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American Enterprise Institute for Public Policy Research

WHO's Comprehensive HIV Treatment Failure: Will We Learn the Real Lessons from 3 by 5?

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WHO's Comprehensive HIV Treatment Failure: Will We Learn the Real Lessons From 3 by 5?

Lorraine Mooney¹ and Roger Bate²

Abstract

It should be a cause for celebration that over 1.6 million people in the poorest parts of the world are now on antiretroviral treatment to halt the advance of HIV. But in a rush to improve access mistakes have been made. These mistakes, many of which were predictable, will be costly in terms of money and lives as drug resistance accelerates and more advanced (second-line) drugs may be unaffordable in poor countries.

The WHO's 3 by 5 Initiative (to treat three million people with HIV drugs by end of 2005) failed to hit its target. Proponents of the initiative nevertheless claim it has generated massive interest to increase treatment and acted as a motivation for those working in health and aid agencies. But as the following paper explains, in some instances it has cut corners, over-strained fragile health systems and increased risk for those it purported to help. A recent report³ states that despite an increase in numbers on treatment in sub-Saharan Africa, AIDS deaths are still rising there.

Unusual features of the 3 by 5 Initiative include a high-level acknowledgement of failure and a comprehensive, (partially) independent evaluation, funded by a major donor. This evaluation vindicates criticisms of 3 by 5 made before and during the Initiative, but makes an optimistic prognosis for HIV/AIDS work at WHO, which seems unwarranted given the findings. Indeed, the international community appears to be moving ahead as though 3 by 5 was a total success. This could be highly damaging to future efforts to combat AIDS around the world.

This paper is the first in a series looking at policy and field practice to find the good and the bad in attempts to fight the AIDS pandemic. Later papers will focus specifically on: the nature and scope of the disease in Africa, whether the treatment model used by Western and mid-income nations is appropriate to Africa; what is being done to effectively combat and treat HIV infections in Africa; and the overall implications of these findings for the future of HIV treatment and control in Africa.

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³ AIDS Epidemic Update UNAIDS & WHO. See www.int/hiv/mediacentre/news62/en/index.html

Introduction

The human immunodeficiency virus (HIV) is phenomenally successful. Virtually unknown 20 years ago, HIV has infected more than 40 million people worldwide and continues at a current daily rate of about 14,000 new infections, more than half of them among young people below age 25. Of those with HIV, about 30 percent are co-infected with another highly successful pathogen, tuberculosis. Over 95 percent of people living with HIV/AIDS live in low and middle-income countries. AIDS is now the leading cause of death in sub-Saharan Africa and the fourth-biggest killer globally.

Nearly 90 medicines for HIV/AIDS have been approved so far, including more than 20 antiretrovirals (ARVs), which have the potential to turn HIV/AIDS into a manageable chronic condition. Part of HIV's success is its ability to mutate in response to attack and because treatment is lifelong, resistance to existing treatments is inevitable, especially if treatment is interrupted or otherwise sub-optimal. There are 77 compounds for HIV/AIDS and related conditions currently undergoing clinical trials in the US or submitted for FDA approval, including 35 ARVs and 19 vaccines and other treatments such as fusion inhibitors, integrase inhibitors and protease inhibitors.⁴

While more drugs are becoming available and prices are falling, the most intractable obstacle to delivering treatment remains the scarcity of healthcare facilities and clinical staff necessary to receive patients and maintain long-term care, especially in remote, rural areas. The role of 'health systems strengthening' as it is known in UN-parlance, has long been an accepted responsibility of various UN agencies, such as the World Health Organization (WHO), the World Bank, UNAIDS and others. As global organizations these agencies theoretically have the requisite global coverage and authority to tackle this large-scale structural problem. However, lack of co-ordination among the agencies and general lack of political will has resulted in little engagement on this crucial but difficult issue, and certainly little improvement has been made in health systems strengthening by the UN bodies.

The World Health Organization has a very curious history of involvement in HIV/AIDS. Ostensibly the best candidate as a leader in the fight against the epidemic, in 1995 WHO actually took a supporting role in the specialist multi-agency partnership, UNAIDS. Later, WHO management seemed to think this a mistake and tried to re-establish itself as a leader by means of a mass treatment initiative. This paper analyses this initiative.

Organization of HIV Area of Work at the World Health Organization

When the campaign to treat three million HIV-positive patients with antiretroviral therapy (ART) was launched by the HIV Department of the World Health Organization on World AIDS Day, 1 December, 2003, it set itself a target of two years. Known as the 3 by 5 Initiative, as in three million on long-term treatment by the end of 2005, it was the first HIV/AIDS strategy action taken by WHO since the closure of its Global Programme for AIDS (GPA) in 1995. When UNAID was established⁵ in 1996, HIV staff at WHO was reduced at all levels, some transferring to UNAIDS, and only a handful of staff remained at WHO and in the regions⁶ (Ann. 7.1;3) whose job it was to 'mainstream' or devolve HIV and sexually-transmitted disease areas of work into a variety of programs across the WHO (Ann. 7.1;8).

In many countries, which during the GPA had had the services of two or three highly qualified WHO technical staff for national support, "no specialised human resources remained. The major elements of organizational competence and corporate memory simply disappeared" (Ann. 7.1;3).

⁴ Data from PhRMA AIDS "R&D Insight" Database and Industry Sources. Information correct as of 2 October 2006.

⁵ UNAIDS was established under Resolution 1994/24 of the Economic and Social Council.

⁶ Annex 7.1, page 3 of Evaluation of WHO's Contribution to '3 by 5' Battistella Nemes et al. June 2006 Published by WHO <http://www.who.int/hiv/3by5evaluation/en/> Accessed 4 July 2006.

“From 1996 to 2001 ... there was no HIV area of work and HIV did not have visibility as such in financial reports” (Ann. 7.1; 8).

Momentum restarted at WHO in 1999 with the publication of “The Use of Antiretroviral Drugs in Resource-Poor Settings” and the request from the World Health Assembly in May 2000 to WHO to prepare a “Global Health-Sector Strategy for HIV/AIDS” (GHSS). Its action points were sensible and realistic and include⁷ the undertaking to provide normative guidance and support to countries in three broad areas: assessing the scale and nature of the epidemics of HIV and other STIs, and providing evidence for effective interventions; prevention of new infections; provision of treatment, care and support to those in need.

WHO made another commitment in May 2000 to a treatment program – the Accelerated Access Initiative (AAI). This was a public-private partnership of five pharmaceutical companies, WHO, UNAIDS, World Bank and other UN partners, to explore ways to accelerate and improve access to HIV/AIDS-related care and treatment in the developing world.⁸ Despite being regarded with suspicion by some who suggest that the program merely gives the pharmaceutical companies cheap publicity while not really delivering improvements, the UN/AAI has been instrumental in reducing prices of ARV treatment to sub-Saharan Africa⁹ and is the single largest provider of antiretroviral therapy.

Despite being a founding member of UN/AAI, which was proving to be a successful model, WHO re-established an HIV Department at the beginning of 2001. The proposed budget presented that year to the WHA ranged from US \$55 million for its first two-year period, to US \$260 million for the 2006-7 biennium. There was to be an increase of 146% between the first and second biennia; then a 59% increase; then 20%. At the same time, the proportion of the regular budget (from WHO funds) compared with external sources was to decrease from 13% to 6% (Ann. 7.1; 9).

Staff numbers increased three fold between 2000 and 2005 (Ann. 7.1; 9). Several staff transferred to the HIV Department from UNAIDS, including Dr Bernard Schwartländer, first as director of the Evidence and Policy Unit and then, from June 2002 to July 2003, as Director of HIV Department itself (Ann. 7.1; 5,8). Dr Schwartländer has a special significance as the main author on a paper published in 2001 about the Brazilian HIV treatment program, which was to form the basis of 3 by 5.¹⁰

In January 2002 the Group of Eight of the OECD formed the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) with the intention of raising significant sums from the most industrialized countries in order to fund agencies active in these areas of work. Almost immediately in the months following this development, WHO's HIV plans became more expansive and ambitious – scaling-up of treatment, the 3 by 5 and universal access targets were all mentioned for the first time. Then the US President's Emergency Fund for AIDS Relief (PEPFAR) was launched in January 2003 with US \$15 billion to spend in five years, and at the next World Health Assembly, incoming Director-General Lee announced that 3 by 5 would have a strategy by the end of the year.

In fact, a Core Team on 3 by 5 was established on 1 September 2003 under the leadership of Charlie Gilks in the HIV/AIDS Department, which duly produced the guidelines for the public health approach in three months, just in time for the launch of 3 by 5. During this time, Dr. Lee Jong-wook joined with Dr. Peter Piot, Executive Director of UNAIDS and Dr. Richard Feacham,

⁷ Action Points for WHO in full as appendix on GHSS. Full version at <http://www.who.int/hiv/3by5evaluation/en/> Accessed 4 July 2006.

⁸ The companies involved are Bristol-Myers Squibb, F. Hoffman-La Roche Ltd, Merck & Co., Inc, Boehringer Ingelheim GmbH and GlaxoSmithKline.

⁹ Significant reductions (some up to 90%) were achieved by UN/AAI. 'HIV/AIDS & Malaria Clusters: Highlights of HIV/AIDS, TB and Malaria Activities' WHO, Geneva, 2003.

¹⁰ Schwartländer, B. et al., 2001. 'Resource Needs for AIDS' *Science* **292** (5526) 2434-6, 29 June.

Executive Director of the Global Fund to declare that the gap between those in need of ART in developing countries and the number of people actually receiving it was an international “public health emergency”.¹¹ It should be noted that while GHSS prioritized assessment, prevention, treatment and care, 3 by 5 prioritized mass access to treatment through a standardized regimen, hoping that this would accelerate prevention – an unrealistic hope as it turned out. The thinking was that “as HIV becomes treatable, this would hopefully reduce the stigma and discrimination attached to HIV/AIDS” and people will come forward for testing and treatment.¹²

WHO had also hoped that GFATM and PEPFAR would be willing to support 3 by 5, but in this too, it was disappointed (26).¹³ In the case of the Global Fund, the governing body simply decided not to contribute directly to the entire UN system at the global level. Despite two high-level meetings in July 2004 and February 2005 between WHO and PEPFAR, no strategic agreement to collaborate was made (27). Top-level meetings between WHO and the World Bank resulted in only one limited collaboration, but WHO was “apparently unable to offer the required technical assistance for this due to capacity constraints” (27).

