



TECHNICAL ISSUE BRIEF

DELIVERING A LIFELINE: COMPREHENSIVE ANTIRETROVIRAL THERAPY PROGRAMS

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Introduction

As part of its broad effort to fight the global pandemic of HIV/AIDS, the U.S. Agency for International Development (USAID) makes large and important contributions to providing antiretroviral (ARV) drugs in developing countries, where HIV infection results in far too many deaths.

Individuals living with HIV do not succumb to the virus itself. Rather, the HIV virus weakens the body's immune system to a point where it is unable to defend itself against illnesses that healthy immune systems are usually able to stave off. Ultimately, it is these other illnesses that cause death. As such, antiretroviral drugs have been a lifesaving advance in the treatment of HIV/AIDS because they limit the virus' power to weaken the immune system.

Evidence shows that programs providing ARVs in resource-limited settings can be remarkably successful, with treatment adherence and clinical outcomes comparable to those in developed countries. In its work in the developing world, USAID recognizes that, in addition to the necessity of ARVs being available and accessible, it is equally important to help host countries provide critical support to ensure drug therapy occurs – and on terms that will make it effective. For this reason, USAID not only focuses narrowly on the provision of ARVs themselves but also works broadly to establish a full system for the achievement of antiretroviral therapy (ART), a term that denotes a comprehensive program of treatment, care, and support.

Antiretroviral drugs are just one aspect of a comprehensive HIV/AIDS treatment, care, and support program that includes meeting the medical, psychological, socioeconomic, and legal needs of those affected by the disease. In USAID's ART programs, the treatment component consists of the use of at least three ARV medications. The objective of the drug component is to suppress HIV replication and slow the progression of HIV disease.

Antiretroviral Therapy: Benefiting Individuals and Communities

When antiretroviral drugs are delivered through a broad ART effort, they provide important benefits for both individuals and communities. For example, they can dramatically decrease the number and severity of illnesses associated with HIV infection. They can prolong the life and reduce the suffering of HIV-positive people.



ART outreach at the Mahatma Gandhi Clinic.

PH/ZAMBIA

Enabling patients to live longer maintains the integrity of families, societies, and economies, particularly in severely affected countries. When HIV-positive people receive ART, they are able to maintain not only their health but also their productivity. They are able to find and keep jobs and to continue to earn an income, provide for their children, and pass on their knowledge to future generations. Pregnant and breastfeeding mothers who are receiving treatment can reduce the risk of passing the virus to their babies. Treatment allows for a more effective, productive workforce, as AIDS patients can continue to work.^{1,2}

Properly implemented ART programs also allow for more effective prevention by reducing the stigma associated with HIV and reducing HIV transmission. Reducing transmission and the number of new cases makes providing treatment more affordable. Because ARV treatment is effective, it has been shown to reduce stigma associated with HIV testing. People are less afraid to be tested and find out their HIV status, since they know they have options if they are positive. Treatment can reduce the stigma associated with HIV, since it enables people to return to a better health status, and others in the community realize that HIV-positive people can continue to live and lead fulfilling lives.

The resources USAID provides for treatment can help improve infrastructure for prevention and other health services. The training USAID provides to health providers and the improvements it brings to laboratory services, pharmacy, logistics, commodity management, and health information systems can benefit both treat-

ment and prevention services. Furthermore, in many countries, a large number of health care workers are themselves infected. Treatment enables these health professionals to continue to provide critically needed AIDS prevention and treatment services, as well as other health care services to the community.

Providing Quality Medicines for People Living With and Affected by HIV/AIDS

As a partner in the U.S. President's Emergency Plan for AIDS Relief (Emergency Plan/PEPFAR), USAID plays a key role in U.S. Government efforts to introduce antiretroviral therapy in countries throughout the developing world. The service delivery systems introduced through PEPFAR will be sustained with increasing support from host-country government budgets and staffed with well-trained personnel who can continue the training process. USAID also supports targeted research, development, and dissemination of new technologies, as well as packaging and distribution mechanisms for antiretroviral drugs.

In fiscal year 2005, for instance, PEPFAR established the Supply Chain Management System (SCMS) project, which is helping host nations increase their capacity for delivering essential lifesaving HIV/AIDS medicines and supplies to people in need of treatment and care. Operating in some of the countries most severely impacted by HIV/AIDS, SCMS works in collaboration with host-country governments and local and global partners; procures essential medicines and supplies at affordable prices; helps strengthen and build reliable, secure, and sustainable supply chain systems; and fosters coordination of key stakeholders.

Administered by USAID, the SCMS technical approach centers on:

- Working with and strengthening existing systems, not creating parallel or duplicate systems

- Building local capacity, empowering in-country partners to enhance and develop sustainable and appropriate responses for their own communities
- Delivering quality HIV/AIDS medicines and supplies at the best value by leveraging industry best practices for planning, procurement, storage, and distribution
- Promoting transparency to ensure that accurate and timely supply chain information is collected, shared, and used to improve decisionmaking
- Collaborating with in-country and international partners to identify needs, fill gaps, avoid duplication, and share best practices

SCMS offers partners a rapid, regular, and reliable supply by storing forecasted quantities of the most frequently requested essential medicines, HIV test kits, and other products close to the point of use at regional distribution centers (RDCs) in Ghana, Kenya, and South Africa. The RDCs follow commercial best practices to ensure security and quality of the products as well as timely delivery. By working closely with partners to plan future procurement, pooling orders to buy in bulk, establishing long-term contracts with manufacturers, and purchasing generic alternatives whenever possible, SCMS helps to reduce the price of essential medicines to treat HIV/AIDS.

