

Scaling Up Antiretroviral Therapy and the Struggle for Health for All

By *moderator*

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Do you remember where you were 8 years ago? I remember it distinctly. In the summer of 2000, I was in Durban for the first ? and so far only ? international AIDS conference held on African soil. There are many unkind things said about these events, but those few days in South Africa changed the lives of millions of people forever. I still get shivers when I remember the challenge directed at us by Edwin Cameron, a justice of the South African Supreme Court of Appeal and an openly HIV-positive, gay man. He said:

Those of us who live affluent lives, well-attended by medical care and treatment, should not ask how Germans or white South Africans could tolerate living in proximity to moral evil. We do so ourselves today, in proximity to the impending illness and death of many millions of people with AIDS.

As Edwin was appealing to delegates' consciences, thousands of ordinary men and women from the Treatment Action Campaign were outside marching on the conference centre demanding access to AIDS treatment. Their message was simple: we are sick and there are drugs that can make us well, we are dying and we want to live.

Edwin's challenge and the marchers' demands could have gone unheeded. There were plenty of naysayers telling us that AIDS treatment wasn't cost-effective in the developing world and that we should only focus on HIV prevention. They said that antiretroviral therapy should wait until we had more robust health systems to manage such a complex intervention. They said such things even though they knew the wait could be decades long?and that tens of millions of untreated HIV-positive people would likely die over those years.

Luckily, the cry for access to AIDS treatment was answered shortly thereafter by a few brave leaders in the public health community. Spurred on and challenged by activists and people living with HIV around the world, they took on the convention wisdom and launched most notably, the 3x5 initiative, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the President's Emergency Plan for AIDS Relief. Such initiatives have now made AIDS treatment (and many other services) available to 3 million people in poor and developing countries who would be dead today without it.

The scale-up of antiretroviral therapy is the most ambitious public health undertaking of our lifetimes. We are making history together--activists, scientists, policy makers, doctors and nurses, government and public health officials and ordinary men and women in communities around the world.

AIDS has radically shifted the trajectory of global public health?instead of settling for the bare minimum of services for people with HIV/AIDS, advocates for the disease have made the case that no one should die from a treatable illness simply because they are poor. Until recently, the idea of health for all?the core promise of the Declaration of Alma-Ata, signed by World Health Organization member states 30 years ago?was, as Paul Farmer has said, the butt of ridicule in international health circles. The promise may have been made by others long ago, but we will keep it. In fact, we are the heirs of Alma-Ata, of the struggle for comprehensive primary care, the campaign that was launched 30 years ago. AIDS treatment can be the catalyst for building comprehensive primary care for poor people the world over, indeed AIDS treatment can only be sustained over the long-term if we can succeed in this. Though the goal is once again ambitious and the conventional wisdom will always tell us to settle for far less, we have already done the impossible.

Where are we today? You've already heard earlier this week from Alex Coutinho that there are now 3 million people alive today on antiretroviral therapy despite the warnings that saving their lives was unwise, unsustainable, and was contrary to expert opinion on how health and development should work. But we've saved lives. Here are the data on CD4 counts in a large cohort of patients on ARVs in low and middle-income countries and mortality data from the largest ARV trial in Africa compared with an untreated cohort.

But how did we do this? How do we sustain and build upon our successes?

First, we set targets. We did not meet the 3x5 goals on time?it took us 2 additional years to reach three million people with antiretroviral therapy. The lesson to learn from 3x5 is not that we shouldn't be so ambitious; instead, it's that setting a goal and striving towards it is the only way to make significant progress toward a destination. Unfortunately, the current campaign for universal access was built without global targets because UNAIDS, DfID and the US government refused to accept them. At the same time, the definition of universal access is now irresponsibly vague ? just take a look at the latest UNAIDS report, which contains more twists and turns than Olympic gymnasts to avoid any concrete commitments. The decision to not include targets and to step back from specificity is a political one taken by organizations and agencies that are political to a large if not complete degree. But that's really just a poor and pathetic excuse, and one with potentially devastating public health consequences. Unless we have clear targets, with clear timelines, we will never reach our goal of universal access. Approximately 10 million people need antiretroviral therapy today. Perhaps we can't reach that goal by the next time we gather, in 2010 in Vienna, but let's not leave Mexico City without attaching a firm deadline nonetheless. And let's not set that goal so far in the future so it becomes essentially meaningless.

