As called for in the UNAIDS “Three Ones” initiative, multisectoral participation in monitoring has increased, but there is still a need for a monitoring strategy capable of assessing how newly released government funds are being used. NGOs and PLWHA groups need to increase their monitoring capacity to realize their vital role in monitoring and reporting on service delivery issues including treatment interruptions due to stock out of medications, discrimination, and other factors.

Advocate for treatment, harm reduction, and other services for IDUs.

Follow-up: In Russia, the majority of those urgently in need of ART are IDUs, and efforts to make treatment accessible to them remain inadequate. Most importantly, substitution therapy is still illegal in Russia. A progressive narcologist who is a proponent of substitution therapy recently was arrested by local authorities for attempting to start a clinical trial (he was later released). In the summary statement produced by the Organizing Committee of the recently held Eastern European and Central Asian AIDS Conference, Russian authorities insisted that substitution therapy not be mentioned. Harm reduction services are still not available on a scale adequate to reach most of the IDUs who might benefit from them. Furthermore, most IDUs are not aware that ART is available—and even if they are aware, they are often reluctant to contact health care facilities because of justified fear of poor or discriminatory treatment by medical personnel.

Provide adherence support. Follow-up: Providing the psychosocial support necessary to promote adequate adherence requires a redesign of the national approach to service provision. In some pilot regions (those targeted by the Round 3 Global Fund project), an approach involving multidisciplinary treatment teams has been undertaken. This approach emphasizes the adaptation of models designed to improve case management and incorporate peer support into treatment delivery. The Round 4 Global Fund project is also gearing up to incorporate peer support in its service provision model. The situation is less hopeful in non-GFATM regions. There is a need to increase the capacity of PLWHA and PLWHA-led initiatives to provide high-quality and professional services nationwide, and to convince public sector and non-governmental service providers of the value in working with PLWHA to improve delivery.

Improve and centralize drug procurement. Follow-up: Russia is still facing major problems with its drug procurement and distribution systems. In the last three months, patients in at least four regions have experienced treatment interruptions due to supply problems. PLWHA groups are discussing ways of more systematically monitoring and responding to such situations. Drug prices, even for governmental purchases, have been lowered to US\$1300–\$1500 per patient per year for first-line therapy. Discussions with pharmaceutical companies for the purchase of licenses for local production are under way. However, the government is not currently considering purchasing and producing generic drugs domestically. This is unfortunate because although ARV prices have fallen in Russia, they are still significantly higher than they are in neighboring countries. For example, in Ukraine generic competition has reduced prices to approximately US\$300 per year.

Work to reduce stigma. Follow-up: Stigma and discrimination of PLWHA and vulnerable groups remains widespread across Russia. Some progress has been made in working with journalists to improve the quality of HIV/AIDS-related reporting, but this is not universally true. (It should be noted that the quality of reporting on World AIDS Day in 2005 was generally quite good.) Meanwhile,

RUSSIA

stigma and discrimination among medical personnel are still quite prevalent. The growing availability of ART could reduce some of the fear that leads to stigma as the population learns that HIV is treatable. But this opportunity is being missed in Russia where the general population remains largely unaware that ART exists. There is, though, a growing recognition of the importance of the issue of stigma and discrimination. In his closing presentation at the recent Eastern European and Central Asian AIDS Conference, Russia's Chief State Sanitary Officer, Dr. Onishenko emphasized the importance of fighting stigma and discrimination.

Valuable lessons are being learned in regions targeted by the Round 3 Global Fund grant and in neighboring countries. These lessons must be taken into account for the government to keep its promise of providing nearly universal access to ART. Broad-based access will require continued emphasis on intensive policy reform, restructuring, provision of new services, and encouraging new attitudes. Civil society organizations must be strong, professional, and vigilant in monitoring, influencing, and participating in the scale-up process. Their ability to achieve these objectives would be enhanced by increased advocacy and service-delivery training as well as by a lessening of government pressure on NGOs.



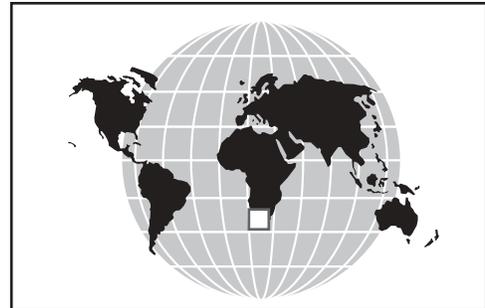
By Fatima Hassan,
AIDS Law Project

The November ITPC report identified the lack of proper leadership coupled with AIDS denialism as the most important obstacles to increasing the number of patients on treatment in South Africa. Other barriers identified were an acute shortage of health workers—mainly nurses and pharmacists—and lack of proper infrastructure; insufficient access to and promotion of voluntary counseling and testing; and too few children on treatment.

