Elements of HIV Care in Resource-Poor Settings: Policy Challenges

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More than 40 million people are now living with HIV infection around the world, and another 20 million have already died from the disease. First recognized in developed countries in the early 1980s, HIV is now an unprecedented global pandemic. The burden of disease is felt most severely in sub-Saharan Africa and other economically disadvantaged countries, where more than 7,000 people die each day from HIV and AIDS.

The sheer scale of statistics such as these does, in fact, tell much of the story. The case fatality rate (the percentage of people who die if left untreated) for HIV approaches 95%. Most past and recent pandemics like influenza, or SARS, have had much lower case fatality rates: 5% for annual influenza, 15% for SARS. (Only bubonic plague, with a 90% case fatality rate, compares to HIV.) However, unlike these other infectious diseases, disability and death from HIV occur during the chronic phase of the illness — some 8 to 10 years after the infection is contracted. Moreover, unlike influenza and SARS, HIV typically affects otherwise healthy, economically productive adults. These facts, combined with the relative success in controlling the spread of HIV in the US since the mid-1990s, means that the devastation of HIV

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and AIDS around the world is, if anything, underreported in the US. A few simple, dramatic statistics enhance the picture:

- In the most severely affected countries in sub-Saharan Africa, Botswana, Lesotho, and Swaziland, one in three adults is now infected with HIV and will likely die from AIDS.
- Since 1990, life expectancy in Zimbabwe has dropped from 57 years to 34 years; in Lesotho, from 54 years to 36 years; in Zambia, from 47 years to 33 years. Thus, half a century of public health improvements in infant mortality, sanitation and disease control have been all but wiped out in a decade.
- In much of sub-Saharan Africa, basic economic indicators such as household income and farm productivity have declined by 15-20% in the past ten years.
- In Zambia, the Ministry of Education has seen its allocations increase by 71% for teacher absenteeism, 22% for new teacher training, and 7% for funerals, all due to the unexpected, unbudgeted problem of HIV-infected teachers.
- In Africa alone, some 12 million children have been orphaned due to AIDS.

Thus, for the first time outside of wartime, governments and multilateral organizations are facing a national and international threat that cuts across all sectors of society, and requires coordinated policy planning and a rapid, multisectoral response. What has been done to date? How effective has it been? And what are the immediate and near-term challenges facing international public health officials?

**A Distant Mirror: The Calamitous 1980s**

Before addressing health policy concerns as they apply to the epidemic in sub-Saharan Africa, it is worth reviewing briefly the policies developed to address the epidemic in the United States in the 1980s. In many ways, the spread of the epidemic through Africa and the developing world is reminiscent of its spread through the United States twenty years ago – only the scale is magnified. We can hope that the policy choices made by US policy makers in the 1980s and 90s – the significant early failures, the subsequent successes, and the ongoing challenges – are sufficiently well understood so that we can avoid repeating the same mistakes, and can apply the lessons learned.

**Stigma and Discrimination**

In the first decade of the HIV epidemic in the US, there was little in the way of a coordinated policy response to HIV. Nearly ten years into the epidemic, the federal government’s response was described by the Institute of Medicine as “woefully inadequate” in supporting AIDS education, HIV prevention, and basic research. To an extent, this reflects the fact that HIV was a new disease, little understood and untreatable. To a greater extent, this reflects the fact that HIV predominantly affected “high-risk” groups with little political advocacy – gay men, intravenous drug
users, hemophiliacs, and commercial sex workers. As Paul Farmer and others have noted, the epidemic in the United States (and elsewhere) diffused into populations traditionally on the margins of society: the homeless, the urban poor, the rural poor, and minorities, as well as gay men and intravenous drug users.\textsuperscript{4,5} Women, in particular, were and remain invisible victims of the epidemic.\textsuperscript{6,7}

As the epidemic grew, several important, politically neutral policies were successfully developed – blood bank and blood product screening for HIV, for example, was rapidly implemented, all but eliminating a major route of transmission. In addition, after 1988, the NIH research budget for HIV began growing exponentially, a trend sustained due to a fortuitous convergence of political pressures on both parties in Congress and on the White House.\textsuperscript{8} But other proven prevention efforts – needle exchange, condom distribution, as well as less proven approaches like school-based AIDS education – were irregularly implemented during the initial response to the epidemic, if at all. Homophobia, racism and stigmatization of the disease profoundly influenced policy considerations, and led to the failure of public health officials to respond to the growing spread of the virus until it entered the heterosexual population at large. The chilling effect of stigma has reverberated through much of the developing world in the years since, with even more tragic consequences.