Second, scaling up antiretroviral therapy in resource poor settings would not have been possible if it was done as it has been in richer nations. The scale of the problem and the paucity of resources meant that a new way of providing care needed to be developed, now known as the public health approach. The public health approach depends on standardizing ARV regimens, thus simplifying formularies and lowering procurement costs through bulk purchasing; simplifying algorithms on when to start, substitute, switch and stop regimens. It involves standardizing monitoring of the response to treatment and management of toxicities and drug-drug interactions; and population-level monitoring of drug resistance. In addition, the public health approach requires decentralizing delivery of care; task shifting; ensuring that services are free at the point of care; strengthening procurement and supply management, and tracking ongoing progress. Finally, the public health approach sees antiretroviral treatment as a matter of chronic disease management to be treated in the context of primary care. Please, remember this last point.

Despite our success, coverage of antiretroviral therapy in low and middle-income countries is still at 31% of need. The lives of millions of people depend on whether we can expand the reach of these programmes. Furthermore, for the three million people on ARVs now, their continued survival depends on long-term management of their HIV disease, which means we must strengthen primary care systems to manage AIDS as a chronic disease. It's going to take sustained commitments from donors, countries, healthcare workers, communities themselves?all of us to make this happen. And it's going to take political will. But, remember, we've accomplished the impossible in the last ten years. We can succeed again, but our future is precarious?the technical challenges are formidable, and the political ones are brutal. Let's start with the technical challenges.

We have a lack of human resources?there are plenty of presentations at this conference about the shortage of health care workers, but while we think of long-term solutions for increasing the supply of trained professionals to manage ART, we need to invest in task-shifting now to deal with the immediate crisis. We can't rely on a physician-driven model for providing antiretroviral therapy?there are simply too few doctors to go around. This means nurses, clinical officers, community health workers and even non-clinical staff need to take on activities they have never been asked or allowed to do, such as allowing nurses to prescribe ART. We need to move beyond the resistance of governments and professional societies, stop talking about this and make it happen.

However, task shifting within the health sector ignores the greatest resource available: communities themselves. What does this mean? ARASA, TAC and our partners have been working in Southern Africa to educate and mobilize communities around their own health, to map services in communities, work in clinics, and act as watchdogs for provision of services. We advocate for what communities need and communicate this to district, provincial and national health officials. This isn't about expanding home-based care, which narrowly casts community's roles in health, but about bolder attempts to turn communities themselves into "the first-line of primary care providers" as Ernest Darkoh has called them. We need to enable patients, with the help of their families and communities to take more control of their own disease and its management. This is a critical tenet of chronic care delivery for problems like diabetes or hypertension, and can be done for HIV if we get away from the need for an expert specialist at every turn.

Though the human resource needs are acute in low and middle-income countries, there is also a shortage of leadership and management skills that is hampering the efficiency of programmes and slowing scale-up of ART. Those working on scale-up of ART often have little training in basic skills like planning, budgeting, strategy development, problem solving, running a meeting effectively, creating a workplan, organizational and project structuring and design, managing teams and monitoring and evaluation. These things aren't very sexy, let's face it, and they sound rather bureaucratic. But in reality they are vital to the core goal of helping as many people as possible get access to treatment in the most efficient, sustainable way. We need to invest in building these skills now in the health sector, while addressing the larger inequities in access to education in low and middle income countries, which have created these problems.

In addition to the shortage of human resources, the physical infrastructure of health cannot cope with the expansion in services required. Clinics are over-crowded with patients with AIDS, TB and many health needs, pharmacy shelves are sagging under the weight of AIDS drugs; laboratories are ill-equipped for even basic services, let alone more complex technologies, such as CD4 counts. We need to renovate existing structures and build new buildings for AIDS and general primary care into the future. And this is not about vanity projects, those glittering buildings you see in many capitals built to house national AIDS commissions, international NGOs or as monuments to new "partnerships" between academic institutions in the North and South. These are basic structures?health posts and health centres, hospitals, hospices, laboratories.