The new director, Dr. Jim Kim, who took office in February 2004, was the twelfth director of the HIV Department since 1996, during which time HIV work at WHO had atrophied until it had no established program or strong organizational capacity. Added to these difficulties, finances for the initiative were particularly precarious. Despite requests to the three major potential donors just mentioned, “WHO had not succeeded in mobilizing sufficient donor support for its own involvement in 3 by 5 before [it] was launched.” (26) Soon after Dr. Kim's arrival the initiative was rescued by a commitment of US \$81.7 million from the Canadian International Development Agency (CIDA) (66), however this money was not available immediately.

The CIDA grant was conditional on the undertaking of an independent evaluation, which it also commissioned. The report was published in June 2006, and was titled, “Evaluation of WHO's Contribution to 3 by 5.” It was published by WHO and a full text can be found online.¹⁴ It is rare that such a detailed, thorough and frank investigation is undertaken at WHO and we make no apology for making heavy reference to this report. The evaluation team was appointed by the WHO and the Steering Committee, which was established at WHO to advise the team, has invited wide dissemination and comment

The original target budget for 3 by 5 was US \$400 million (US \$350 million for ART and US \$50 million for prevention and other work) but the WHO Executive Board revised this in January 2004 to US \$218 million. It was decided early in 2005 that 65% should go to the regional and country offices (8). Eventually about US \$195 million was raised (67) but the organizational backwardness of WHO and HIV Department meant that 3 by 5's early work was mainly internal restructuring, operational planning, fundraising and staff recruitment (65). Consequently, funds to regional offices were very late. For example, having initially been promised US \$11 million, the Eastern Mediterranean office finally received US \$3.5 million in total, with the first payment of US \$1.4 million arriving in April 2005.¹⁵ (66) At the end of 3 by 5 the overall disbursement rate of available funds was 61%, while the African Regional office had disbursed only 47% of its final, reduced allocation, “despite Africa being the priority with 19 of the 34 focus countries having a high HIV burden.” (66) On the other hand, the allocation for Geneva Headquarters nearly doubled from US \$28 million to just about US \$50 million (Ann. 7.3; 19).

¹¹ 22 September 2003, United Nations General Assembly.

¹² WHO/UNAIDS, 2003, Treating 3 million by 2005, Making it happen, The WHO Strategy, December, 9-10.

¹³ Where numbers appear in brackets, these refer to page numbers of the 3 by 5 Evaluation Main report, detailed in note 4, above.

¹⁴ World Health Organization, “Evaluation of WHO's Contribution to 3 by 5,” 30 March 2006, available at <http://www.who.int/hiv/topics/me/3by5evaluationreport.pdf>, accessed 28 November, 2006.

¹⁵ CIDA transferred US\$1.4 million. Pan-American Health Office (PAHO) scaled down original expectations from US\$12 million to US\$4.5 million, which it received seven months before the end of 3 by 5.

The problems of the African Regional Office were blisteringly exposed by *The Lancet* in August 2004,¹⁶ but it is not alone among the six WHO regional offices in being largely under-resourced, poor at devolving control to local offices and persisting in using outdated management procedures (63). The HIV team at the Africa office has a total of 15 professional staff, but only four have a fixed-term contract. Even at Geneva headquarters at the end of 2004 most staff at the HIV/AIDS Department were on temporary contracts, although since restructuring in 2005, 80% have a two-year contract (63).

The HIV Department's standing within the WHO Headquarters at Geneva was inevitably low because of “ten years of constant organizational restructuring and changing leadership” (64) and despite being able to disburse US \$18 million of 3 by 5 funding among other departments and units, the results were extremely variable with “a number of examples where funds remain under-spent and the collaboration has been suboptimal.” Such difficulties have arisen from “long-standing interdepartmental politics, overlaps in areas of work, or interpersonal conflict that need to be resolved through stronger managerial action.”(64)

Directorship of the HIV Department changed again in January 2006 and Dr. Kevin de Cock inherits a staff still smarting from sharp criticism of its failed initiative¹⁷ and a weak financial position with only 4% of planned expenditure for 2006-2007 biennium coming from the regular budget and a shortfall of US \$164 million (67). As of November 2005 “there had not been a single official commitment from previous donors” (67). The process to establish a framework for the current set of commitments¹⁸ is now being led within the UN system by UNAIDS.

3 by 5 and Its Misconception

According to the Evaluation Report “when WHO launched 3 by 5 in Nairobi on World AIDS Day in 2003, the Organization was barely able to finance its existing HIV work.”(60) This work was minimal since WHO had abdicated responsibility to UNAIDS in 1996 and had no HIV-dedicated country officers.

The Schwartländer study of Brazil found that about half the estimated number of people in need of treatment actually had access¹⁹ and WHO's 3 by 5 was based on this result (32). Targets were arrived at by taking the (very rough) estimates of the total number requiring treatment in each country and simply halving them. Thus, at a time when Lesotho was managing to sustainably treat at most 3,000 people it was unilaterally given a target of 28,000.

WHO attempted to justify the lack of program structure by presenting 3 by 5 as an emergency measure, but “this was not largely an appropriate operational model for urgently scaling up the systems, finances and activities what would be needed for implementing a global health initiative of this magnitude”(60). As the current ‘epidemic’ is more than 20 years old, the generally accepted model is a medium- to long-term effort spanning generations which would aim to reduce transmission and enroll those infected on a lifetime treatment regimen. The two-year timetable is perhaps explicable as it falls within a normal budgetary biennium and also perhaps as a political measure designed to add momentum to the re-establishment of an HIV department at WHO which saw “the challenges of HIV and AIDS appropriately for the first time in many years.”(62) But the precipitous time scale was never justifiable on public health grounds.

¹⁶ The Lancet (2004) *WHO's African Office Must Evolve or Die*, 364 9433, 475-476.

¹⁷ Numerous statements and reports even from generally sympathetic partners were published at the end of 2005, which clearly were very critical of WHO. Evaluation Report, footnote 33, p.25.

¹⁸ UNAIDS first meeting of Global Steering Committee June 2006 undertook to work towards fulfilling the commitments made under the Millennium Development Goal 6 – to reverse the spread of HIV by 2015; 2001 UNGASS Declaration to expand the global AIDS response; 2005 UNGASS World Summit Outcome; G8 2005 declaration; EU commitment to scale-up treatment. www.unaids.org/en, Universal access now encompasses prevention, treatment, care and support.

¹⁹ B. Schwartländer et al. *supra*

The 3 by 5 Initiative departed from the HIV program already ratified at the UN General Assembly (the Global Health-Sector Strategy for HIV/AIDS (GHSS), mentioned above) which broadly aimed to first, assess the problem; second, stop the problem worsening; third, look after those suffering from the problem. 3 by 5 seems to have entirely ignored this and reinterpreted its mission as increasing the numbers of people who are receiving ART; then in a second planning document from 2004, strengthening health systems and intensifying prevention efforts (60).

The key planning document 'Making it Happen' stated that the goal of the Initiative was to make the “greatest possible contribution to prolonging the survival and restoring the quality of life of individuals with HIV/AIDS.” (7) It presented 76 indicators (61 verifiable indicators for five strategic 'Pillars' or objectives and 15 monitoring indicators) with 48 assumptions (60) by way of a metric framework.

The five strategic Pillars or objectives of 3 by 5 were:

- i. global leadership, strong partnership and advocacy;
- ii. urgent, sustained country support;
- iii. simplified, standardized tools for delivering ART (the 'public health approach');
- iv. effective, reliable supply of medicines and diagnostics; and
- v. rapidly identifying and reapplying new knowledge and successes ('learning by doing').

These are analyzed in turn, but it can be seen straight away that only objectives 3 and 4 are specific to an HIV/AIDS program as such. The other three objectives concern routine procedures which might be expected to be in place before a global program could be undertaken.

Objective 1 concerns preparatory work necessary to build credibility for the HIV Department, and the need to establish relations first with focus countries and then with partners. Before 3 by 5, the HIV Department had no standing as a global leader or a partner – even among other WHO departments. Two years may have been a realistic period to achieve only that, given that funds had to be raised, staff had to be recruited and operational systems devised and established.

Similarly, objective 2 requires that objective 1 has been firmly achieved and country officers are in place and well briefed before any sustainable assistance can be given.

Objective 5, 'Learning by Doing' was made necessary as there was almost no planning time before 3 by 5 was launched. WHO has very little experience of self-evaluation or assessment activities, so the expertise needed to perform real-time analysis and ongoing program modification would also have to be learnt by doing.

The 'public health approach', objective 3, had been devised just prior to the launch of 3 by 5 as a way of getting large numbers on treatment. It departed from existing treatment models and did not have the benefit of evidence to show that it might be effectual.

Objective 4 was to make treatment available by encouraging a rapid increase in production of untested drugs by poorly-regulated manufacturers, and to develop the means to diagnose large numbers of people with limited access to laboratory capacity.

Clearly, 3 by 5 was more of a “political declaration and an act of faith than a systematic programme of work” (60) and as such, it was “ambitious, weakly conceived ... with insufficient structure against which results could be measured.” This made performance monitoring and resource planning difficult (60) but 3 by 5 also incorporated significant risks which would be borne by those it purported to help.

Objective 1: Global Leadership, Advocacy and Partnerships

The 3 by 5 Evaluation Team and Steering Committee give much emphasis to WHO's "major role in making mass access to ART a widely accepted essential public health intervention." While it is true that 3 by 5 did adopt this as its main thrust, the idea had already been aired at the International AIDS Conference held in Durban in 2000 (23) and was common currency among AIDS activists who demanded free treatment for the poor. 3 by 5 responded to popular pressure but ran against the lack of general consensus among governments, funding institutions and the WHO itself, that large-scale ART access should be implemented as a priority public health intervention (23). Doubts among experts centered on a lack of capacity: "To scale up antiretroviral therapy for HIV without ensuring infrastructure, including trained practitioners, a safe and reliable drug delivery system, and simple but effective models for continuity of care, would be a disaster, leading to ineffective treatment and rapid development of resistance."²⁰

WHO clearly had no such doubts and enthusiastically encouraged governments to develop national plans for scaling up treatment – assured of forthcoming assistance from 3 by 5. Cosponsors and donors did have doubts, however. Partnering institutions were persuaded to endorse 3 by 5 as an emergency initiative led by WHO, but some development partners criticized WHO quite strongly for its lack of strategic and programmatic preparation (23), and considered 3 by 5 unrealistic because it had been constructed without adequate participation of the countries involved (24).