**Supporting Care and Treatment**

By the early 1990s, through public pressure from organized advocacy groups and a growing awareness of the impact of the epidemic – assisted by high profile cases in celebrities like Rock Hudson and Magic Johnson – policy decisions supporting HIV prevention, care and treatment were developed. The most notable of these was the Ryan White CARE Act.\textsuperscript{9} The Ryan White legislation provided federal funding for the delivery of essential health services – beyond just HIV-related services – to HIV-infected individuals. Prior to the availability of effective antiretroviral drugs (ARVs), Ryan White funding supported clinic infrastructure, antibiotics for opportunistic infections and palliative care. With the arrival of effective three-drug ARV therapy in 1995, Ryan White served as a mechanism to deliver high quality HIV care, including ARVs, to all HIV-infected Americans.

Despite the evident successes of Ryan White and other programs, the 40,000 new HIV infections and 16,000 HIV-related deaths in the US each year since effective treatment became available underscore the ongoing shortcomings of American domestic HIV policy. As the Institute of Medicine has recently noted, short term success has been undermined by failures to address the central role of ARV adherence, leading to widespread drug resistance and increased HIV treatment costs; changing demographics, including the spread of the virus into even more difficult to reach communities; and the impact of co-morbid medical and social circumstances, including hepatitis, tuberculosis, homelessness and compromised nutrition.\textsuperscript{10} All of these are important lessons to be applied in attempts to address the global pandemic.

In sum, prior to the widespread availability of effective antiviral therapy, AIDS
policy in the United States can be described, albeit superficially, as both reactive in nature and unsuccessful at stemming the tide of the epidemic. It enabled the marginalization of the disease into mostly poor communities. In 1995, effective antiretroviral treatment became available in the form of three-drug therapy. Under the auspices of far-sighted funding mechanisms like Ryan White and some state Medicaid provisions, effective therapy was rapidly made available to HIV-infected people across the US, despite its enormous cost, some $10,000 per person per year for the antiretroviral drugs alone.

Once effective ARV therapy became available, the means to implement ARV-based care, including strategies to treat HIV infection, to prevent and treat the opportunistic infections, and to prevent mother-to-child transmission were established quickly within the existing primary and tertiary care systems in the United States. Comprehensive HIV services that include prevention and treatment of HIV and opportunistic infections have become the standard-of-care in the US and other developed countries, and have had an enormous impact in lessening the toll of HIV disease (Figure 1).

### Treatment Efforts in Sub-Saharan Africa and Resource-Limited Countries

The social, economic and political consequences of the ongoing global pandemic have prompted an international effort to bring similar treatment and prevention programs and other HIV-related services to all HIV-infected and at-risk persons throughout the world. This response has been led by non-governmental organizations (NGOs), private foundations, over-
seas development agencies from high-income countries, multinational public health and political agencies, the private sector and, more recently, the US government. As in the US in the 1980s, policy coordination has been lacking. The three largest or most visible efforts that have emerged and helped set the policy agenda are the World Health Organization’s 3 by 5 Initiative, the United States government’s President’s Emergency Plan for AIDS Relief (PEPFAR), and the Global Fund to fight AIDS, Tuberculosis and Malaria (the Global Fund).

The 3 by 5 Initiative is essentially a target: to treat three million of the estimated six million HIV-infected people in urgent need of ARV therapy by the end of 2005. While an unfunded mandate, “3 by 5” has successfully accomplished two objectives. First, it has established treatment with ARVs as a top global health priority, putting to rest a once contentious debate over the feasibility of ARV treatment in resource-scarce settings. Second, it has galvanized the global HIV treatment community, made up of an assortment of public and private sector groups with disparate agendas and disconnected resources. “3 by 5” has effectively prodded fledgling national treatment programs around the world, while its connection to global HIV policy making is less clear. Global HIV policy development falls squarely within WHO’s mandate as part of “3 by 5.” To a great extent, however, policy implementation is left to national governments and their partners. This discordance between policymaking and policy implementation may continue to hinder the 3 by 5 Initiative’s efforts to meet its ambitious targets.