In its recommendations section, the report called for a new and more effective Global Fund CCM; fewer restrictions and more collaboration from the PEPFAR programme, including using generics registered in South Africa; increased visibility and leadership from UNAIDS and WHO; and greater involvement from civil society in treatment expansion. This update assesses what has happened since.

Treatment programme

By January 2006, the total number of people on ART in both the public and private sectors totaled about 200,000 to 220,000. Some 110,000 to 120,000 of them were accessing ART in the public sector, with an additional 90,000 to 100,000 receiving it in the private and not-for-profit sectors²⁰. The majority of people receiving public-sector care continued to be concentrated in three provinces: Gauteng, KwaZulu Natal, and Western Cape. About 60% of patients receiving publicly funded ART were women. Paediatricians estimate that about 10%–15% of them were children. In many smaller and less resourced provinces, the percentage of children on treatment is much lower²¹; children therefore continue to be neglected.



Update on treatment delivery

- Total number receiving treatment grew to 200,000–220,000
- Limited ART delivery to children and to men in the public sector
- Continued lack of national leadership and pervasive AIDS denialism
- Limited public consultation on new HRH (human resources in health) plan
- Inadequate action to ensure availability and affordability of second-line therapy
- Continued non-functioning of GFATM CCM
- Continued restrictive policies by PEPFAR
- Continued government efforts to inhibit full participation of civil society

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Relatively few men are accessing treatment in the public sector, but in the private sector men outnumber women on treatment. This is because workplace treatment programmes are generally more available to male workers. Most patients on ART in the public sector are still receiving care at academic hospitals and so-called main sites, with very few patients accessing ART at rural and remote sites.

There is no proper monitoring and evaluation (M&E) system for ART provision²², a situation that has been confirmed by the national Department of Health²³. Recently, some 30 months after the Operational Plan was adopted by the government, the department admitted that the total number of people receiving ART is “not yet known, as the patient monitoring system is not yet able collect information to this level of detail in a reliable manner”²⁴.

According to public health experts, the failure to institute a reliable M&E system has resulted in provinces employing different solutions and approaches to ART. Even though revised indicators are available, many of them are not feasible without a facility-based system through which data can be aggregated. The indicators themselves are often confusing and do not follow principles of collecting limited but necessary information²⁵.

Missing the Target, ITPC’s November 2005 report, also identified acute human resource shortages as a major barrier to speedier treatment implementation. These shortages have not abated. Since then, the national Department of Health has released a country plan for human resources in health (HRH), yet to date there has been very little consultation with civil society and health workers regarding the HRH plan. It remains to be seen how effectively the plan will be implemented²⁶.

The South African government has not sought or secured licenses for the generic manufacture and production of second-line drugs. It has also not responded to calls from HIV clinicians to remove d4t from the national treatment protocol and replace it with tenofovir (which has fewer side effects). Tenofovir is still not registered in South Africa.

The lack of effective national leadership and AIDS denialism continue to undermine the implementation of the government’s Operational Plan. There are no signs that these problems are abating. For example, in legal papers filed by the national Department of Health in a high court case, the director general of health reported finding no wrongdoing by a notorious denialist organization—the Rath Foundation—or its associates. Government officials therefore have not taken any steps to end the distribution of false information suggesting that vitamins are an effective substitute for ARVs.

Relevant international progress

GSC and UNGASS

At the country level, South Africa has had minimal effective consultation on universal access, largely because this process was part of the UNGASS reporting process (see below). UNAIDS and the UK Department for International Development (DFID) invited civil society representatives to the recent Global Steering Committee (GSC) meetings, but the convening agencies did not include leading advocacy NGOs such as the Treatment Action Campaign (TAC) and AIDS Law Project (ALP). At the request of international civil society representatives, both were invited to attend two of the last three GSC meetings as observers²⁷. In general, the GSC process has been rushed at both a regional and international level and has failed to properly include the views of civil society. It remains to be seen what will happen after UNGASS, when country delegations announce their plans (and targets) for universal access.