Several countries, particularly in Africa, were encouraged to make commitments they could not afford and undertook revisions of existing treatment targets in line with 3 by 5 on the "expectation of substantially increased financial support which did not materialize" (24).

South Africa which runs and funds its own national program now treating 178,635 patients²¹ was thoroughly incensed by WHO's unwanted and heavy-handed interference. Relations with WHO and South Africa have all but broken down (36), but South Africa is the major economy in sub-Saharan Africa and carries a great deal of influence with its neighbors. The health minister has also made clear her determination not to "cut corners in terms of the systems that must be put in place and the medical protocols that must be followed if treatment is to be as effective and life-prolonging as we can make it and the program is to be fully sustainable."²²

This seems to be a reference to the WHO's public health approach (PHA) which advocates abandoning individual case management where resources are tight in favor of standard mass treatment. It is hard to see how WHO's standing as a leader and advocate of health policy can have been enhanced by its actions in Africa. Indeed, little leadership was in evidence in November 2005 when Dr. Kim announced that 3 by 5 was missing its target. The responsibility for a global HIV/AIDS program was handed back to UNAIDS in December 2005 and "even WHO country offices ... were unclear about the next phase." (25) Attempts to establish leadership on HIV even within the UN never really succeeded and although UNAIDS co-launched 3 by 5 and contributed US \$28.5 million in start-up funds "the subsequent commitment of the UNAIDS Secretariat (and other partners who initially signed in on the initiative) seemed to be less enthusiastic."⁽²⁵⁾

Beyond the realization that it was essential to work with many partners to achieve the 3 by 5 goal, WHO "never came anything close to establishing a global partnership network." (25) Only in the Americas and Eastern Mediterranean did any lasting concrete cooperation take place. The 180 potential partners identified at the one-and-only Global Partnership Meeting in May 2004 (i.e. six

²⁰ Merle A. Sande and Allan Donald, "Treatment of HIV/AIDS: Do the Dilemmas Only Increase?" *Journal of the American Medical Association* 292(2) July 14, 2004):267.

²¹ Roger Bate interview with South African Minister of Health, Dr. Manto Tshabalala-Msimang. Copy of interview published in "South Africa's Grown-Up Response to the AIDS Crisis" AEI Health Policy Outlook, 28 September 2006. Available at http://www.aei.org/publications/filter.all.pubID.24957/pub_detail.asp, accessed 28 November, 2006.

²² Ibid.

months into 3 by 5) would have made too big a network to be manageable and resources were not available for planned follow-up (25).

Despite its intentions to make 3 by 5 a universally accepted target, it never went “beyond providing a handy ‘catch-phrase’, with which to generate expectations, it was therefore unlikely that this target would be achieved because neither WHO nor the international community were really adequately prepared to make it happen.” (24)

Since the WHO had had so little involvement with HIV for such a long time, it was “perceived as a weak partner in the United Nations.” (27) It therefore struggled to establish a niche for itself, but a Global Task Team convened in 2005 with the intention of improving coordination among multilateral institutions and international donors to strengthen the AIDS response in countries (27 footnote 44). It was decided that WHO take the role of 'lead technical agency' for the health sector response to HIV and AIDS within the United Nations (27). While this was fully agreed, there are still perceptions among stakeholders, developmental partners, other United Nations institutions and national governments “that the Organization has yet to fulfill its role to meet this level of expectation.”²³ and there are still “counter-productive areas of competition between individual agencies that need to be addressed.” (27) For instance, the continuing lack of resolution between WHO and UNICEF about which organization is responsible for activities relating to²⁴ the prevention of mother-to-child transmission (PMTCT) and pediatric ART (28) goes a long way towards explaining the lack of progress in these crucial areas of work.

The Evaluation Report makes an outright criticism that the process intended to harmonize and coordinate work among UN agencies may be 'missing the point'... “where little progress has been achieved in controlling the HIV epidemic in the last 20 years, it seems futile ... to focus exclusively on distributing short-term roles and assignments for HIV and AIDS work ... rather than ... on the underlying reasons for these failures.”(28)

Perhaps as a result of this long-term disarray, other responsible bodies were formed to address the needs which parts of the UN were neglecting. As mentioned above, WHO was disappointed in its expectations of external funding from major donors, such as the World Bank, GFATM and PEPFAR. Many observers at country level were found by the evaluation team to be of the opinion that WHO had already lost influence with these partners before 3 by 5 and further that, unless it makes long-needed changes, it will become increasingly marginalized by other contributors (65).

A recent study conducted by Alex Shakow and jointly commissioned by the Global Fund and the World Bank notes that while global health programs have made valuable contributions, their “collective impact has created or exacerbated a series of problems at the country level...[including]...poor coordination and duplication, high transaction costs, variable degrees of country ownership, and lack of alignment with country systems. The cumulative effect of these problems is to risk undermining the sustainability of national development plans, distorting national priorities, diverting scarce resources and/or establishing uncoordinated service delivery structures.”²⁵

The above-mentioned report recommends that the World Bank and Global Fund work together to coordinate plans to maximize their respective advantages and expertise. This approach is highly desirable, but it only addresses part of the problem. Most obviously, it omits coordination with other large organizations involved in global health programs, such as the World Health Organization and UNAIDS, but WHO, in particular, has shown little inclination or ability to work

²³ Executive Summary or Evaluation Report, p. xxi

²⁴ WHO's role is technical and UNICEF's is operational, so there is great need for cooperation and integration.

²⁵ Shakow, A. 2006 “Global Fund and World Bank HIV/AIDS Programs: A Comparative Advantage Study” Prepared for the Global Fund to Fight AIDS, Tuberculosis and Malaria and the World Bank HIV/AIDS Program, available at <http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1103037153392/GFWBReportFinalVersion.pdf>

effectively with other groups.

A key feature of the standardized treatment approach advocated by 3 by 5 was that NGO and private organizations, collectively referred to as people living with HIV/AIDS (PLHA), would be assigned crucial roles in support of scaled-up therapy. In some countries WHO did enable these groups to participate in policy discussions and service delivery, for instance in India and Ukraine, but these were rare (29). In many cases, particularly where governments are reluctant to accept the involvement of these groups in their official national programs, WHO country officers seem to have been without influence (29). Indeed, the International Treatment Preparedness Coalition (ITPC), a network set up by WHO, stated that WHO lacks visibility on the ground, with many of its members actually being unaware of what the Organization is doing in their country (29). In these circumstances, charities and NGOs have little incentive to work through the WHO country officer and may do better to group together within their country and other groups abroad, to lobby their governments and try to raise external funding through their own efforts.

The Technological Network on HIV/AIDS is a joint initiative between Brazil, China, Nigeria, the Russian Federation and Ukraine to cooperate on research, development and production of HIV medicines, diagnostics and other commodities. Another South–South collaboration which is funded by the German Agency for Technical Cooperation (*Gesellschaft für Technische Zusammenarbeit* (GTZ), a government agency) has enjoyed the active assistance of the WHO European, Eastern European and African Regions. This initiative coordinates training and technical assistance between local organizations and HIV/AIDS services in countries and is so successful that it now has seven 'knowledge hubs' which have trained more than 1500 'resource people' reaching 41 countries. The WHO itself cannot claim anything like this achievement (31).

A supposed strength is that WHO's presence in country offices gives it a key advantage over other agencies and NGOs, but the involvement and influence of these officers is highly variable. It is characteristic that a country officer has good relations with the ministry of health but very little engagement with 'partner' groups. In Kenya, for example WHO has little or no involvement with the national AIDS council or the interagency coordinating committee, which are managing to make their own applications for Global Fund money without WHO's technical assistance (65).

The ITPC, mentioned above, was given US \$1 million in start-up funding by the WHO, which it then used to attract further private funding. The ITPC runs a fast-growing network of local groups and is functioning quite independently of WHO, which is not pursuing further collaboration or information-sharing with the network (30.)

Far from establishing it as an international leader, its promotion and involvement in 3 by 5 has further damaged what remained of WHO's reputation. The HIV Department failed to achieve respect even within the WHO; WHO has been sidelined in the substantial global effort against disease by the major funding bodies, NGOs and the UN organization itself. The Evaluation Report made many helpful, hopeful suggestions as a way forward for WHO, but long experience of WHO's actual capabilities shows that the possibility of it achieving the required potential is minimal.

Objective 2: Urgent, Sustained Country Support

The intention of 3 by 5 was to focus on 49 countries which between them carried most of the burden of HIV-infected people. The campaign to provide access to treatment for half of those in need was based on research carried out in Brazil by a former director of HIV/AIDS Department, as explained above. This self-referential attitude may have contributed to the introspective nature of the whole process but it was not helped by the imposition of targets on recipient countries, which was resented by some, especially in those countries which had already undertaken plans of their own.

Some countries welcomed the support, but money that was promised to help with technical development never fully materialized and the expected funding was revised downward twice during the campaign, requiring redrafts of plans that had been made. This created delay and uncertainty and contributed to the situation in which, at the end of the campaign, less than half the funding available under 3 by 5 to sub-Saharan Africa had actually been used (66).

HIV country officers were engaged or redeployed from other duties and stakeholders interviewed by the Evaluation team said they had greatly improved HIV activity in those countries. However, it must be remembered that previously nobody had been doing this job, and many country officers felt they could have been more useful if they had had “direct guidance and a clearly defined scope of what WHO could (or should) be offering.” (32) As there were no fewer than 60 standard training packages and other key guidance documents pertaining to 3 by 5 (not including revisions) (9) it is not surprising that newly-arrived country officers may have been confused about what they were supposed to be doing.

There is also some discrepancy in the number of staff assigned to the HIV area of work under 3 by 5. The introductory section of the Evaluation Report mentions 179 additional staff deployed and/or realigned to WHO country offices for 3 by 5. However, Annex 6.1 of the same report, in describing its methods for surveying 3 by 5 country officers in November 2005 explicitly states (with an exclamation) that only 35 out of 49 focus countries actually had a country officer (Ann. 6.1;7).