In his January 2003 State of the Union address, President George W. Bush announced his intention to provide $15 billion for HIV prevention, care and treatment programs worldwide. The resulting program, PEPFAR, represents the largest current source of funding for global HIV efforts. Although funding through PEPFAR has provided some basic support for multilateral HIV programs, including the Global Fund, the bulk of PEPFAR represents a unilateral US effort. Thus, new global HIV policies and procedures have been established within PEPFAR’s administrative home, the Office of The U.S. Global AIDS Coordinator (SGAC). Many PEPFAR efforts countermand existing policies within sub-Saharan African countries, as well as presumptions made by global HIV treatment programs, such as the use of generic drug formulations, or the role of expensive laboratory monitoring. In addition, PEPFAR’s emphasis on abstinence, its hard line with respect to capping US contributions to the Global Fund, and its unwillingness to confront the realities of commercial sex work and men-who-have-sex-with-men in developing countries has put it at odds with much of the global HIV treatment community. Nonetheless, the major financial and programmatic commitment to HIV care that underlies PEPFAR makes it a central constituent in global HIV treatment efforts.

The Global Fund was established in late 2001 as a grant-making institution, supported by donations from UN member nations and philanthropic organizations. To a significantly greater extent than PEPFAR, GFATM-funded programs rely heavily on policies established by national governments, working through their Ministries of Health and their technical assis-
Procuring drugs, supplies and equipment? Which of these program components are scalable directly with the simple addition of resources, and which require new approaches, new capital, technical investments and new systems? How can these efforts be evaluated and the results disseminated? How can appropriate policies be developed and implemented to meet the needs?

**Policy Issues and Challenges**

To begin to answer these questions, it will be useful to identify the distinct elements of global HIV care and treatment programs. Because HIV prevention and treatment are linked, there is significant overlap between the two. Here, however, the focus will be on care and treatment for persons already infected with HIV.

**Entry into Care**

The path to effective HIV care begins with testing. The majority of HIV diagnoses are made in one of four settings: voluntary counseling and testing (VCT) centers; antenatal clinics; tuberculosis clinics; and inpatient hospital wards. Issues around testing that need to be addressed include opt-in vs. opt-out testing; confidentiality; space requirements (especially in TB clinics, where transmission of TB to HIV-infected patients is a significant concern); testing protocols; counselor staffing and training (especially in non-VCT sites); and test kit procurement. Many effective testing policies have been carefully considered and developed, including the WHO-sanct...
tioned use of less expensive rapid test kits in most settings.

Implementation has proven much more difficult. Development of mechanisms to link patients who test positive to an appropriate site for enrollment in an HIV care program is even more difficult. First, test results are not always available in real time, while patient tracking after they leave the test center is all but impossible. (Again, similar challenges exist in the US.) Second, many sites at which HIV testing occurs do not have a specific mechanism to link newly diagnosed patients to HIV care and treatment programs. For instance, prior to “MTCT-Plus” programs, antenatal clinics have traditionally focused on the baby, leaving the mother with little recourse after she delivers. Similarly, many VCT sites were established as stand-alone programs. Thus, while patient registration, HIV test result tracking and recording, disease staging at the time of diagnosis (largely by CD4 count measurement), and needs assessments are all crucial parameters to ensure a smooth entry into care at the time of a new diagnosis, these linkage systems have frequently been neglected.

Sites of Care

Once patients are diagnosed or enrolled in care, the sites of care delivery need to be defined. Ultimately, HIV care will need to be integrated into community-based primary care, given the numbers of infected people. But should HIV care initially be delivered as part of tertiary care hospitals, primary health centers, or sexually transmitted disease clinics? Should mothers who are diagnosed receive care through their antenatal center? More importantly, how can a site establish the necessary resources – staff, policies, clinical space – to provide high-quality care? What should the accreditation process be, if any? To date, answers to these questions have varied widely, and successful efforts have been established using a range of approaches. For example, in Botswana, the government program began at a large tertiary hospital in Gabarone. In Haiti, treatment began at primary care clinics, and new ones were built amidst high-prevalence areas. In general, and perhaps unsurprisingly, local needs, local geographic and structural constraints, and local resources have driven the most successful approaches.

