# ANTIRETROVIRALS ARE COMING TO AFRICA: ARE YOU READY?

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***Abstract***

*International agencies are beginning a rapid scaling up of antiretroviral distribution programs in Africa. Some are particularly looking for "faith-based organizations" (FBOs) as partners. The new initiatives may offer both unprecedented opportunities and some dangers for FBOs who wish to join in. The opportunities include increasing our capacity to provide not only HIV/AIDS care but other aspects of health care, and a potential for increased communication and cooperation between Christian organizations. The dangers include the likely widespread appearance of antiretroviral resistance; long term sustainability; negative impact on other aspects of HIV care and prevention; indirect costs to FBOs; corruption; encouragement of a culture of money and power, drawing FBOs away from their perceived missions; overextension; and harmful competition among FBOs. Organizations should be aware of the opportunities and dangers, and review their own calling and mission, before embarking on large-scale, externally-funded programs of ARV distribution.*

## Introduction

At the Christian Medical and Dental Association's Continuing Medical and Dental Education (CMDE) meetings in Kenya last February, many of us met to discuss what is happening in the area of HIV/AIDS in our respective countries. Most of us were Western and African clinicians working in mission clinics and hospitals, but we also had some representation from US-based physicians specializing in HIV, from a donor organization (Catholic Relief Services), and from WHO (one presentation). Although our discussions and presentations covered many aspects of HIV/AIDS (including biology, prevention, social impact, involvement of churches, care of orphans), this summary focuses on what provoked the most discussion and controversy: the emerging programs to provide antiretroviral treatment in Africa.

WHO has announced their "3 by 5" plan, to scale up ARV programs so that 3 million people will be on treatment by the end of 2005, less than 18 months from now (WHO, 2002). Other major players include the Global Fund to Fight AIDS, Tuberculosis and Malaria, the US initiative, the President's Emergency Plan for AIDS Relief (PEPFAR), and the Bill and Melinda Gates Foundation. One of the earliest facts to emerge at CMDE was that there seems to be no clear plan yet about how this will be accomplished, even in the most general terms. That is not unexpected given how suddenly the international interest and support has materialized. Clearly, though, there is about to be an outpouring of assistance to Africa which is probably unprecedented in both scale and in rapidity. It appears that the time is past for debating the usefulness or practicality of mass ARV programs. Now we are entering the era of living with them and doing what we can to shape them.

One new twist in this semi-coordinated set of initiatives is some donors' interest in working through "faith based organizations" (FBOs). PEPFAR is setting aside resources specifically for FBOs. I don't know the details in the cases of the Global Fund or others but they are also, at least apparently, interested in working with FBOs.

Many people who have worked in the area of HIV/AIDS much longer than I have and will have a better understanding of what is already in place in your area, what is working, what might work, and what might not. However, I noticed during the CMDE meetings that even some who have been working with HIV/AIDS for a long time are getting caught off balance by these new developments-only two years ago few of us dreamed that we would be dealing with large-scale use of ARVs in Africa. I hope that this summary will reflect the main points discussed during the CMDE meeting. I'm presenting it to all of you because I think we need urgently to consider what is going on, for two reasons. First, so that we can continue doing our part fighting HIV/AIDS in the best ways we can. Second, so that we can maintain the integrity of our churches and other FBOs in the face of new pressures. I'll limit my comments to the issue of ARVs in the FBO context, as that is what most of us will be concerned with and are most competent to address.

## Lack of capacity

Many of us at CMDE were working in institutions where ARVs are already in limited use or where it would not be difficult to introduce them. I think it would be feasible in many cases to have them integrated into a comprehensive HIV/AIDS care program within a year. The problem, though, is how to expand the numbers treated, and corresponding geographic coverage, 10-fold or more. It is one thing to build a well-functioning program under the dedicated and knowledgeable leadership. Doubtless many such projects are in place and serving many people; we heard about some of them at CMDE and visited one, the Holy Family Center at Nazareth Hospital outside Nairobi. However, it is another thing to multiply this outreach by 10 or 20 times. That is not to say it is not possible or desirable, but it will take some new thinking. A central approach will be using existing "centers of excellence" (and strengthening some sites to become centers of excellence) as a foundation on which to build a broader network of service. The Browns at Holy Family Center have already been doing this, for example, by mentoring health workers from other clinics, and by publishing a practically-oriented newsletter.