At least once a week, I get an email about an AIDS or a TB drug stock-out somewhere around the world. The lack of secure and reliable drug supplies is the Achilles' heel of ART programmes, risking drug resistance and undermining AIDS treatment success. Central medical stores in many countries often can't handle this task?we need to be honest about this and contract out this effort if necessary. This is where the sterile debates about horizontal vs. vertical approaches to health are over-simplistic: we've got to do what works in the short-term and get drugs to people while simultaneously trying to address the longer term challenges to supply chain management in the health sector. This isn't rocket science but we can't hold decisions about supply chain management hostage to theoretical debates and political dogma.

We need regular and reliable national data on ART scale-up, not estimates but real numbers. This means that the capacity of countries and donors, and health care workers, to collect, compile and evaluate the data needs to be enhanced. There needs to be standardized registration, recording and reporting procedures, allowing for quarterly cohort analyses of treatment outcomes, particularly survival, at all sites. These data need to be reported to WHO and back to the sites on a regular basis. This kind of programme monitoring needs to be integrated into and highlighted in

the public health approach and endorsed by WHO. And we need to keep things simple. Government attempts to develop simple and uniform monitoring systems are all-too-often undermined by a multitude of donor requirements, while these requirements themselves are frequently difficult to collect using paper-based systems, and are spawning an industry where untested technology solutions are offered as a panacea to ease reporting requirements.

The public health approach to ART demands we used simplified and standardized regimens, the backbone of ART programmes around the world currently depends on d4T-based regimens? with the sole advantage of cost?the median price was US\$91 per person per year in 2007. However, the toxicities associated with d4T, including painful peripheral neuropathy and lipoatrophy, neither of which are likely to be reversible, make it highly problematic. Yet the simplest change has significant cost implications because the most common drug used to replace d4T, tenofovir, is much more expensive. Tenofovir alone is slightly under US\$200 per patient per year from generic suppliers; therefore, for example, making a switch from d4T to tenofovir cost-neutral for the South African government would mean bringing the drug's price down to \$74 per patient per year, according to a recent study by Sydney Rosen at Boston University.

But the costs of switching regimens, indeed making any changes in ART programmes, have other hurdles as well. Staff need to be trained, there are procurement issues, with tenofovir there are renal toxicity risks?do we need to do creatinine screening at baseline, and if so what are the implications for this, not just in terms of costs, but in the complexity it adds to ART scale-up? There are other problems with other drugs. Nevirapine's interactions with rifampicin make it a sub-optimal choice in settings of high TB prevalence. Switching from nevirapine to efavirenz would make ART more costly for more programmes. In addition, since efavirenz is contra-indicated for pregnant women, moving away from nevirapine would mean perhaps having two different regimens for men and women, increasing the complexity of drug supply management for programmes. Challenges like these are straining the need to depend on simplified and standardized regimens over the long term.

Other pressures seek to move us away from a public health approach. For instance, there is compelling evidence that earlier initiation of ART at 350 CD4 cells is superior to long-established guidelines recommending that individuals begin treatment when their count is below 200 cells. However, it should be pointed out that much of the new data is from cohort studies, not randomized controlled trials, and from resource-rich countries rather than resource-poor settings. Raising the threshold for starting therapy may be clinically beneficial for individual patients, but its wider impact on health services may end up weakening ART programmes by creating longer queues, in already saturated national programmes using relatively temporary facilities, where even now the sickest patients still have trouble accessing medicines.

Lifting the threshold for initiating ART to 350 cells without assessing the effectiveness and indeed the feasibility of this intervention at a population level in low and middle income countries may end up doing more harm than good. The question of when-to-start antiretroviral therapy has vexed the field for years now?it's time to do a study to answer this question for resource-poor settings.