Perhaps WHO's biggest problem in positioning itself in a role of authority and leadership is that 3 by 5 had nothing to build on after it had given up specific HIV work in 1995. By the time WHO wished to become an active partner the vacuum had already been filled by other groups, such as UNAIDS and more recently, PEPFAR and the Global Fund. This was not helped by the late arrival of 3 by 5's country officers. Annex 7.5 shows that by the end of January 2006, 39 officers were in place, but the longest serving of these only took up their positions in the last quarter of 2004. South Africa obviously has no country officer as WHO and South Africa have fallen out so badly (36) but Rwanda and Cameroon were still waiting for a recruitment to be finalized as 3 by 5 came to an end (Ann. 7.5 ;25).

The problems that WHO had in establishing meaningful partnerships were demonstrated by its struggle to find a niche in the 15 countries where PEPFAR and other agencies were already operating. However, in other countries it took on some responsibility by assisting with the writing of proposals for Global Fund money. Despite this being a time-and resource-intensive procedure which diverted attention from other priorities, WHO received no compensation for its efforts. Furthermore, ministers of health expressed concern that while external consultants had been provided and had been successful in attracting funding for ambitious projects, they were not available later to assist with implementing what had been proposed (33).

Even within their own operations, country offices have achieved little integration or synergy between HIV and other technical or programmatic areas, such as TB, reproductive and sexual health, child and adolescent health and health systems strengthening (34). Some African health ministries and civil society groups have been disappointed by the lack of help in strategic planning which they hoped WHO would provide (35).

Nevertheless, government representatives who responded to the survey²⁶ generally expressed themselves highly satisfied with WHO's work – especially its role in scaling up access to treatment, although much less so in its prevention and health systems strengthening efforts (35) – but this may be more of a reflection of friendly relations among individuals involved (36). WHO regional officers are appointed by the host country governments and WHO's mandate requires it to support all member states but the relationships between WHO and national governments were viewed by

²⁶ The response rate among national AIDS program managers was 31%. Among PLHA NGOs, only 3 organizations responded. This was compensated to some extent by confidential interviews. (Section 1:ii of Evaluation Report)

some as being closer and more closed than is helpful (36). For instance, a study in Malawi found that non-compliance with treatment regimes and death rates were twice as high in those patients paying for treatment compared with patients receiving free treatment. When Kenya substantially reduced service fees there was a direct increase in patients coming forward for treatment from poor communities. This was supported by other evidence and the consensus in the United Nations was that free access improved compliance and survival. However, rather than publishing a position paper giving WHO's normative guidance, a discussion document appeared. "Disappointment was expressed both within the WHO and among external partners that the Organization had been swayed by political pressure."(77).

3 by 5 partners within countries are ambivalent about WHO's role, sometimes seeing WHO as a barrier to access to government rather than a facilitator. Development partners in the United Nations system, civil society, PLHA²⁷ and the private sector criticized the WHO for sometimes hiding behind government policy, not addressing controversial issues or neglecting other players (36). The toning down of advice about providing ART free at point of use is one example of this. Instances of useful co-operation with partners were found in the evaluation, but these were highly variable and dependent on the "efforts of dedicated and experienced individuals [rather than] the result of applying any organisational policy" (36).

The late arrival of country officers was largely due to the unavailability of funds, which in turn is due to lack of foresight. However willing a donor may be, funds are subject to annual budgets which have to be arranged well ahead of time and 3 by 5 did not allow for this. For example, US appropriations for the new fiscal year, which begins in October, are often made in the November prior to that. So an initiative introduced in January, may not have funds available until October of the following year.

Funding for most 3 by 5 activities in countries was derived from extra budgetary allocations, particularly from the Canadian International Development Agency. Country officers reported that having some money available for problem-solving or strategic initiatives was important for WHO's credibility (40), however, the late arrival of (a reduced level) of funding meant that it could not be systematically integrated into the country office planning cycle or contribute strategically to national programs (39).

The country officers who responded to the evaluation's questionnaire complained of a lack of useful guidance from head office that may have helped them plan strategically. Some found themselves in countries where they couldn't speak the language, and most have a strong medical orientation, whereas management and development skills are at a premium in strengthening health systems. Monitoring of activities was reported to be perfunctory and monthly reports were treated as compliance tools which did not form part of program development, nor were they part of a systematic follow-up (39).

Where country officers were present some notable achievements were made, but it was also found that countries with no 3 by 5 assistance also did much good work (40). For instance, the survey responses of national program managers showed that 60% already had a national plan for providing ART through the public sector prior to the launch of 3 by 5 (Ann. 6.2;52)

The country support that was given cannot be described as urgent since it took a year before the first implementing officers were in place. Whether this presence can be sustained depends on funding, but as we shall see later, funding for WHO's involvement in HIV work is extremely precarious. During the period of 3 by 5 the evaluation team found that little progress had been made in country offices towards achieving synergy and integration between HIV and other disease and public health work. This technical and programmatic organization is supposed to be a strength of WHO, but 3 by

²⁷ People Living with HIV/AIDS

5 failed to achieve it even within its own country operations. Explicit complaints from national AIDS program managers included weak support from WHO in terms of prevention of HIV infection and systems strengthening strategies.

Strategic Objective 3: Simplified, Standardized Tools for Delivering Antiretroviral Therapy

The main feature of this objective is the public health approach (PHA) which was “designed to achieve standardization, decentralized coverage and service integration that would benefit as many people as possible.”(41). Essentially, WHO recommendations are a top-down standard approach to treatment, with no scope for personal prescription, which overtly advocate diagnosis and prescription based on medical criteria without the benefit of laboratory testing, at the same time as monitoring for non-compliance or resistance to drug treatment at the population level, that is, not on an individual basis. However, WHO is still failing to make inadequate arrangements to ensure that monitoring and safeguards are in place.

There are guidelines for resistance surveillance and the consequences of wide-scale resistance to first-line treatment are well known. It is fully acknowledged that drug resistance to HIV could have catastrophic population-level health and economic consequences and plans have been drawn up to minimise these risks but these are not properly implemented. The evaluation report is quite explicit about this:

The WHO HIV Drug Resistance Surveillance programme is currently under-resourced and dependent on one key technical officer who is externally funded. Failure to invest more in the programme infrastructure is likely to [have] important implications for the sustainability and effectiveness of antiretroviral therapy as a public health intervention in the future (48).

Quite simply, if scale-up continues without sufficient safeguards, antiretroviral drugs could quickly be made useless. This means that patients who develop resistance can no longer be treated with standard drugs. There are second- and even third-line drugs which have been developed by research-based pharmaceutical companies, such as Merck, GSK and Gilead but these are inevitably more expensive to manufacture (e.g., protease inhibitors), with little effective demand and therefore limited supply, and so are not used in the public health approach.

So far, however, “most antiretroviral treatment is still delivered through dedicated (usually hospital-based) clinics or 'outreach services, staffed by doctors or clinical officers.” (46) It can only be hoped that before the public health approach is taken further, the facilities will be built, the staff trained and importantly, the systems for monitoring and feedback are in place.

The Evaluation makes the extravagant claim that WHO's public health approach to antiretroviral therapy (ART) 'shifted a scientific paradigm that previously considered ART to be a specialized medical intervention requiring skilled decision-making and “ ‘individualised’ treatment approaches” (41). But no evidence is offered to show that the mass treatment public health approach will be effectual or even safe (48). South Africa, with 178,635 patients on ART, has pointedly refused to adopt this approach and has no involvement with 3 by 5, preferring to fund and manage its own program. The health minister has spoken of not chasing numbers²⁸ and insisting that systems are in place and medical protocols followed to make sure that treatment is as effective and life-prolonging as possible and the program is fully sustainable.²⁹

²⁸ Bate, R. 2006a. “WHO's AIDS Target: An Inevitable Failure,” Health Policy Outlook, AEI, Washington DC., available at http://www.aei.org/publications/filter.all.pubID.23712/pub_detail.asp, accessed 28 November, 2006.

²⁹ See Roger Bate, “South Africa's Grown-Up Response to the AIDS Crisis.” AEI Health Policy Outlook, 28 September 2006. Available at http://www.aei.org/publications/filter.all.pubID.24957/pub_detail.asp, accessed 28 November, 2006.

The reality of this shift towards a standardized approach is illustrated by the difficulties experienced in Kenya. While the national program has changed in line with the public health approach, the staff in rural sub districts are still operating on the previous guidelines which required monitoring patients using laboratory tests. Unfortunately, 'laboratory services are mostly unavailable' and so treatment is delayed (45). Clearly, this is an example of lack of capacity which has proved so difficult to remedy and is the key impediment to access to treatment. The shortage of trained clinicians is the most serious deficiency in weak health systems but the public health approach advocates that more reliance is placed on the clinical judgment of staff in rural areas, precisely because they have limited access to laboratory support. This strategy would seem to increase the risk to patients of misdiagnosis and mis-prescription.

Inasmuch as a significant change has taken place in treatment, this has been afforded by the 'fixed-dose combination' therapy, first developed by manufacturers in India using reverse engineering techniques to produce copies of branded drugs. The rationale for combining drugs that work on different parts of the virus's actions at the same time is that the virus will be overwhelmed by a multi-pronged attack before it can mutate to survive any single drug. Fixing the dose and presenting several pills in the same 'blister pack' or even combining drugs in one pill also shifts the responsibility for prescription onto the manufacturer, as well as helping to ensure compliance by the patient.

While fixed-dose combination therapy offers the possibility that treatment may be safely standardized and avoid the need for close clinical attention, mass treatment for HIV has never been studied or evaluated. It is very important, therefore, that protocols are followed precisely. While WHO is acknowledged as being good at developing normative guidelines the process is slow and obscure and the reviews and timelines are haphazard; the result is that protocols are still not ready. Again, the Evaluation report offers what comes as close as can be expected to an explicit condemnation:

Guidelines cannot be promoted without technical support for implementation and mechanisms to provide early feedback about what is not working...WHO has not yet made much progress in providing the necessary technical guidance, analytical assistance and country-level support to operationalise these activities.
(45)

Drug Resistance Monitoring

Limiting drug resistance will soon be as important as scaling up access to treatment and in view of the existing problems of maintaining safe, reliable supplies, this could happen very quickly indeed. Brazil, which is a middle-income country with perhaps 160,000 receiving free ART³⁰ in well-defined demographic groups, is already struggling to provide second-and even third-line therapy to patients who have developed drug resistance.³¹

AIDS is a chronic disease if treated, but as HIV's replication and mutation rates are high and treatment is lifelong, it is particularly well-suited to develop drug resistance. A serious problem of the public health approach (apart from prescription not being possible on an individual basis) is that HIV drug resistance monitoring is to be carried out only at the population level through random sampling (53.) By contrast, Brazil and South Africa, which both designed and run their own HIV and AIDS programs, provide individual ARV treatment and regular viral load laboratory tests

³⁰ Center for HIV Information, "Brazil's HIV/AIDS Programme is a Model for the Rest of the World, But the Cost of Second-Line Therapies and the Spread of HIV-1C Could Spell Danger for the Future," by Theo Smart, 18 August, 2005, available at <http://hivinsite.ucsf.edu/InSite?page=pa-hatip-53>, accessed 28 November, 2006.

