



WHO's AIDS Target: An Inevitable Failure

By Roger Bate

The World Health Organization (WHO) initiative to treat 3 million HIV-infected people in low- and middle-income countries by the end of 2005 (popularly known as the “3 by 5” initiative) has failed. Unrealistic assessments of how many people could be treated in the time frame explain the failure. But there has been additional fallout from the fiasco. Relations are frayed between WHO officials and South Africa’s health minister, who is trying to step up her nation’s AIDS treatment program responsibly. Additionally, because drugs were qualified for use before they had been properly tested and then later withdrawn, the “3 by 5” initiative added to uncertainty about how to proceed in many treatment programs around the world.

The WHO’s constitution states that its mission is “the attainment by all peoples of the highest possible level of health.”¹ The organization’s major task is to combat disease—especially key infectious diseases that ravage the world’s poor—but a long-running dispute over the preferred approach has left the organization divided and ineffectual.

From its main headquarters in Geneva, Switzerland, the WHO has the expertise and experience—and historically, the resources—to coordinate and support a limited number of high quality health interventions throughout the world. The mass campaigns the organization ran to combat smallpox, malaria, and leprosy established the WHO’s credibility by greatly reducing the burden of infectious diseases. But these top-down programs, in which the WHO oversaw all activities from the national to the local levels, have fallen out of favor with advocates of community-based systems. Furthermore, the WHO is and has always been a membership organization, with its members having far more capabilities on the ground than does the organization itself.

The early belief of the organization was that endemic, preventable, and treatable diseases should be attacked through national and international initiatives to interrupt the transmission of the infection, while the remaining, much smaller number of cases should be dealt with through the gradual development of community-based primary care facilities. But rather than coordinating these two approaches to achieve optimal results, factions emerged within the WHO that at different times favored one approach to the exclusion of the other. Many who should have known better had unrealistic expectations for both approaches.

With this fundamental difference in strategy still unresolved, the management of WHO programs is floundering. It is losing touch with the countries it is supposed to be helping and is instead causing frustration and resentment around the globe. The WHO’s attempt to improve treatment for HIV/AIDS through its “3 by 5” campaign provides an illustration of what has gone wrong. This initiative aimed to treat 3 million HIV-infected people in low- and middle-income countries by the end of 2005. The 192 WHO member states that endorsed it in June 2005 apparently considered it ambitious but feasible. Feasible, that is, “if global treatment access efforts

Roger Bate (rbate@aei.org) is a resident fellow at AEI. Kathryn Boateng contributed to this piece.

were supported by full political commitment and increased resources, and if countries successfully undertook a range of activities to rapidly expand services and build health systems capacity.”² When “3 by 5” was launched in December 2003, it was not officially presented to each country for endorsement. This lack of consultation contributed to the rift with the South Africans.

The figure of 3 million represented only about half of the estimated number of AIDS patients worldwide in need of antiretroviral therapy (ART). Like its early mass treatment top-down campaigns, the WHO took a leading role in the implementation of the “3 by 5” program. It appointed Dr. Jim Kim as global director and provided him with a large staff to help participating countries set up plans of their own. As it stood at the end of 2005, only 1 million of the 3 million AIDS patients in need of ART were receiving treatment. Fourteen countries are providing treatment to half or more of the people who need it, which is “consistent with the ‘3 by 5’ target.”³ However, none of these countries were really helped by the WHO. Many were funding their own programs before the WHO’s campaign even began (for example, Brazil started its program in 1996, and Thailand did so in 2000). Furthermore, the WHO did not even recommend the use of antiretroviral drug (ARV) treatment for poor countries until April 2002.

Additionally, the UN/Accelerated Access Initiative, an independent group consisting of seven research-based pharmaceutical companies, was supplying over 400,000 patients with drugs for free or at non-profit making prices. The WHO was a founding member of this group. One wonders why a new WHO target was required at all since this initiative was moving forward and achieving results.