Investments in Health Infrastructure: Clinics, Laboratories, Information Systems, Drug Procurement Systems

Whatever site is chosen, there is an urgent need to increase the capacity of existing health systems beyond the clinics in order to address the HIV pandemic. There is no health system in sub-Saharan Africa with sufficient capacity to handle chronic disease management for 5-30% of its population. The wealthiest countries – Botswana and South Africa – are already struggling with capacity-driven problems as they attempt to provide care for the first 25,000 HIV-infected patients.

The term “capacity-building” is used loosely in HIV treatment scale-up efforts. At a minimum, it requires expanding the physical infrastructure of a national health systems, including bricks and mortar for testing centers, clinics and hospitals; medi-
cal equipment for clinical facilities and HIV and CD4 testing laboratories; medical records systems that allow tracking of patients enrolled in chronic care; motorcycles, cars, and trucks to transport patients, health workers and specimens; and administrative resources – computers, offices, and operating procedures – to manage a complex health delivery system involving international commodity procurement and delivery, three tiers of service delivery, and multiple financing sources. Moreover, all of this must be coordinated in a way that neither overwhelms the management of dozens of other health services – childhood vaccines, diabetes control, malaria and tuberculosis control, for example – nor establishes a higher standard of care for HIV than for other conditions.

The challenge of laboratory infrastructure is noteworthy. As ARV prices have fallen, the cost of laboratory tests have threatened to become the largest single component in HIV care. Moreover, the kinds of tests needed to monitor for HIV patients in the US, particularly CD4 counts and HIV RNA measurements, are technically complex and expensive. Most sub-Saharan African countries simply lack the facilities, trained technicians and resources to perform them. The choice between forgoing essential tests and investing heavily in laboratory infrastructure has proven to be a major challenge for national treatment programs.

Human Resources for Health

As capacity-building efforts have expanded under WHO’s 3-by-5 Initiative and GFATM, PEPFAR, World Bank, the Clinton HIV/AIDS Initiative and other multilateral funding, there is a general consensus that the most challenging bottleneck limiting scale-up is the lack of trained healthcare workers available for HIV care. There are simply not enough trained nurses, doctors, laboratory technicians, counselors and administrators in most developing countries to handle an increased patient caseload.

The problem is compounded by the dramatic impact of HIV on the skilled labor force: in some sub-Saharan African countries, the public sector health force has seen a 600% rise in attrition in ten years, and half of these losses are due to death from HIV. Most fledgling efforts are addressing the problem by focusing on training. External technical assistance partners – typically multinational public health organizations like WHO and the Centers for Disease Control, American and European academic medical centers, and AIDS service delivery NGOs – are being relied on to provide the expertise, teachers and curricula for training doctors, nurses, counselors and laboratory technicians in HIV care. While variably effective in the short-term in addressing treatment delivery for 500,000 HIV-infected people, increasing the supply of trained healthcare workers will quickly exhaust the available pool. New delivery models that recalibrate the human resource requirements of ARV-based HIV care will likely be needed in order to bring care to the subsequent millions.

ARV Use and Adherence

The establishment of adherence support programs deserves special mention. In the United States, levels of ARV drug resistance approach 50% in urban clinics, and
the critical factor in the success of HIV treatment and the prevention of drug resistance is adherence to ARV regimens.12,13 Evidence from ARV programs in Haiti, South Africa and elsewhere has confirmed the importance of adherence, and established that excellent adherence rates are feasible in resource-constrained settings. To achieve rates above 90% requires a commitment to adherence support programs, typically in the form of adherence counselors and close patient follow-up. As with other aspects of HIV care, the ability to scale up adherence support programs remains a critical challenge.