³¹ Annex 9.3 of Evaluation report "Focus Study on WHO's Efforts to Establish a Global Strategy on HIV Drug Resistance, Prevention, Surveillance and Monitoring" by Public Health Consultants, Peter W Carr and Tracy L Sides of Minneapolis. p54. Comments to hivdr_evaluation@yahoo.com. Accessed via WHO website 4 July 2006.

which indicate build-up of resistance. If resistance to a particular drug does emerge – the treatment fails – the patient's doctor can prescribe alternatives, but this requires that each drug is also available individually.

Patients can limit the risk of treatment failure by taking their medicine regularly and consistently. Fixed-dose triple-drug therapy also gives some protection by being easier to take, but neither approach is foolproof and since individuals are not to be monitored for resistance under the public health approach, the population-level testing will be the only indicator that a problem has arisen.

A recent press release by Médecins sans Frontières (MSF), which appeared on 13 November 06, outlines how serious this problem has become. MSF says “treating 58 patients on second-line therapies in South Africa costs the same as treating over 550 patients on first line therapies.” That means that if there are two million patients on ARV by the end of this year, it is more than reasonable to expect that 20%, that's 400,000, of them will be drug resistant to first-line therapies. Using the MSF ratio above, $9.5 \times 400,000$ on second-line therapies would equal 3.8 million on first-line therapies.

Despite recognizing this as a serious problem, 3 by 5 pays little more than lip service to the need for collecting data on resistance. A network of external experts exists (HIVResNet) and its members are willing to help, but it is underutilized. For example, the Network devised the HIV Drug Resistance (HIVDR) surveillance strategy in 2001, but as late as December 2005, experts were yet to arrive at a consensus on an HIVDR laboratory strategy (Ann. 9.2;58). There is a strategy for minimizing and dealing with drug resistance but it is not well documented and there are no formal policies or guidelines. One sentence is given to drug resistance monitoring in the June 2005 Update³² and little appears elsewhere on WHO-related sites. The patient monitoring guidelines give only peripheral mention of viral load laboratory tests (Ann. 9.2; 62) and the guidelines for surveillance of drug resistance have not been updated since 2003³³.

Some routine data are collected on country ART programs, but these do not include drug resistance elements (Ann.9.2; 62) nor even the most basic disaggregated data required for strategic planning. For instance, data on the sex of patients on ART are unreliable and not always reported (77). “Negative outcomes such as drug resistance and toxicity are also not being routinely assessed to determine what guideline changes or service improvements could be necessary” (57). There is no regular communication between HIVDR and other programs, such as the AIDS Medicine and Diagnostic Service (AMDS - this is discussed later) (77).

The status of the HIVDR program is precarious – a far from ideal situation given its crucial role in maintaining the sustainability of scaled-up access. Its leader is funded by external support; the staff is over-extended has been rushing to develop a global drug resistance program in a very short time; no staff member is dedicated to such tasks as pursuing external funding, documenting program activities, integrating activities with other relevant WHO programs or maintaining a web site with up-to-date activities and materials. The belief among external partners questioned by the authors of Annex 9.3 who rely on WHO for coordination, is that the staff is inadequate to implement a global HIV drug resistance strategy (Ann. 9.2;62).

The Evaluation Report sums up the situation as follows:

WHO has not established adequate arrangements for tracking the evidence for scaling up the public health approach to antiretroviral therapy (including monitoring the outcomes of treatment at the population level, on survival and

³² WHO/UNAIDS, 2005. “Progress on the Global Access to HIV Antiretroviral Therapy. An Update on 3 by 5”, June 2005.

³³ WHO 2003. “Guidelines for Surveillance of Drug Resistance”. Available at http://www.who.int/3by5/publications/guidelines/en/resisguide12_12.pdf Accessed 5 October 2006.

quality of life, or the public health consequences of treatment toxicity and treatment failure). There has not been a coordinated effort to evaluate the effects of treatment scale-up on health systems, HIV prevention or on other priority public health programmes (49).

The public health approach was promoted without evidence that it could work, and without safeguards against the significant risks inherent in such a coarse-grained, wide-scale approach. There was no justification for designating a need for mass HIV treatment as an international emergency, but even disaster conditions could not justify such a cavalier and callous disregard for human welfare and life. However, this was not the only risk to other peoples' lives that the promoters of 3 by 5 were prepared to take: the drug supply proposals were an outright scandal.

Strategic Objective 4: Effective, Reliable Supply of Medicines and Diagnostics

In 2001 drug authorities in developing countries were so worried about the poor quality of antiretroviral copy products which were becoming increasingly available in the world's poorer regions, that they contacted the WHO for help in assuring the quality of copycat drugs.³⁴ These worries were well-founded. Contemporaneous information available to the WHO database on 325 known cases of substandard copy drugs,³⁵ including antibiotics and treatments for malaria, TB and HIV, found that 60% contained no active ingredient at all. Other faults included wrong ingredients or wrong amounts, which may be more harmful to the patients than taking what are effectively, placebos.

In the 1949 classic movie, "The Third Man," Harry Lime was a criminal who had sold penicillin on the black market having first diluted it to increase his profit. In a memorable scene on a Viennese Ferris wheel, he explains his deeds to his friend Holly Martins and outlines his scheme's horrible consequences to those who had taken his product in good faith. He dismisses his victims as little people, but Holly's outrage and revulsion prompt him to pursue Harry and bring him down.

That was when movies were made in black and white and morals came the same way. Today, it seems to depend more on who is adulterating the drugs – if a manufacturer copies the products invented by others and slightly undercuts the price of the branded-quality drug, he gets off lightly if his products aren't quite the same as the original or don't really conform to quality standards.

Thus it presented a dilemma for the WHO when in 2001 "for financial and compliance reasons, the Organization was obviously promoting the use of multi-source [generic] drugs, for which there were no guarantees of safety, efficacy and quality." (Ann 9.1;12). The WHO Model List of Essential Drugs for April 2002 included many generic drugs and particularly fixed-dose combinations of HIV drugs.³⁶ In 2003, 3 by 5 was launched with the main aim of increasing access to treatment by relying heavily on such drugs as these.

In 2001 non-research manufacturers³⁷ had started to combine medicines invented by different research-based pharmaceutical companies into a single pill. Because of exemptions allowed to generics manufacturers, none of the combined formulations had been registered in countries with

³⁴ Annex 9.1 of 3 by 5 Evaluation Final Report. "The WHO/UN Prequalification Project." Author: Christophe Bonsmann Dec. 2005 christophe.bonsmann@medeor.org

³⁵ Figure 1 of Annex 9.1 using data presented by Dr Lembit Rägo, Co-ordinator of Quality Assurance and Safety of Medicines, Department of Health Technology and Pharmaceuticals, WHO, Geneva.

³⁶ This same version appears to be still the most recent (accessed 15 September, 2006) guideline information available www.who.int/3by5/publications/briefs/arv_guidelines/en/ It contains a note saying that consultations have been launched which will produce recommendations which 'will be used to develop our operational manual for scale up, which will be available at the end of March 2004'. A search of the WHO site produced no such result.

³⁷ Cipla of India and the Government Pharmaceutical Organization of Thailand combined a fixed dose of two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor.

strict drug regulatory authorities. Further, no monographs³⁸ required for quality controls were available. For example, many drug regulatory authorities in developing countries do not require bioequivalence assays for reverse-engineered drugs.

The author of Annex 9.1 seems to share the generally-held view that mixing drugs in a new way is merely a question of patent freedom. Many, including the director of GFATM, Richard Feacham, were seduced by the idea that a cheap, fixed-dose pill would enable a simplified, standard treatment to be administered on a massive scale, reducing reliance on a complicated regime that required skilled monitoring, repeated laboratory tests and treatment changes on an individual basis. Indeed cheap, copy fixed-dose combination therapy was the basis of the public health approach and a cornerstone of 3 by 5.

While individual drugs may be fully authorized by the most stringent regimes, when taken in combination with other drugs, they may have different and even dangerous effects, which is why the combination has to be submitted for registration as a novel product, to the FDA, for example.

When Bristol-Myers Squibb and Gilead wanted to produce Atripla,³⁹ a single-pill triple-combination therapy taken once a day, it took several attempts over several years to achieve bioequivalence, even though these companies produced the original drugs. It makes it rather surprising therefore that Cipla, the Indian generics firm, believes it can produce its own version, especially given the lack of provable bioequivalence of its previous attempts to produce a simpler and more easily manufactured fixed-dose combination therapy⁴⁰. In July 2001 the Indian Drugs Controller General gave permission to Cipla to manufacture a triple-therapy ARV (largely intended for export) but stipulated that: “No reference in the advertisements or medical literature is made that the government has approved the drug.”⁴¹

In fact, there are many serious implications of product safety which were well understood by experts within WHO, namely those in the Quality and Safety of Medicine (QSM) technical unit of the department of Medicines Policy and Standards (Ann 9.1;12). The Prequalification Project was launched as a pilot project by the UN in 2001 with the objective of providing quality assessment on a selected number of new pharmaceutical products being considered for purchase by United Nations

³⁸ Monographs (developed by the International Pharmacopoeia and issued by WHO) are approved laboratory procedures to control the quality of, for example, active pharmaceutical ingredients, excipients and dosage forms.