Ideally, donors are well aware of the capacity of the groups they partner with. However, we noted that in the present climate of an urgent push to distribute ARVs, FBOs could get into the position of "biting off more than they can chew," or perhaps more accurately, being force-fed more than they can chew. For the sake of our reputation and effectiveness, it will be very important to consider not only what we want to accomplish in the next year or two but what we are likely able to accomplish. If we can identify specific areas of capacity building that are needed, we may be able to find donors to help (adding, of course, another layer of administrative complexity).

## Lack of prepared workers

Who will be in charge of identifying the right 3 million patients, educating them, and prescribing and distributing their ARVs? Who will maintain the warehouses, audit the books, monitor the stocks in local distribution centers, and so on? The global health community recognizes these issues and is addressing them. The WHO "3 by 5" initiative is developing training curricula for various cadres of workers. Strategies such as using traditional healers and paramedical personnel have been proposed and tried with some success. Again, a pressing issue is whether such successful demonstrations can be scaled up to mass projects. FBOs interested in becoming involved in ARV use would do well to examine their current human resources and consider how to strengthen them in the near future.

Sustainability

This is a huge issue. No one knows how long these new programs will be supported. The HIV epidemic is going to be with us for decades. Where will we be in five or ten years if the external supplies of ARVs dry up? It would be nice to believe that the developed world will provide them indefinitely, but we've all seen donor fatigue in the past, and we know that other issues will arise to distract attention from HIV/AIDS. Are we going to be moving people toward being able to pay? Is the African economy strong enough to pay even for generic ARVs on such a scale? What will happen when the initial NNRTI-based regimens begin failing-will the international community up the ante with protease inhibitors or newer drugs? What will be the impact on FBOs if we significantly add to our staff and infrastructure, then lose the funding needed to sustain it? Is there a risk of loss of public confidence if we build such programs, run them for a few years, and then cannot continue? Again these are not necessarily reasons to avoid involvement in ARV programs, but rather points to consider so that future options are maintained.

## Drug Resistance and patient compliance

The issue of concern is not simply that the ARV programs might be slow, inefficient, or even a failure. Rather the larger concern is that they could have negative impacts on public health as well as on the integrity of the FBO partners.

The specter of the emergence of drug resistance was probably the greatest concern voiced at CMDE. Experts differ in their assessments of the likely impact of resistance, but a few points are becoming clear.

- Very high levels of compliance, i.e. in the range of 95-100%, are needed in order to minimize the emergence of drug resistance in NRTI-NNRTI regimens. For patients taking two pills daily, 95% represents missing a maximum of three doses per month. Several speakers noted that this is higher compliance than we expect in almost any other medical regimen in the developed countries.

- People who take most of their doses but do not reach the very high 95-100% level are actually *more* at risk for resistance than those who are fairly non-compliant. Dr. Uy mentioned at least

one study showing that those taking 80% of their doses had the highest risk. (A. Sethi., 2004).

- The emergence of resistance does not necessarily spell the immediate end of effectiveness of ARV, but it does have a negative impact. Dr. Jonathan Uy discussed the recent research from Thailand showing that the single-dose nevirapine regimen in general use for prevention of mother-to-child-transmission (PMTCT) is associated with the risk of failure of viral suppression when the women later receive NNRTI-based treatment (Jourdain et al., 2004). Even women in whom no resistance mutation was detected were less likely to respond. In other words, our PMTCT programs may be harming the future prospects of the mothers. (WHO, 2004.)

- Resistance is *unforgiving* (Dr. Uy's term). Virus resistant to one NNRTI is usually resistant to all (class resistance). Dr. Uy also presented some of the mounting evidence for the transmission of drug resistant HIV. Around 10% of newly diagnosed HIV in Europe and the US is already resistant to at least one drug. The most common mutation in the single-dose nevirapine treated women (K103N) is transmitted and has good reproductive fitness, so that it persists in the individual and population.