**Branded vs. Generic ARVs**

Perhaps no other policy debate has received the attention of the use of generic ARVs in lieu of branded drugs in sub-Saharan Africa.14 Three-drug regimens in the US average approximately $7,500 per patient per year, a cost prohibitively expensive in Africa and elsewhere. Tiered pricing strategies by branded pharmaceutical companies have reduced the cost of regimens to between $350 and $1,000 per patient per year, depending on the regimen and the program. While an improvement, these preferential prices are still too expensive for widespread ARV use in most settings. Generic manufacturers based in India, China, South Africa and elsewhere offer prices as low as $250 per patient per year. Negotiated discounts based on high-volume purchasing are available through the Clinton HIV/AIDS Initiative for as low as $150 per patient per year. In addition, fixed formulations that combine three first-line drugs in a single pill are available through generic firms. For treatment efforts critically sensitive to pricing, like the cost and distribution of ARVs, the savings and convenience offered by generic drugs appear essential.

Generic drug use has been hampered – largely by PEPFAR policies, and by the efforts of branded drug manufacturers – on two accounts. First, quality control mechanisms to ensure bioequivalence – that generics work as well as branded drugs – are often limited or lacking. Studies have shown bioequivalence for some drugs, and the WHO has developed a process for approving specific generic formulations.15,16 Second, efforts to import generic ARVs into countries without a domestic pharmaceutical industry have run afoul of patents and international intellectual property rights agreements that govern generic drugs. Resolution of this disagreement, or another mechanism through which ARV regimens could be made available for $150 per patient per year or less, are essential to the effort to scale-up treatment to millions of people.

**User Fees**

The introduction of user fees for basic services in the 1980s was extremely controversial, and the application of user fees to HIV care has sparked an ongoing debate. Largely at the behest of the World Bank and International Monetary Fund structural adjustment efforts, user fees introduced into health services were justified on two accounts: as a means of cost recovery, and as a tool to increase buy-in and acceptance of health programs. Within existing HIV care delivery programs the track record on user fees is limited. For most programs, at least for the foreseeable future, total pro-
gram costs dwarf the percentage of costs recoverable by charging even nominal user fees to HIV-infected people living in poverty.

The evidence supporting user fees as a tool to increase appropriate patient participation is also lacking. In Hlabisa, South Africa, the removal of user fees after the fall of apartheid led to major increases in the use of curative health services, although a decline in preventative services was also noted. Similarly, the introduction of user fees in Burkina Faso in 1997 led to a dramatic drop in health service utilization. These findings reflect the US experience with the Ryan White CARE Act, where the availability of free care for HIV-infected patients significantly enhanced the quality of care and patient outcomes. Nonetheless, several developing countries in Africa and elsewhere continue to rely on user fees for health services, including HIV care.

Care Models

One of the major policy decisions facing national governments in low-income countries is the type of health delivery model through which to implement HIV care. Broadly speaking, there are two distinct questions: first, should HIV care and treatment be implemented through a stand-alone, vertical program, or should it be integrated horizontally, across the health sector? And second, at what healthcare level should various HIV services be organized and delivered: centrally, at the provincial/district level, or in community-based settings?

Perhaps the most important lesson to come out of the pioneering work of Zanmi Lasante/Partners in Health (ZL/PIH) in rural Haiti, where ARVs have been used since 1998, is not that ARV care is possible in developing countries, but that ARV care may be most successful where it is incorporated into primary health care delivery. Using the critical measurement of patient adherence to their ARV regimen, primary care-based approaches have reported adherence rates of greater than 90%, far better than have been reported in the US. By contrast, vertical programs, notably the national ACHAP program in Botswana, have struggled with the enormous logistical challenge of matching resource to need outside the context of primary care, with significantly lower rates of ARV adherence.

Nonetheless, the efforts to scale-up care along a primary healthcare model have also struggled. MSF and similar clinics worldwide appear to reach capacity at ~1,500 ARV-treated patients per site. ZL/PIH and other similar primary care settings have not grown beyond that scale either. Thus, it is a different, but equally daunting challenge to scale primary care services to 5-30% of an entire population using a community-based primary care model. Can community health workers deliver ARVs at a national level? If not, then given the overwhelming burden of disease and limited supply of trained health professionals, how can the needs be met? In the legacy of structural adjustment and its harsh impact on basic primary care health systems in most African nations, dollars alone will be insufficient to address the operational and logistical challenges of scaling up community-based care.
Donor and Program Coordination