³⁹ See <http://www.fda.gov/cder/drug/infopage/atripla/factsheet.htm>. The Food and Drug Administration (FDA) on July 12, 2006 approved Atripla Tablets, a new fixed-dose combination of three widely used antiretroviral drugs, to be taken in a single tablet once a day, alone or in combination with other antiretroviral products for the treatment of HIV-1 infection in adults. Atripla is the first fixed dose combination available in the United States to combine two different classes of antiviral drugs in a single pill. This “one-pill-once-a-day” product to treat HIV/AIDS combines the active ingredients of Sustiva (efavirenz) a Nonnucleoside Reverse Transcriptase Inhibitor (NRTI), with Emtriva (emtricitabine) and Viread (tenofovir disoproxil fumarate), two Nucleoside Reverse Transcriptase Inhibitors (NRTIs). Emtriva and Viread are also available in a fixed dose combination known as Truvada.

Atripla is the result of an unprecedented inter-company cooperative effort between Gilead Sciences, the manufacturer of Emtriva and Viread, with Bristol-Myers Squibb, the manufacturer of Sustiva. Merck controls the marketing of Sustiva outside the United States. The approval of Atripla will not only make the new fixed dose combination available in the U.S., but also permit its purchase under the President’s Emergency Plan for AIDS Relief (PEPFAR) program.

Atripla was approved in 3 months under FDA’s fast track program. The approval is the result of an expedited review process outlined in guidance for industry from the FDA in May 2004.

⁴⁰ Cipla seeks approval for cut-price Atripla in India, Scrip Pharmaceutical News 7-20-06 India, 7/20/2006 - The Indian company Cipla shortly expects to introduce in India a cut-price generic version of the antiretroviral Atripla, which has just been approved in the US.

Cipla’s joint managing director, Amar Lulla, told Scrip that the company had applied to the Drugs Controller General of India seeking approval for its version of Atripla, and another Indian generics company, Hetero Drugs, is also reported to be working on a version of Atripla.

⁴¹ Letter from the Drugs Controller General (India) to Cipla Limited granting permission to manufacture the triple dose combination AIDS drug. Dated July 26, 2001 and signed by Asliwini Kumar, Drugs Controller General (India).

agencies (Ann 9.1;13).

The guidelines for the Prequalification List require a high standard but the Project itself has neither the authority to enforce standards, nor the capacity to buy drugs or otherwise offer manufacturers guaranteed sales (48). This facility may have enabled the Project to encourage manufacturers to undertake production runs and have given it some authority in demanding quality standards. This was part of the initial plan but it was quickly realized that WHO would not have the necessary wherewithal. It also raised difficult questions about commercial activities undertaken by WHO which are contrary to its Convention.

The evaluation found the Prequalification Project to be under funded and its staff, which consists of three professionals and 0.6 of a secretary, to be demoralized. Despite not having enough people to carry out basic safety assessments, the Project has to raise its own funds to make up the 70% of its total requirement which the regular budget does not cover. When it is also understood that dossier and audit work is undertaken by an external team made up of experts from drug regulatory authorities, who volunteer their services and are only paid expenses, it seems that the project is surviving only by over-reliance on the goodwill of those working for it (Ann 9.1;19). A member of the AIDS Medicines and Diagnostic Service (AMDS) expressed concern that this left crucial work vulnerable to donor pressure (Ann 9.1;20).

The author of Annex 9.1 warns that despite the efforts of the hard-working, highly competent and committed staff “there is a backlog of dossiers, site inspections, web reports etc. which, if not addressed, will endanger the quality and reputation of the project”. Moreover, there is the danger that experienced and highly-qualified staff may leave the project due to work overload (one experienced auditor left the project in 2005). (Ann 9.1, p20)

Aside from staff and funding problems, the question of drug quality remains pertinent, notwithstanding the stringent safety guidelines. Prequalified drugs are never referred to by WHO as 'generics.' WHO simply states that they are drugs of “acceptable quality,” or that they “have been found acceptable, in principle, for procurement by UN agencies.” When licensed by the Drugs Controller General (India) he only used the term ‘formulation,’ never even copy or generic.⁴² Prequalified drugs are essentially untested drugs of indeterminate quality. Indeed, WHO issues a Disclaimer with every issue of Prequalification; “Inclusion in the list does not constitute an endorsement, or warranty of the fitness, of any product for a particular purpose, including in regard of its safety and/or efficacy in the treatment of HIV/AIDS.”⁴³ However, in a recent development some of the drugs which have been approved by the FDA as 'true generics' are being manufactured in India. WHO now accepts the FDA's designation of a 'true generic' and prequalifies those drugs.

These faults in the Prequalification Project were catastrophically exposed in 2004, when many HIV copy drugs supplied to 3 by 5 were de-listed, and then voluntarily withdrawn by the companies involved, after the companies had persistently failed to produce quality-control evidence.⁴⁴ No mention at all was made of this in the WHO’s June update on the 3 by 5 campaign or in its director’s July speech. All Dr. Kim 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

⁴² Letter to Cipla Limited, 26 July 2001, granting the license to manufacture Stavudine+Lamivudine+Nevirapine as a single table or triple dose combination, signed by the Drugs Controller General (India) Asliwinl Kumar.

⁴³ The Disclaimer appears in all 43 editions of WHO's Prequalification Program, up to and including 16 November 06. Proper title of this document is: Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality, Prequalification Program, WHO/Geneva.

⁴⁴ A number of CIPLA and Ranbaxy drugs were de-listed by WHO in May and August 2004, when inspections at the contract research organization used by the companies revealed non-compliance with Good Clinical Research Practice, Good Laboratory Practice and data verification of the bioequivalence study. Following a 'warning letter to all manufacturers to check the contract research organizations that conduct bioequivalence studies, Hetero and Ranbaxy voluntarily withdrew all their products (3 by 5 Evaluation Annex 9.;35).

up in the longer term.”⁴⁵

Perhaps more surprisingly, no mention of the calamitous withdrawal episode is made in the 3 by5 Evaluation Report either. Only in the special report of a supposedly independent evaluation do we find any information. The author of Annex 9.1 deals with the extremely damaging incident by praising the Prequalification Project for insisting on quality standards, as well as emphasizing that the final responsibility for the product lies with the manufacturer.

The danger for patients who had been prescribed the withdrawn drugs is that they may have received a sub-optimal dose, because of poor formulation or poor quality drugs or because patients discontinued the treatment before it could be effective. Clinical uncertainty and possible drug resistance are the inevitable results. As it now stands, only those patients who have never taken ARVs (‘treatment-naïve’) will be accepted onto national programs operating under the public health approach and anybody who may not benefit from first-line treatment because they have taken drugs that were discontinued, or that may have been sub-standard, may be refused further treatment (76). Effectively, unless individuals can apply to a private or NGO treatment program they will be left to die, possibly while carrying a mutant strain of HIV.

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. 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.

However, the author of Annex 9.1 adopts an attitude of exasperation with critics (Hudson Institute, American Enterprise Institute Ann 9.1;36) claiming that the Prequalification Project’s standards are more stringent than those of the United States FDA or the European Medicines Agency, which have no specific requirement to inspect contract research organizations. In fact, this argument is a red herring: While it is true that the FDA does not inspect contract research organizations, it requires manufacturers to submit data, such as bioequivalency data, that has been independently validated by an external firm. Without that data, the FDA will not consider a file from the manufacturer for approval of a product. However, this does not mean that the FDA can’t, when it wants to, inspect a contract research organization.

The most damning suggestion of fault is made by the author in the form of an attack on manufacturers: “As is evident to WHO, contract research organizations should have been checked before, but if a manufacturer really tries to save on quality or tries to cheat, it always finds a loophole. Only regular controls will identify these manufacturers in the end.”(Annex 9.1;35)

This is a significant problem because, as the author of Annex 9.1 is eager to point out, many national drug regulatory authorities (where they exist) do not require bioequivalence studies from manufacturers, lack confidence in making their own decisions and look to the WHO for assurance on drug quality (Ann 9.1;36). This means that the WHO has an implicit responsibility to maintain standards or withdraw endorsements for drugs, as shown by the appeal by national drugs regulatory bodies mentioned above, even though it has neither the regulatory authority nor the legal power to issue or withdraw marketing authorization (36).

The greater responsibility for which WHO which must be held accountable is that the 3 by 5 campaign was predicated on using large quantities of cheap copy drugs, manufactured by companies known to be insufficiently regulated and whose products had been previously found by the WHO itself to be substandard in very serious ways. Despite this, the message sent to

⁴⁵ See supra note 28

manufacturers from 3 by 5 was to ramp up production as quickly as possible.

And, since the WHO promoted the campaign to focus countries, issued unilateral targets for treatment and promised the necessary technical support and funding, it is not unreasonable that those countries should look to the WHO to guarantee quality and supply of drugs. It is clear that WHO knows what is required in this respect and has a good model for achieving it: “The workload of the 'mini' team [of the Prequalification Project] is tremendous and the output in terms of dossiers assessed and products prequalified is high.”(Ann 9.1;39) However, there are too few staff operating on too small a budget to be able to do its job effectually. The backlog of inspections still exists and the department is not well prepared for another incident of quality failure. “Prequalification ... cannot guarantee the quality of a product” (Ann 9.1;37).

A serious consequence of the drug withdrawal was mentioned. This was that a shipment of drugs intended for scale up was returned to India by the Tanzanian authorities after WHO information on the withdrawal was published, which delayed the start of treatment by three months. Apparently, this was not necessary as 'option 3 (b) for programme managers' states that the use of withdrawn drugs could be justified (Ann 9.1; 36). This seems to make a nonsense of safety standards, but the graver consequences would surely fall on those patients who had already started treatment with drugs which may have had the wrong dosage of active ingredients. As indicated above, these patients will be left in an extremely precarious position as regards further treatment.

No data have yet been collected on build up of resistance so the extent of this problem may never be fully known. For patients who received substandard drugs, the best hope is that the pills contained no active ingredient at all. In the meantime few second-line or pediatric products have been prequalified despite urgent need for both.

As it is, delays in prequalifying generics are pushing procurers back to the quality and reliability provided by the innovator companies. If things do not change, and there is little sign of this being achieved, the Prequalification Project is in danger of becoming redundant (51); a move these authors would welcome because presently it gives the impression of being able to offer meaningful quality control when in fact its resources are too stretched to do anything but belatedly discover some system failings.

The mistakes of 3 by 5 have been made evident by CIDA's Evaluation, but they were always highly predictable. Those who expressed doubts about scaling up have been fully vindicated. The WHO and its HIV Department should accept the blame for the dangerous situation it has created through ineptness. There was easily enough knowledge and expertise within WHO for it to be aware of the risks of rapid expansion of mass treatment programs, but these risks, the most serious being the probability of breeding resistant strains of HIV at a population level, were too heavily discounted. and the Initiative was pushed ahead for political reasons.