Part of the WHO’s problem with setting targets like “3 by 5” is that it does not control enough funding to substantially increase treatment. Much of the funding is managed by purpose-designed organizations such as the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Funding is also provided by other bilateral donors, the World Bank, international nongovernmental organizations (NGOs), and the private sector, with technical support from UN agencies and many other organizations.

But even with \$27 billion pledged by all donors to HIV/AIDS treatment, care, and prevention over the next three years, major challenges and bottlenecks to improving treatment programs quickly appeared. Among

the most important: overworked clinicians—in short supply themselves—struggled to find trained staff or facilities to treat rural patients.

The difficulties in rapidly scaling up AIDS treatment in low- to middle-income countries were so well known that when, in December 2004, the WHO and UNAIDS⁴ (co-sponsors of “3 by 5”) estimated that 700,000 people were receiving ART, many observers were skeptical. In February 2005 at the World Economic Forum in Switzerland, PEPFAR and GFATM officials pointed out that of the total number of people receiving treatment, 63,000 of them had received funding from both agencies. The WHO haughtily but rather unconvincingly rebuffed the charge of double counting, claiming that the 63,000 patients were considered to benefit from both initiatives and so were rightly counted in both totals.⁵

Drug Quality Issues

The second contentious problem of the WHO’s “3 by 5” campaign involved drug quality and management. This arose from the efforts to drive down the costs of antiretroviral therapy while simultaneously simplifying drug regimens. In October 2003, the Clinton Foundation claimed it had brokered a deal with generic drug manufacturers in India to supply fixed-dose triple-drug therapy for only \$140 per person per year (this price did not include freight, foreign exchange costs, insurance, tariffs, taxes, and other costs, so the real price to the user was much higher). Furthermore, it applied to only one product and other organizations, such as the WHO itself and Médecins Sans Frontières (MSF), could not purchase the regimen at that price. The best price MSF could get was \$214 per person per year.

However, the Clinton Foundation’s work let the generics (or strictly speaking, copied drugs) genie out of the bottle and, in an apparent attempt to hit the target it had established, the WHO relaxed approval requirements for new drug combinations.⁶ In their well-meaning effort to get as many people on treatment for as little cost as possible, the WHO pre-qualified non-FDA approved triple-drug therapies supplied by generics manufacturers. Some drugs, which had not even been pre-qualified, were bought at costs ranging from \$169 to \$415 per person per year. This strategy turned out to be a disastrous mistake.

Generics manufacturers in most countries are required to submit documentation to the WHO to prove the “bioequivalence” of their versions (and even novel

compounds). But delays in filing adequate supporting data and apparent sloppy practices at the WHO meant that thousands of patients around the world received drugs of substandard quality. Other countries such as India do not require bioequivalence data for exported drugs, and the WHO just assumed that the Indian drugs would be bioequivalent. But the Indian drugs controller general in July 2001 even said of the Indian export drugs: “No reference in the advertisements or medical literature is made that the government has approved the drug.”⁷ This is hardly a ringing endorsement of quality. Eventually, some of these drugs (most were from Indian manufacturers and hence probably not tested for bioequivalence) were removed from the WHO’s pre-qualification list when it became apparent they failed bioequivalence tests. This was done by the WHO or, more often, by the companies themselves to escape the embarrassment of having them withdrawn.

The danger for patients who had been prescribed these drugs is that they may have received a sub-optimal dose, either because the drugs were of poor quality or because patients discontinued the treatment before it could be effective. Clinical uncertainty and possible drug resistance are the inevitable results of these questionable practices, and they end up wasting highly scarce doctor-patient time. Also, since second-line treatment—which is both extremely expensive and difficult to administer, often involving hospital stays—is required if a patient fails to respond to first-line treatment, it may have been better for the patient to have never received treatment and avoided the risk of developing drug resistance. In its enthusiasm to meet an ambitious, politicized target, the WHO took this risk.