- *Interruption* of treatment as opposed to irregular compliance is less likely to lead to resistance. Interruption leads to viral rebound but without the selective pressure caused by the drugs. Because the drugs protect each other from resistance by keeping replication at very low levels, the drugs should always be stopped and started together. (However, there is some concern that drugs with long half-life, such as NVP, are in effect "unprotected" during the time when they persist in the body days after the shorter half-life drugs have disappeared. The clinical relevance of this is uncertain.)

The obvious conclusion of all this is that no one really knows whether the mass use of ARVs (and NNRTI in particular) in Africa will lead to rapid and widespread resistance, and if so what the public health impact would be.

Some would like to minimize these issues by pointing to studies that show compliance in Africa that is as high as that obtained in developed countries. I think that this misses the point. Ultimately the question is not whether compliance is as good in Africa as in, say, New York, but whether a given ARV policy is in the best long-term interest of Africans. Africa is not New York:

- HIV in Africa is not limited to certain sub-populations but is everywhere.

- Africa does not have the resources to provide tailored, "boutique" treatment to HIV patients.

- The consequences of resistance are much worse for Africans than for patients in the developed countries. Few Africans experiencing failure on the initial ARV regimen will get a second chance.

As much as I would like to believe that with some enthusiasm and faith we will be able to establish extensive, effective ARV programs in Africa, it stretches my credulity beyond the breaking point to think that *across the continent and in the next 5 years* we will be able to achieve such a goal. We must make every effort wherever we are to enhance ARV programs with education, behavioral interventions, primary health care, community involvement, and broad-based HIV/AIDS care. At the same time we should be planning for what we will do when ARVs begin losing their effectiveness.

Dr. Uy said that some experts would rather see more efforts toward the use of PI-based regimens in Africa because the resistance issues are much less severe. Even though the initial costs are larger, the long-term costs could be less and the results better. Currently there are logistical problems with PIs as well as cost, but the limitations (e.g. refrigeration requirement and pill burden) are gradually being removed.

## Other Concerns

Unfortunately, resistance is not the only or even necessarily the most potentially damaging result of mass ARV programs. The other major area of concern expressed by CMDE participants was that the new thrust could lead to a weakening of other facets of prevention and care.

- Brain and resource drain. How will the billions of dollars affect other programs, either in HIV or in other areas of health and development? We have already seen workers leaving primary care positions to take up much better paying positions with NGOs and agencies involved in ARV initiatives. Donors are not unaware of this problem and will try to limit it, but, realistically, they also have their own agenda. Horizontal programs might be preferable but probably are not in the near future for most of us. Even if your

organization has the capacity for a large-scale ARV program, can it establish one without depleting resources from other, equally important areas?

- Will widespread availability of ARV lead to an increase or a decrease in HIV transmission? No one knows. There have been some epidemiological studies in the US but I don't know of any in Africa (where after all we are only beginning ARV). Will the availability of ARV undermine the ABC (Abstinence, Be faithful and Condom use) messages we're working so hard to convey? Will people understand the difference between ARV and a cure for HIV?

These concerns are not in any way arguments against using ARV to improve health and prolong lives, and in any case that decision has already been taken by the international community. Rather we need to keep these questions in mind so that we can, as far as possible, exploit the benefits of ARV without losing ground in other areas. From a more positive perspective, we could see the ARV initiative representing a unique window of international interest in the health of Africa. Perhaps much can be accomplished in terms of capacity building, training, public awareness of health, community action, and international cooperation, developments that could outlast the effects of the ARV initiatives themselves.

## Issues to Consider

***Indirect costs***

Before embarking on projects to supply ARV in large quantities, we should consider the indirect costs that might arise. Depending on the situation, an institution's financial position could improve or worsen. If your institution or program were to experience a dramatic increase in the number of HIV patients being seen, what would the financial impact be? Will donors pay for all the associated expenses (lab, administration, health care worker salaries, waiting rooms)? Will these costs be borne by the patients, and are they able to pay? Are there other donors (perhaps home churches) who are able and willing to step in to help with these costs?

***Outright fiscal corruption***

This hardly needs mentioning as we are all familiar with the dangers of pouring money and other resources into any organization. Even with the best supervision and accountability mechanisms, the risk is real. If we are going to participate in scaling up ARVs, we need to be sure that assistance is given and received in ways that minimize the risk of corruption.