The two main features which underpinned 3 by 5 were the most dangerous: the use of cheap drugs and a corner-cutting treatment program.

The quality standards of the Prequalification Project were high but they were unenforced and enforceable given the staff, funding and time available. The problems of substandard, counterfeit and fake drugs made in countries with insufficient governance was apparent to the WHO – indeed those countries had themselves appealed to WHO for quality control assistance. A unit had already been established and was operating a pilot program intended for internal use by the UN in advising on drug procurement. With insufficient capacity on a very short time-frame, the unit was supposed to police the entire manufacture of enough copy drugs to treat 3 million people in 49 countries.

Aside from the manufacturing standards, the combination therapies given assumptive approval by the Prequalification Project, had not been tested for bioequivalence. The catastrophic consequences

of the eventual de-listing of 18 copy products on those patients who had been taking them will probably never be known.

Under the Public Health Approach, these patients will be denied further treatment because first-line drugs will probably have been compromised and second-line drugs are too expensive for mass treatment programs. Those patients will probably go unrecorded by and excluded from a program which favors the many over the few. Similarly, the recommendations under the Public Health Approach to suspend basic testing in resource-poor settings means that information on co-morbidities is not discovered. Essentially, HIV infection is nearly always accompanied by so-called 'opportunistic infections' (Ois), commonly TB, STIs, hepatitis and others. However, patients with hepatitis B or C would be ineligible for most ARV therapies, as their livers are already seriously compromised and at risk of great damage. But if patients with hepatitis are entered into mass public health ARV programs in the absence of testing, ARV treatment will do them more harm than good.

Antiretroviral Drug Prices, Procurement and Supply

The 3 by 5 Initiative rested on the public health approach and cheap copy drugs to enable mass treatment programs in 'resource-poor settings'. In support of this WHO runs a price monitoring system and database that is designed to help negotiate better ARV prices. The Organization was involved in negotiating price reductions in the pan-American region (51) but 'a focus study commissioned as part of this evaluation reported that there is no evidence that 3 by 5 has reduced the prices of ARVs significantly in Africa' (51).

Negotiating hard bargains in one market obviously can force a tiered system, where preferential prices are awarded to the most vociferous customers, or hopefully those with the least ability to pay, but others have to pay higher prices to compensate. Since at least the 1930s it has been understood by economists that price discrimination across markets for the same goods is efficient and equitable. It makes sense for EU/US patients to pay far more than Africans for ARVs (US \$15 pd v. US \$1 pd), however, middle-income countries like Brazil should pay more than Africans and less than Americans. One size does not fit all. Unsubstantiated media reporting of apparent prices for one drug cocktail in one location implying availability of many ARVs at that price everywhere leads to unnecessary pricing battles. The Clinton Foundation triumphantly announced a deal it had brokered with a copy manufacturer in October 2003. But it emerged that this was a one-off available only to a particular fixed-dose triple-therapy drug bought by the Foundation. The health NGO, Médecins sans Frontières (MSF) could not access the drug for anything like the Clinton price.⁴⁶ This led to Brazil threatening Abbott, Gilead, Merck and other companies over their drug pricing policies.

There remain concerns that secure and adequate supplies of high quality drugs can be found to support the scaling up initiative and WHO seems also to have been ineffectual in improving access to diagnostics. "Work being undertaken by WHO to improve the availability and prices of HIV diagnostics has not achieved any significant breakthroughs" (51.)

Problems with drug procurement and supply management are widespread and have held up Global Fund disbursements. Evidence that the rapid treatment scale-up has over-stressed existing supply systems was seen in reports of 'stock-outs'; diversion of supplies and irregularities in procurement practices (i.e. problems of counterfeits); concerns by health workers about the quality of drugs in use; mixed supply of copies and branded products causing upsets to prescription, administration and undermining confidence in copy drugs; and a lack of drugs to treat the opportunistic infections and sexually-transmitted infections which flourish in the presence of HIV infection (52).

Having brought about the situation by its poorly thought-through 3 by 5 Initiative, WHO has not

⁴⁶ See *supra* note 28. The Clinton Foundation price from the manufacturer was US \$140 per patient per year. However, this did not include freight, foreign exchange costs, insurance, tariffs, taxes etc. The best price MSF could get was US \$214 per person per year.

been substantially involved in resolving supply chain problems. This responsibility has fallen to a Global Task Team that has been formed among multilateral agencies and international donors to draw up regulations, guidelines and procedures and to apportion roles amongst themselves in an effort to ease the strain on country procurement systems (52).

By contrast, PEPFAR announced in November 2006 that in its 15 focus countries, 70% of ARV use was now with true generic products, as compared with 11% in 2005. This is the direct result of the FDA offer in May 2004 to fast track any application from any country for the approval of true generic drugs. These drugs now come from India and South Africa via voluntary licenses awarded by the innovator companies. Of note, no patent holder has challenged the FDA on the use of its intellectual property in this way, provided the product is a faithful copy – a true generic. The UN/AAI, which treats more patients than any other single body, only uses drugs approved by FDA/EMEA.

AIDS Medicine and Diagnostics Service (AMDS) Network

This was originally conceived as a procurement agency, but these plans were abandoned with the acknowledgement that WHO does not have the capacity for large-scale procurement. However, as WHO was asking manufacturers to re-direct production to large quantities of drugs for which there was no guaranteed market, this may have been a useful facility.

As it is AMDS has confined itself to functioning as a clearing house for information relating to drugs and diagnostics and to dealing with problems. The AMDS secretariat has also arranged a series of workshops carried out by its network of collaborators whose chief activity is teaching Global Fund recipients to write grant proposals (53). While the Global Fund recognises that training is needed to help recipients produce the procurement and supply management plans which are required before grants can be disbursed, WHO is not compensated for its services.

Some specific goals have been identified by 3 by 5 partners, such as monitoring, research and maintaining a knowledge base. But procedures to achieve these goals have not actually been established. At the same time, some of the tasks AMDS has undertaken have overlapped with the work of departments at the WHO's Health Technology and Pharmaceuticals Cluster (HTP), and has even duplicated the work of external partners (53). Moreover, while the AMDS secretariat struggles with a partnership organization which is not well structured or optimally managed (54), departments within HTP have already established good working arrangements with these same external partners which allow their various scientific, strategic and operational skills to be used effectually (54).

While the Evaluation Report recommends that AMDS “will need to focus on becoming more relevant”(53) it seems that WHO is trying to replace it with another ill-conceived venture of dubious legitimacy to act as advisor, market-fixer and buyer-on-commission of drugs and diagnostics for HIV, TB and malaria. The putative International Drug Purchase Facility, known as UNITAIDS, is supported by France, UK, Russia and Brazil and the Clinton Foundation, but is encountering stiff opposition, significantly from the Global Fund.

Strategic Objective 5: Rapidly Identifying and Reapplying New Knowledge and Successes; 'Learning by Doing'

The 3 by 5 Initiative was developed and launched with great speed. As has been made evident in preceding sections, this haste left many crucial functions underdeveloped. “In implementing 3 by 5 as an 'emergency' initiative, WHO could not wait for a more complete evidence base to guide its technical strategies” (55). The developers' remedy for this was to propose a new process of information gathering, analysis and feedback which would enable continuous development and improvement. But this has proven to be far too ambitious and unrealistic given the lack of capacity

both in 3 by 5's target countries and in WHO itself.

Activities for generating and managing knowledge relating to 3 by 5 have been poorly organised at the WHO headquarters level (spread over five different departments/units) with inadequate coordination and cooperation between them to effectively harness the wealth of information that flows through the Organization. At times, this has affected the ability of WHO to generate internal consensus on technical approaches (such as which monitoring systems to use) and has led to inconsistent collaboration with external partners (for example in countries where WHO has been promoting electronic patient registries while at the same time working with ministries of health to implement paper-based systems (55).

Despite investing significant resources WHO is still not systematic in collecting, synthesizing or disseminating information to guide decision-making with the result that available evidence for designing service delivery is still extremely limited (57). The normal methods of operational research at WHO are retrospective observations and these have been few in number and thin on rigorous evaluation and analysis. It would have required a drastic change of culture (albeit a desirable one) for WHO to take on this fluid, responsive knowledge management system.

In fact, the system of internal program monitoring, established to learn from results and to track the progress of 3 by 5, has not been put into operation because nobody has been given clear responsibility for it and it is not usually included as a funded activity in workplans (58). The exhaustive indicators that were set out in *Treating 3 Million by 2005; Making it Happen* publication have not been systematically tracked to monitor results or to find out whether the programme is achieving its five main objectives.

Progress has been reported only at a 'global' level and is mostly for the benefit of external stakeholders. Further, it is far too aggregated to be useful for any kind of analysis. Even at this macro level of reporting, the performance indicators used are often not appropriate. For instance, it was found that 3 by 5 country officers were using national indicators of the number of people on treatment to measure their own progress (58).

An example of this was revealed in treatment numbers announced by 3 by 5 managers. The numbers were found to be inflated by 63,000 as the same patients were being assisted by both GFATM and PEPFAR.⁴⁷ The admission was made of double counting at the late January 2005 World Economic Forum meeting in Davos, Switzerland, but the question of whether those receiving treatment under programs which have no connection with 3 by 5 should be included in 3 by 5 totals remains. For instance, it is often repeated that prior to 3 by 5, 400,000⁴⁸ were receiving treatment and the figure has now risen to 1.3 million,⁴⁹ but these are not disaggregated or explained in any way.

Considering the findings of the Evaluation and the admissions forced by public exposure, it is unsafe to assume that 3 by 5 was responsible for all the increase. Most tellingly, the WHO itself announced at the end of 2005 that 716,000 were receiving treatment under the UN/AAI program of which WHO is a founding member. This number is projected to rise to 825,000 by the end of 2006, but it is not clear how these numbers fit with the figure of 1.3 million.⁵⁰

⁴⁷ See Roger Bate, "WHO AIDS Target: An Inevitable Failure," Health Policy Outlook, AEI, Washington DC., available at http://www.aei.org/publications/filter.all.pubID.23712/pub_detail.asp, accessed 28 November, 2006

⁴⁸ WHO "Treating 3 Million by 2005: Making it Happen: The WHO Strategy." The World Health Organization, 2003. Pg. 5, available at http://www.cinu.org.mx/temas/vih_sida/doctos/3x5sida.pdf, accessed 28 November, 2006.