No mention of this disaster was made in the WHO’s June 2005 update on the “3 by 5” campaign⁸ or in a speech the director gave in July. All he said then was that the organization had a “much clearer idea about the kind of technical support that is needed by countries right now to enable treatment scale up in the longer term.”⁹

It seems inconceivable, given the WHO’s long experience, that these factors were not known prior to the start of the “3 by 5” campaign. Similarly, since the goal of the campaign was to massively increase the numbers on treatment, it is dismaying that so little consideration was given to the efficient management of supplies of drugs and diagnostics.

A more professional approach would have put systems in place in advance of the campaign rather than waiting for problems to arise later. A better use of the WHO’s resources would have been to slowly build up

local treatment facilities—an approach successfully used by several governments, NGOs, and private for-profit actors. Instead, this increasingly wayward health cheerleader favored an ineffectual top-down approach with unrealistic targets. Not only are problems much more difficult to deal with in the field after implementation, but patients already enrolled also risk the grave consequence of having their treatment disrupted.

WHO and South Africa—Daggers Drawn?

An important part of building primary health care capacity is to adapt programs to local customs and requirements. It is a pity then that South Africa, which is one of the few sub-Saharan countries to develop its own primary health care strategy for AIDS, has been vilified by the international health community. Some of the criticism is justified, especially regarding President Thabo Mbeki’s flirtation with spurious ideas about the cause of AIDS. Yet many criticisms, especially recent ones both from UN officials and AIDS activists, have been misguided.

South Africa’s health minister, Dr. Manto Tshabalala-Msimang, has been quoted in the media making several seemingly perverse comments, including overplaying the toxicity of the drug Nevirapine for pregnant women with AIDS. Moreover, she has still not fully distanced herself from dangerous opinions about the efficacy of dietary supplements in treating AIDS (some claim that better diet will cure the disease¹⁰). But she is often unfairly lambasted for her view that dietary supplements are as important as ARVs in combating AIDS. This may not be true in America, but it is the case in rural Africa—a fact that Western reporters often ignore. As the minister points out, over 80 percent of people seeking testing for HIV in South Africa are undernourished, and undernourished patients are provided with nutrient supplements as part of their treatment.

Adult patients who have access to ARVs often take a child’s dose over an adult one because of a nutrient-deficient diet. But as a patient’s diet improves through good nutrition, adult doses can be given and the future health of the patient will improve. Dr. Tshabalala-Msimang’s remarks about diet are often taken out of context by reporters to sustain the narrative that she endorses crank science.

South Africa’s 2004 comprehensive treatment program, which Dr. Tshabalala-Msimang oversees, has established all the steps required for sustainable treatment, and

the government now has over 85,000 patients on treatment. It is a far cry from the half million people or so who need treatment, but the program is sustainable, unlike many in other parts of Africa. It is also a more responsible approach than is the target set by the World Health Organization, which would have required South Africa to have 375,000 people on treatment by the end of 2005. According to the health minister, South Africa was not consulted on this figure.

Without cheap testing—which South Africa has now made possible—and the medical personnel to oversee it, the WHO's call for 375,000 South Africans to receive treatment by the end of 2005 was never likely to be achieved. Besides, there were always valid reasons for delaying drug rollout until it could be achieved sustainably: issues involving the consistent availability of bioequivalent and reasonably priced drugs; resistance buildup; the cost of second-line therapy; and the shortage of doctors and technicians. Indeed, part of the WHO's annoyance at South Africa stemmed from that country's refusal to bypass the testing of drugs in the way that the WHO had desired. The South African Medicines Control Council described non-bioequivalent drugs as "undesirable" in August 2004—in effect putting itself at odds with WHO policy. The World Health Organization also thought that other testing, such as immune system CD4 counts, should be ignored in poor settings; once again South Africa disagreed and has routinely tested CD4 counts in HIV patients.

The WHO's intervention may be pushing countries to embark on unsustainable treatment programs to secure Western dollars and a good name at the organization. Lesotho's WHO-AIDS program is one notable example. Currently, it is being pushed towards a totally unrealistic target and largely failing. Half of the approximately 3,000 people on treatment there are not being treated properly with the requisite triple-drug therapy. This encourages resistance and demoralizes health workers. The WHO's "3 by 5" campaign target for Lesotho was to have 28,000 on treatment by the end of 2005—an impossible goal to achieve given the country's current capacity and infrastructure.