In February 2006, the national Department of Health on behalf of the South African government submitted its *Progress Report on the Declaration of Commitment on HIV and AIDS*²⁸ (Progress Report). It did so unilaterally and without any significant or extensive consultation with stakeholders. The department also excluded the views of civil society, private groups, and health academics²⁹. The Progress Report has been criticized by many organizations in South Africa for glaring inaccuracies as well as its attempt to gloss over key shortcomings of the country's AIDS policies³⁰. By all accounts, it is not an honest reflection of the government's performance in meeting certain obligations to prevent and treat HIV/AIDS. Significantly, the Progress Report fails to include information, data, and statistics regarding HIV incidence, mortality, and prevalence; TB incidence; ART patient numbers; or ART targets. The government submitted a second and final updated report to UNGASS, dated March 2006, titled *Republic Of South Africa: Progress Report on Declaration of Commitment on HIV and AIDS*.

In addition, the South African government recently denied two leading NGOs (TAC and ALP) UNGASS accreditation—and thus participation at the UNGASS meeting in May–June 2006—by using the General Assembly's "no objection" clause. According to the national Department of Health, TAC and ALP were denied accreditation because they would use the UNGASS platform to "rubbish government policies." The minister of health's decision to deny TAC and ALP accreditation has been attacked by organizations and activists locally and internationally³¹. However, multilateral organizations such as WHO and UNAIDS have not formally criticized the government's decision—with the notable exception of Stephen Lewis in his capacity as Special UN Envoy for HIV/AIDS in Africa.

Subsequently, TAC (but not ALP) was invited to be part of the official South African delegation. TAC refused the invitation because of ALP's exclusion, and both organizations will participate instead through other international organizations.

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GFATM

In the November 2005 ITPC report, the ineffectiveness of South Africa's Global Fund Country Coordinating Mechanism (CCM) was identified as one of the main reasons that GFATM funds have been denied to South Africa in previous funding rounds. In July 2006, the GFATM Partnership Forum will be held in Durban, South Africa, and the GFATM's global board is also expected to meet then. At this forum, South African civil society organizations—including specific sectors that currently participate in the country's National AIDS Council and CCM (including the human rights, PLWHA, and business sectors)—intend to submit recommendations for the restructuring of the current CCM. AIDS activists want it to be replaced with a better functioning structure that is totally outside the control of the national government and is capable of functioning in a timely and transparent manner. Activists also want greater civil society participation and input in future applications for funding from the GFATM.

In general, the consistent failures of the CCM suggest the need for alternative funding structures and application processes. Nearly all non-government stakeholders working on HIV/AIDS issues in South Africa are hopeful that the GFATM will take appropriate action to end the consistent ineptitude and lack of independence exhibited by the existing CCM.

PEPFAR

PEPFAR continues to apply restrictive funding conditions, including not actively promoting the use of condoms and only using drugs registered by both the U.S. Food and Drug Administration (FDA) and South Africa's Medicines Control Council (MCC). This means that until both regulatory agencies register generic versions, PEPFAR partners cannot use them.

PEPFAR's international partnership meeting will be held in Durban, South Africa, in June 2006. Only partners (funded programmes) are entitled to present and submit abstracts; however, other organizations are entitled to attend the meeting. It is therefore unclear to what extent civil society (including PLWHA) will be given the opportunity to critically evaluate PEPFAR programmes and question the conditions imposed by programme administrators in Washington, D.C.

Conclusion

A number of the barriers identified in the November 2005 report continue to inhibit the rapid and effective scale up of treatment and prevention efforts in South Africa. What is worrying is that it appears that the implementation of the Operational Plan is being deliberately stalled for a number of reasons ranging from denialism to a lack of proper leadership and massive human resource shortages. The reality is that many more adults and children in South Africa need treatment than are able to access it.