Given the severity of the global AIDS crisis, there has been an understandable, headlong rush to develop prevention, care, and treatment programs since the Durban international AIDS conference in 2000. Often, these efforts have resulted in overlap, redundancy and lack of coordination among foundations, NGOs, local and national governments, international agencies and academic institutions. Organizations extending themselves beyond their traditional areas of expertise have often been forced to develop ad hoc solutions to unanticipated problems, particularly with respect to clinical training, program assessment and operational research. Given the extreme need, and the importance of a multisectoral approach to the crisis, a certain amount of overlap and innovation has been appropriate. Nonetheless, each type of organization responding to the epidemic has its own set of resources and competencies. But, while funding sources have expanded quickly, this has not yet been matched by mechanisms to ensure coordination and avoid redundancy and conflict. In some countries, it is not uncommon for three or four groups to receive funds from multiple donors for the same project.

Figure 2. Unmet implementation needs influencing policy decisions in HIV-infected South Africans.
– physician training, or ARV-based care provision – with a net result that progress is stalled for months while the details are sorted out among groups.

**South Africa – A Brief Case Study**

The Republic of South Africa is home to the largest population of HIV-infected people in the world: more than five million of South Africa’s 48 million people are HIV-infected. (India and China may have already overtaken South Africa, but figures there are unreliable). In November 2003, the South African government – long criticized for its dismissive stance and unresponsiveness to the growing AIDS crisis – approved a comprehensive operational plan to address the HIV epidemic. Because of its position at the epicenter of the epidemic and its leadership position within sub-Saharan Africa, South Africa’s approach to HIV is likely to establish benchmarks in HIV policy development.

Within South Africa’s operational plan, each of the policy challenges described above is confronted directly – some more thoughtfully and successfully than others, as the slow pace of the current rollout confirms. Entry into care is established through formal linkages between pre-existing VCT programs and known hospitals and antenatal clinics. The South African government has chosen to base ARV care at district hospitals, taking advantage of a robust healthcare infrastructure. District hospitals are linked to primary care based sites in nearby communities, however, so that the intent is to base non-ARV care more peripherally. According to the plan, significant investments will be made in laboratories, medical record systems and commodity procurement systems. Most critically, the challenge of developing human resources for health has been, at least, acknowledged, although details are lacking beyond basic principles such as promoting a national health service corps, and leveraging private sector expertise.

The pace of the rollout suggests, unsurprisingly, that implementation is difficult. Projections of 53,000 people on ARVs within the first year will not be met. The South African operational plan for HIV comes amidst a decade of health system reform in South Africa that has been focused on redistribution of care to redress the racial health disparities left by apartheid. Thus, the implementation of successful HIV care must also be reconciled with existing healthcare priorities.

One way to evaluate the challenges facing a country like South Africa is to break the problem down into the populations accessing care at each stage, from HIV testing, to entry into care, to ARV use (Figure 2). Visualized this way, the challenges are daunting. At each step, financial, technical, political and social barriers exist against implementing adequate care. For appropriate and effective policy development, each of these factors must be taken into account at each stage in the process.

**Conclusions**

In its recent 2004 review of Ryan White financing for US HIV programs, the Institute of Medicine recommended a minor overhaul to the system:
The goal of the [new] program is to provide timely access and consistent benefits to individuals with HIV, with a strong focus on comprehensive and continuous primary care and access to antiretroviral therapy. The program supports this goal by entitling program eligibility to HIV infection rather than AIDS, and by specifying a set of benefits that meet the standard of care for HIV. The Committee further recommends that demonstrations be undertaken to create Centers for Excellence in HIV Care as a method to improve the HIV care delivery system. Finally, the Committee recommends that the federal government seek opportunities to reduce the price of prescription purchased on behalf of the new program.25

It is perhaps unsurprising that, given the benefit of hindsight and twenty years of HIV policies to analyze, the Institute of Medicine has laid out a prescription for domestic HIV care that applies equally well internationally. A focus on primary care, the critical role of adherence, the ability to connect community-based care to centralized HIV expertise, and the need to reduce costs and make drugs and care affordable are all apparent in the early efforts to address the epidemic in Haiti, South Africa, and around the world. Whether these efforts will succeed depends largely on a rapid but reasoned approach to the many questions that exist over the best ways to implement HIV care. 

References