***"Land Rover syndrome"***

You have seen this, have you not? Working for an NGO becomes an avenue of wealth and power. If you do not believe that the gospel is about acquiring wealth and power, then this is an area of concern. Just a week before the CMDE meetings, I took part in a policy and planning workshop. At the end of four days of work, the participants (all employees of our denomination, meeting during regular working hours), were each given an allowance amounting to more than half the annual per capita income of Nigeria. I was told that NGOs and donors expect to pay such fees in order to get people to come and participate. I am less concerned about the issue of waste than about the negative impact of such methods if they become widespread in our churches. What expectations will be created? What will be the impact on honest volunteerism and servanthood?

What steps can we take, from the initial planning through the execution of our projects, to minimize this factor? Choosing the right leadership, modeling servanthood and accountability, oversight boards, external evaluations … what other ideas do you have?

***Overextension***

We need to "count the cost" of program expansion at the same time as we ask God to "enlarge our territory." We should be looking for new opportunities to minister and serve, while at the same time being wise about the commitments we make lest we promise more than we should, perhaps out of self-confidence rather than God's calling. What have we already handled well? What are our strengths and weaknesses? If we are using ARVs now, are our programs scaleable, or do we need to explore new avenues?

***Distraction***

A large infusion of money and resources into the single area of ARV distribution could distract our organizations from their more fundamental purposes, or cause us to lose sight of them altogether. We will have to work to maintain healthy perspectives and to remember that ARV projects are means to an end, not an end in themselves. At each step of the process we should review our own mission statements to be sure that we are not being overly influenced by outside pressures.

***Competition between organizations***

Ideally the new programs will include incentives to increase communication and cooperation among FBOs. No one wants to see duplication of effort, or groups working at cross purposes to each other. We do need to be aware, though, of the temptations we will face to act on the basis of self interest (for our own FBO) rather than in the interest of the whole body.

Perhaps some of these problems could be reduced by having an inter-agency body responsible for ARV programs (or HIV/AIDS care including ARV) and nothing else; people could all be directed there for equal access. Individual FBOs would not be exposed to the risks above but would supply personnel, encourage volunteers, etc. In this way FBOs would be working together, learning from each other, and involving their people, and would be less likely to become fractured and distorted in their purpose.

## Networking and planning

It appears that there is already much networking and communication among those working with HIV/AIDS. There is probably considerably less among the mainstream FBOs such as church denominations and church- or mission-operated health care institutions. Now we need to use existing networks, and create new ones as needed, to address the specific issues of large-scale ARV programs in relation to our own communities and institutions.

Churches and other FBOs need to think about the issues even if they do not plan to be actively involved in ARV programs. If nothing else, we need to educate our members so that they will receive the maximum benefit. For example, we can help them understand the difference between treatment and cure, and the importance of adherence. We should also address the moral and ethical issues.

Getting into large-scale, externally-funded ARV distribution will likely be a major commitment for an organization, starting from an initial vision, to concrete planning, to applying for donor support, to implementation, assessment, and sustainability issues. Clearly it is not something to be taken on lightly, but only after prayer, seeking God's leading, and consideration of the organizations overall mission. In the process, we should keep in mind the need to reach beyond our own geographic areas into the places that are harder to reach.

For those wanting to begin, one issue will be how and where to start. In contrast with NGOs, which are often "professional" grant recipients and project implementers, major FBOs such as church denominational bodies and mission hospitals may not be attuned to international health programs, requests for applications, and the mechanics of proposal writing, even though they may have good-faith and solid programs in place already. Donors may bypass groups like these, at least initially, in favor of those who are eager and ready to take on the job (and money). If this protects the FBOs from premature and ill-considered plans, then so much the better. At some point, though, such organizations will need to become more pro-active in seeking support. Perhaps one of the uses of networking can be to help each other in that way. Can we identify and share sources of technical support for planning, grant application writing, and project implementation?

## Conclusion

Large-scale ARV programs are coming whether or not we are ready. They will be here for at least next 2-5 years, and will have a significant impact on many areas of health care. Not every FBO will need or desire to be involved directly, but as a group we need to assess the impact, and do what we can maximize the benefits and minimize the possible problems. If we do not get organized then we will be marginalized. The time is past for any churches to be in denial.

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