Endnotes

1. See: www.redribbon.org.in/news/april06/025040601. NACO wants to ensure adequate supply of second-line drugs for AIDS treatment. New Delhi, 24 April 2006.
2. <http://timesofindia.indiatimes.com/articleshow/1521399.cms>
3. See: www.aidsmap.com/en/news/F612510C-677F-4286-BE95-91A637033A82.asp.
4. NACO originally planned to meet this target of 100 ART centers by the end of December 2005. However, as noted directly by NACO itself in communication with INP+, as of 28 February 2006 only 54 NACO-supported ART centers were functioning.
5. Based on e-mail communication from NACO to INP+.
6. See: www.youandaids.org/News/Headlines.asp?ID=8D0BD150275041308B19DEC8BDF0214B.
7. See: www.doctorswithoutborders.org/pr/2006/03-30-2006_1.cfm.
8. http://www.thebody.com/cdc/news_updates_archive/2006/may10_06/india_patent_protest.html
9. <http://news.ft.com/cms/s/694ee44a-e043-11da-9e82-0000779e2340.html>
10. See: www.redribbon.org.in/news/march06/16030603.
11. Research for this section consisted of a review of current status reports of public institutions, including the Ministry of Health, NASCOP, and the National Leprosy and TB programme, and funding initiatives such as PEPFAR. Interviews were also conducted with a PEPFAR technical expert and a member of the Kenyan ART Taskforce.
12. See: www.aegis.com/news/afp/2005/AF051250.html
13. The treatment scale-up meeting was held on 31 January 2006 in Abuja, the Nigerian capital. In attendance were the Nigerian health minister and chief medical directors of tertiary institutions, including ART centers.
14. Report on monitoring and supervisory visits to ART sites, presented by Annette Akinsete/NASCAP/FMOH on 31 January 2006.
15. The consultation was held 22-23 February 2006.
16. KaiserNet Daily HIV/AIDS reports, 13 March 2006. See www.kaisernetwork.org.
17. Report on monitoring and supervisory visits to ART sites, presented by Annette Akinsete/NASCAP/FMOH on 31 January 2006.
18. Global Fund Observer, Issue 57, 30 April 2006. See: www.aidspace.org/gfo.
19. www.aidspace.org
20. i) See Hassan F and Bosch D, Monitoring the provision of ARVs in South Africa – a critical assessment. ALP Briefing for TAC NEC. 17 and 18 January 2006. CAPE TOWN. ii) Hassan F, Tracking patient numbers in the private sector – January 2006. Available from author. And see Social Cluster briefing: Parliamentary Media 10 February 2006, available at www.doh.gov.za/docs/pr/2006/pr0210.html where the Minister's stated that there are 229 sites treating 117 897 patients on ARVs at the end of December 2005. For a more detailed analysis of the Operational Plan see Hassan F, forthcoming publication by Equinet "The Provision of ARV Treatment in SA" www.equinet africa.org
21. At the end 2005, about 245 000 - 300 000 children were estimated to be living with HIV. Some experts suggest that based on these figures, about 50-60% need immediate access to ARVs. At present we estimate that only about 10 000 – 15 00 children are receiving ARV treatment.
22. Clinicians have warned that accurate data is absent on the number of patients on ARV's. For example there are 2 separate systems (pharmacy and clinical) for capturing key data, and they rarely agree. In one 'defaulter' study, 1/3 of defaulters had actually transferred elsewhere when traced.
23. Republic of South Africa: Progress Report on the Declaration of Commitment on HIV and AIDS Prepared for: United Nations General Assembly Special Session on HIV and AIDS, February 2006. Available at <http://www.doh.gov.za/docs/reports-f.html>
24. Ibid, at p.26
25. See Hassan F, forthcoming publication by Equinet "The Provision of ARV Treatment in SA".
26. "A National Human Resources Plan for Health", April 2006. <http://www.doh.gov.za/docs/hrplan-f.html>. See also ALP and TAC "Joint Submission on A Strategic Framework for the Human

Resources for Health Plan: Draft for Discussion". Available at <http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=261>

27. At the last GSC meeting held in Geneva in March 2006, the SA government delegation complained that the TAC and ALP, though given observer status, were speaking. As a result at the final plenary of the third meeting, the ALP and TAC were told by UNAIDS that they were not able to speak and that they were only allowed to act as observers.
28. See <http://www.doh.gov.za/docs/reports-f.html>
29. At a public meeting of the JCSMF held in March 2006, participants and members of the JCSMF were informed of one consultative meeting hastily convened by the national department of health on 2 March 2006 to discuss SA's report to UNGASS on progress with the implementation of the UNGASS Declaration of Commitment (2001). At that meeting, civil society and other stakeholders were told to submit comments on the draft Progress Report within a week. But even though some organisations managed to submit short recommendations within a week, those recommendations were subsequently ignored.
30. See South Africa Joint Civil Society Monitoring Forum: Resolutions And Minutes. <http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=8>. See also letter from JCSMF dated 6 April 2006 to Kofi Annan regarding SA's Progress Report.
31. Including a global petition to 'Break the Silence' around the SA governments conduct. COSATU, the largest trade union federation in SA also criticised governments sidelining of TAC and the ALP. See here 'COSATU slams government's sidelining of TAC' at http://www.mg.co.za/articlePage.aspx?articleid=268484&area=/breaking_news