⁴⁹ WHO "Progress Report on Global Access to HIV Antiretroviral Therapy." The World Health Organization. March 2006. pg. 5, available at http://www.who.int/hiv/fullreport_en_highres.pdf, accessed 28 November, 2006.

⁵⁰ Norris, Jeremiah and S. Jean Weicher. "UNITAID/IDPF: An Analysis of the International Drug Purchase Facility."

The proposition that 3 by 5 could develop real time systems of data gathering and analysis in time to allow any program development within the lifetime of the initiative was delusional. Apart from WHO's organizational deficiencies the CIDA Evaluation points out, 'learning by doing' would not be possible without outside help, as 'WHO is not a research institution' (57).

A consistent feature of the CIDA Evaluation is that the authors persist in their belief that the Organization could be successful if only certain changes were made, despite a long history of evidence which suggests the opposite.⁵¹ As an example of what has been achieved by Objective Strategy 5, the Evaluation Report points to WHO's action on policy analysis made in response to a need expressed by 3 by 5's partners. WHO hosted a consultation, drew together existing evidence and facilitated a technical review of the analysis (59). The issue in question was whether there should be free access to ART, and as mentioned above, this was a clear example of where WHO should have taken a strong stand, but shirked responsibility under political pressure.

The International Treatment Preparedness Coalition (ITPC) is another example of where WHO recognized a shortcoming in its own operations and helped to facilitate a new way of collaboration and knowledge-sharing through a self-organizing community of interest. The ITPC comprises a diverse range of voluntary participants from around the world who help each other to identify practical solutions for all types of problems relating to treatment scale-up. They also provide 'real-time' answers to requests for technical assistance. As such, it would seem to offer help with 3 by 5's problems in 'Learning by Doing' but WHO does not formally participate in the forum. There are people within WHO who believe this is just the sort of thing the Organization should be doing, as such collaboration would make the most of its institutional influence, technical linkages and relative advantage of having an extensive presence on the ground (59). It is baffling that WHO should have the wherewithal to recognize a problem, help set up an outside body which effectively addresses it, but refuse to engage with that body while continuing to struggle with its original problem.

As mentioned above, the ITPC has criticized the WHO for its lack of visibility on the ground, but perhaps of more real relevance, it has also criticized national governments for their failure to provide for their own citizens. ITPC conducted a six-nation survey and published this comment in November 2005: "in every country surveyed there were concerns about inadequate leadership at the national level and the subsequent failure to dedicate sufficient resources or mobilize governments. Scale up of treatment will not happen unless countries fulfill their responsibilities to those living within their borders--and national governments must be the primary engine for increasing access to care."⁵²

One country in the survey was India, which had some US \$300 million in donor contributions for AIDS. For the 2005-2006 period, however, the Government of India had committed only US \$5 million to the effort. WHO reported that of the 785,000 AIDS patients needing treatment, only 12,000 were receiving it as of 31 December, 2005, despite India being the main supplier of ARVs to poor African and Asian countries.

The Hudson Institute. Nov. 2006. pg 10, available at <http://www.hudson.org/files/publications/UNITAIDAnalysis.pdf>, accessed 28 November 2006.

⁵¹ Recent commentaries on the UN show similar leanings, despite the damning evidence of atrocity, cowardice and corruption by UN troops and Executive. "Complicity with Evil," Adam LeBor, 2006 Yale University Press; The Best Intentions' James Traub, 2006 Bloomsbury.

⁵² ITPC, "Missing the Target: A Report on HIV/AIDS Treatment Access from the Frontlines," International Treatment Preparedness Coalition, 28 November, 2006, available at <http://www.aidstreatmentaccess.org/itpcfinal.pdf>, accessed 28 November 2006.

Further Issues Ignored By WHO 3 by 5

Prevention of HIV infection did not feature at the launch of 3 by 5, possibly because “WHO believed that ART delivered as a public health intervention could have a positive impact on HIV prevention at the population level (although conclusive evidence for this is still not yet available).”⁵³ (69). Prevention is strictly the responsibility of UNAIDS, but this was a serious omission given that prevention was a key feature of the Global Health-Sector Strategy, ratified by the entire UN, which pre-dates 3 by 5 by two years. Some efforts are now being made to focus on interventions that are delivered through existing health services, NGOs and other partners.

However, guidance is still missing on crucial but 'controversial' issues such as routine HIV testing for children, prevention among discordant couples (only one partner is infected) and partner notification and disclosure. In October 2005 UNICEF and UNAIDS launched a joint campaign to achieve 80% access to HIV-infected women during childbirth by 2010 (70). Prevention of mother-to-child transmission (PMTCT) is well-proven to be a successful intervention, requiring only short-term intermittent therapy to keep a baby free of infection, but WHO did not participate in this initiative and has shown weak leadership on the issue within its own operations. Whether WHO's participation would have made a positive difference is questionable, given the general level of failure of 3 by 5, but if it is to be taken seriously, WHO should at least try to live up to the principle of prevention, as ultimately, treatment can never succeed if infection is ever-rising.

Similarly, the 3 by 5 Initiative could never have succeeded while it relied on the existing fragile health systems which exist in many HIV-affected areas and most of sub-Saharan Africa. Any success in scaling up services has been made through enhancing of existing facilities and re-deployment of staff, supported by extra funding and infrastructural improvements (71).

The critical shortage of human resources and skills in all functions of managing, supporting and delivering health services in Africa is the single biggest health system constraint to scaling up (73). However, simply giving extra funding to HIV work without boosting the budgets of existing programs is likely to have detrimental distorting effects. The experience of Sierra Leone⁵⁴ suggested that the best qualified doctors and nurses were being drawn away from working on child immunization, respiratory infections and malaria control to work in HIV clinics where the pay was higher. It was reported that a pediatric doctor could triple his salary, but this would mean abandoning other essential health work which has a higher cost-effectiveness ratio than treatment with antiretrovirals, that is, work which would have saved many more young lives.

Existing facilities are largely in towns and cities therefore any further increase in capacity will have to come from entirely new infrastructure and newly-recruited and trained staff in rural and remote areas if there is not to be the distortion of services that was evident in Sierra Leone. This will be difficult from a human perspective as staff will have to be persuaded to live and work in villages with much poorer facilities than they enjoy in towns, but it will also be logistically difficult and expensive to build and maintain clinics in hard-to-reach places.

Health systems strengthening can be undertaken by WHO yet it has all but been ignored, not only by 3 by 5, but for many years. Managers from National AIDS programs interviewed for the Evaluation gave WHO a low ranking on this metric and specifically ranked technical contributions to human resources strategies and financing as weak. Executives from the Global Fund Technical Review Panel reported that many proposals from African countries for health systems strengthening had to be rejected because they were too vague or overly ambitious (71). This suggests that the technical assistance which is supposed to be the unique specialization of WHO was missing or deficient in the preparation of these crucial funding applications. If WHO has a future, health

⁵³ As at June 2006

⁵⁴ Bate, R 2006. “Low Sierra” *Tech Central Station*, February 14, 2006, available at http://www.aei.org/publications/filter.all.pubID.23884/pub_detail.asp, accessed 28 November, 2006..

systems strengthening is a key technical area in which it must excel.

WHO management and cosponsors may have believed that crucial, fundamental requirements could be achieved instantaneously, but that would suppose an improbable degree of ingenuousness. Perhaps they hoped that a brave declaration would inspire a following, which did happen to a limited extent. However, this Initiative was fatally under-planned and under-resourced which placed the burden of risk on the people it was intended to help. Sadly, most observers find such mistakes easy to forgive so long as the protagonists mean well, but this is a good way to ensure that mistakes are made again.

The CIDA Evaluation gives evidence that a major initiative has been managed in a politicized, precipitate manner which negated much good work and possibly endangered the lives of those targeted for treatment. Such complaints about poor management have persisted for many years, but the prevailing belief that the 'world needs WHO' prevents a full discussion of what appropriate action should be taken. This benefits nobody.

Conclusion

UN Secretary General, Kofi Annan said in the week leading up to World AIDS Day 2006: “The challenge now is to deliver on all the promises that governments have made. Leaders must hold themselves accountable — and be held accountable by all of us. Accountability — the theme of [this year’s] World AIDS Day...requires every president and prime minister, every parliamentarian and politician, to decide and declare that AIDS stops with me.”⁵⁵

But accountability must begin at home and there is much which the UN itself should answer for. UNAIDS reports that the HIV/AIDS epidemic is worse than ever and given the poor standard of the UN's latest big effort, this is not surprising. The “3 by 5” initiative cut corners on drug quality exposing thousands of patients to drugs of unknown quality (all over Africa); it over-strained poor countries' fragile health systems, potentially undermining small-scale but successful treatment programs (notably Sierra Leone and Lesotho); failed to maintain dialogue or even consult with some countries that disagreed with its targets and methods (notably South Africa); furthermore, it failed to promote good clinical practice, so it is unknown how many patients are failing treatment (all over Africa).

In December 2005 WHO admitted that “3 by 5” failed to meet its target, but otherwise implied the program a success: it 'proved' that mass treatment was possible. Actually it did no such thing, as the CIDA evaluation made clear, no evidence has been presented (or even collected) to show that the model was successful. The campaign created an unquantifiable mess which others are left to clear up, and UNAIDS is now promoting universal access using the same model of medical malpractice employed by 3 by 5.

Mr. Annan is correct that accountability is important but seems to think it is only for other people. John Williams, a Canadian MP and chairman of GOPAC (the Global Organisation of Parliamentarians Against Corruption), defined accountability at the Transparency International conference a couple of weeks ago as ‘force beyond your control that makes you change your behavior’. There seems to be no force capable of bringing necessary change at the UN.

It is imperative that the international health community working to combat AIDS reevaluates what needs to be done. That means appreciating the nature and the scope of the disease, implementing treatment models that are proven to work in the targeted areas, entering into partnerships with local and global groups where necessary, ensuring more resources for the people on the front lines who need help, and most important of all, never failing to learn from past mistakes and poor choices.

⁵⁵ Bate, R., “New Research Looks at the UN’s Failure on AIDS” *TCS Daily*, 1 December, 2006.

The UN system has the potential to play a useful, integral role in this process but has not, so far, shown itself to be worthy of a place at the table.