We cannot forget perhaps the most basic obstacle: most patients don't come forward for testing and care until they are very sick. We're going to have to do a whole lot better in getting people to know their status and getting them into care before earlier initiation of therapy becomes more than a theoretical concern. In fact, if we could address tuberculosis, both in terms of treating active disease and preventing development of disease with preventive therapy, we might make a greater impact on the survival of people living with HIV/AIDS than by changing the guidelines for the initiation of ART. Even when we do have data on changing treatment guidelines from randomized controlled studies in resource-poor settings as we have from the CHER study, how to provide universal access to ART for infants before 12 weeks of age has some significant hurdles?from lack of access to diagnostics, to pediatric formulations, to health care workers trained in how to treat young children. Perhaps the best way to deal with complexities of treating pediatric HIV infection is to ensure that infants are not infected in the first place, by making sure that all pregnant women get the treatment and care they need.

Finally, there is a great deal of pressure to institute virological monitoring in treatment programmes, but often this comes from researchers and some activists in the North, who see any detectable viral load as anathema. However, if

you look at a recent study in the Lancet by Andrew Phillips, for patients on the first-line regimen of stavudine, lamivudine, and nevirapine the benefits of viral load or CD4 cell count monitoring over clinical monitoring alone are modest. The conclusion was not to delay access to treatment while waiting for new diagnostics. Before rushing to make treatment programmes more complex, more costly, we need to weigh the evidence on both the clinical benefits and risks, but also on the feasibility, on the operational risks and benefits for programmes.

As we look into the future with millions of people on ART, we're going to need to manage the longer term complications of not only ARV therapy itself, but also the other diseases that are now going to strike people living with HIV/AIDS as they live longer lives. This brings us back to the issue of comprehensive primary care

Scale up of antiretroviral therapy in low and middle income countries has been a miracle for millions of people who are alive today because of these drugs. Technical challenges can be overcome, but the political challenges ahead are toxic. This means all of us in this room, in fact, all who believe in the struggle not just for AIDS treatment but for "health for all," for comprehensive primary care, need to make a commitment today to become activists, in whatever way you can.

Right now, we're seeing a backlash against AIDS that is being led by some very senior figures in the health and development community. You've likely heard their three-pronged mantra. Put simply, it goes like this: the threat of AIDS has been exaggerated, AIDS gets too much money, and AIDS is destroying health systems. These people want to take us backwards, their vision is essentially destructive, their hopes for the future small. They are saying we must be satisfied with doing less for less, that we should provide a few basic interventions in the health sector because doing anymore will create unsustainable entitlements to health for the poor. Their words and attitudes threaten to hobble if not kill our efforts to scale-up ART and to strengthen primary care for low and middle-income countries. They are public health minimalists promoting Malthusianism for the masses, while they have easy access to the highest level of care for themselves and their families.

These naysayers are wrong in so many other ways. First, they make the naive assumption that funding for AIDS can be quickly and easily shifted to fund their utterly vague notions of the "horizontal." Activists for primary health care have been screaming for more funding for years but until the movement for AIDS treatment, we did not have the billions we need to make a real run at health for all. They also completely miss the point of AIDS treatment ? it is fundamentally a health system function. If you ask the most competent health ministers in the world today they will tell you that all health systems need both focus and breadth. Without continued and sustained focus on AIDS treatment, many millions of the poorest and most marginalized will die. Period. And without breadth, not only will AIDS treatment be incomplete but we will miss the greatest opportunity in history to build functioning health systems in some of the poorest countries in the world. Let me say it clearly ? stop the inane, sterile arguments about AIDS funding vs. health systems strengthening. The real task is to bring everyone together. By everyone I mean not just those of us working in health, but systems engineers, architects, management and operations specialists and other unusual suspects whose expertise and insights will prove invaluable.

Let's move forward together. Scaling up ART depends on a new movement to provide comprehensive primary care in low and middle-income countries to all who need it. The systems that will sustain ART provision and make AIDS a chronic, manageable illness are the same ones that will ensure health for all, that will allow us to address sexual and reproductive health, maternal and child health, the management of other infectious diseases and chronic conditions, to provide care for marginalized populations, including substance use treatment and harm reduction. We've got a chance to fulfill the dream of Alma-Ata from 30 years ago not by going backwards to old debates about horizontal versus vertical initiatives, but by building on the innovations, the successes, the vitality of people working on HIV/AIDS for a better future for all of us. This is just the beginning of our work together. Let's get busy.

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