Dr. Tshabalala-Msimang bristles at suggestions that by failing to meet the target set unilaterally for it by the WHO, the South African government is deliberately denying drugs to people who need them: "[Our] Government is not withholding treatment for opportunistic infections, including ARVs, but our objective is to promote quality healthcare. We are not just chasing numbers."¹¹

All in all, South Africa is heading in the right direction. Testing and treatment programs, once too sporadic to be effective, are now being ramped up as quickly as is sustainable, which is providing hope for the millions who need treatment. Furthermore, and just as important, HIV patients kept alive by the programs serve as reminders to others of the benefits of prevention.

It is not the WHO's current policy to become involved with mass campaigns. Consequently, its influence is limited to cajoling countries into following its recommendations. When goals are set unilaterally without reference to the realities on the ground in targeted countries, they are rarely fulfilled successfully. In the case of South Africa, this has resulted in unhelpful acrimony. Since it offers so little useful assistance, the WHO has no moral authority for taking the high-handed attitudes we have seen in the "3 by 5" campaign.

Unfortunately, the failure of "3 by 5" has not led the WHO to abandon treatment targets for HIV. Instead the organization has announced a new target: treatment for all by 2010.¹² Given that there will likely be a sharp increase in HIV cases in Asia and Russia, that treatment will not reach those in need in some of the poorest African countries in the next few years, and that bioequivalent drugs are in far shorter supply than perhaps the WHO imagines, this new target should be ignored—much as "3 by 5" was by knowledgeable commentators.

Notes

1. World Health Organization Constitution, art. 1, available through the Avalon Project at the Yale Law School website, <http://www.yale.edu/lawweb/avalon/decade/decad051.htm> (accessed January 18, 2006).

2. World Health Organization, *Progress on Global Access to HIV Antiretroviral Therapy: An Update on "3 by 5,"* UNAIDS/WHO report, June 2005, p. 9. A full report is available at www.who.int/3by5/fullreportJune2005.pdf.

3. *Ibid.*, 12.

4. UNAIDS is a joint United Nations venture on AIDS.

5. WHO, *Progress on Global Access to HIV Antiretroviral Therapy*, 29.

6. "Generics" mean truly bioequivalent drugs identical to the branded originals. "Copy drugs" are approximations of generics, without the quality control, and may be of inferior quality.

7. Asliwini Kumar, drugs controller general of India, in a letter to Cipla Limited granting permission to manufacture the triple-dose combination AIDS drug, July 26, 2001.

8. WHO, *Progress on Global Access to HIV Antiretroviral Therapy*.

9. Jim Yong Kim, "The '3 by 5' Initiative: Progress and Challenges" (plenary address, VII International Congress on AIDS in Asia and the Pacific, Kobe, Japan, July 4, 2005).

10. Dr. Matthias Rath, physician and scientist, has led breakthrough discoveries in the natural control of cancer, cardiovascular disease, and, recently, AIDS. Dr. Rath believes that the course of AIDS can be reversed naturally through the use of micronutrients over drugs. During a June 15, 2005, press conference in Cape Town, South Africa, he called upon the governments of South Africa, Africa, and the entire world to embrace this breakthrough in natural health to help end

the AIDS epidemic. For more information, visit the Dr. Rath Foundation at http://www4.dr-rath-foundation.org/THE_FOUNDATION/press_release20050615.htm (accessed December 12, 2005).

11. Manto Tshabalala-Msimang, personal communication with author, November 2005.

12. WHO, "Access to HIV Treatment Continues to Accelerate in Developing Countries, but Bottlenecks Persist, Says WHO/UNAIDS Report," press release, June 29, 2005, available at <http://www.who.int/3by5/progressreportJune2005/en/> (accessed January 18, 2006). Incidentally, the target for "treatment for all" being pushed by the WHO is actually 80 percent of those who need treatment, not 100 percent.