Components of Quality Antiretroviral Therapy Programs

To assist in reaching the new PEPFAR goal of providing 3 million people with ART, USAID focuses on activities that directly or indirectly support the provision of antiretroviral therapy. Antiretroviral drugs themselves may be less than half of the total cost of treatment, and ARVs are just one aspect of USAID's comprehensive ART programs, which have many other components. These com-

Delivering Antiretrovirals Swiftly, Safely, and Effectively: SCMS Project Marks Third Year



PHOTO COURTESY OF PHD.

Essential HIV/AIDS medicines and supplies flow through this SCMS warehouse.

October 2008 marked the third year of the PEPFAR Supply Chain Management System (SCMS) project, administered by USAID. SCMS has had continued success in establishing secure, reliable, and sustainable systems for procuring quality pharmaceuticals and other products for care and treatment of persons living with and affected by HIV/AIDS. In fact, since the beginning of the project, SCMS has delivered just over \$200 million in HIV/AIDS commodities. In fiscal year 2008, SCMS purchased pharmaceuticals in 25 countries, managing more than \$140 million worth of procurement worldwide. This effort made it possible for roughly 850,000 patients to receive antiretroviral (ARV) medications. Consistently, more than 90 percent of ARVs purchased through SCMS are generics, amounting to savings of approximately \$200 million from the cost of equivalent branded drugs – savings that can be used to fund treatment for even more patients.

SIX CRITICAL COMPONENTS OF USAID'S HIV/AIDS ANTIRETROVIRAL THERAPY PROGRAMS

There are many complex issues related to delivering ARVs in resource-constrained settings. USAID has been a leader in developing responses to these issues, providing support directly to patients and health workers, as well as building the capacity of national health systems.

Infrastructure for ART Services: Improving infrastructure, including laboratory capacity, health facilities, and procurement and distribution of ARVs and other treatment-related commodities, is critical to quality provision of services. Many countries do not have the resources for building facilities or creating space within existing structures for providing ART programs. They also lack laboratory equipment and supplies to provide quality assurance or conduct training. USAID supports health system facility infrastructure, including building or repairing facilities and electrical systems, installing communications and information systems for record keeping, and supporting facility supervision and management. USAID also improves and updates laboratories, providing quality improvement and information systems.

Support for National Policies and Monitoring and Evaluation Systems: USAID supports the development and improvement of national-level ART delivery policies and guidelines. This includes working with manufacturers and the U.S. Department of Health and Human Services' Food and Drug Administration to facilitate a fast-track approval process to review and approve appropriate high-quality ARVs. USAID also supports the development of laws and policies that ensure a quality program for procurement, delivery, and administration of ARVs. In order to guide the planning and management of national programs, USAID provides comprehensive monitoring and evaluation of ART activities and supports the development and implementation of information systems for both facility-level ART programs and community-based programs. The data provided from these systems allow USAID's partners to examine key indicators, such as retention rates from ART clinics, and allow for continuous program improvement.

Innovative Models for Quality ART: USAID-supported ART programs use "network" models of ART service delivery. These models reflect country-specific strategies to deliver ART services and seek to allocate personnel who are highly specialized in HIV to work in central hospitals and general health workers trained in ART to administer treatment at clinics and primary care facilities. Programs are also designed around the local context and circumstances, including the political, social, cultural, economic, and epidemiological context (such as the prevalence of HIV). The level of personnel and physical infrastructure available to deliver ART varies among countries and affects service delivery – some countries have more facilities and health professionals to provide ART, while others have far fewer of these resources. USAID works with local health systems to determine appropriate and acceptable models for ART services and supports operations research to ascertain and demonstrate that models are safe, effective, and sustainable.

Strengthened Logistics Systems to Ensure ARV Availability: Providing support for treatment programs requires a serious commitment to supply chain management. Weak supply chain infrastructure, difficult environmental conditions, and a lack of human capacity to ensure that essential products reach ART points of service are considerable hurdles. Medications must be stored and transported in climate-controlled containers to ensure they arrive in usable condition. USAID programs strengthen the procurement, supply, storage, and distribution systems for drugs.

Support for Patient Adherence: A large component of USAID support for ART is ensuring that patients adhere to therapy. Adherence to ARVs is crucial to a patient's treatment success because nonadherence – even taking less than 95 percent of the medication – puts patients at risk of viral resistance to their current regimens. A resistant virus lowers the efficacy of the therapy. Interruptions in adherence contribute not only to treatment failure in individuals but also to widespread therapy resistance. Once individuals are determined through clinical evaluation to be eligible for ART, they enter treatment readiness programs. These programs educate patients on the importance of adherence, how to deal with side effects of ARVs, and how to maintain good nutrition to ensure medications work properly. Adherence to ARVs is often challenging because the side effects, including headaches, nausea, and skin rashes, can be severe. Once they begin therapy, patients enter adherence support programs in which health workers, close friends, or family members also educated on ART conduct follow-up visits to see if the patient is taking his or her medication correctly, maintaining a balanced diet, and avoiding opportunistic infections. These adherence support workers are a critical part of maintaining the effectiveness of ART programs.

Capacity Building for Sustainability: USAID recognizes that expanding the provision of ART while maintaining high-quality services requires ensuring a supply of skilled health professionals. However, trained health workers are in short supply throughout the developing world, particularly in countries with a high prevalence of HIV/AIDS. The high demand for services coupled with limited human resources creates an incredible strain on health professionals. USAID helps countries overcome the challenges in expanding ART provision by improving the training, mentoring, and morale of health care providers at all levels of the health system. Quality training of health care workers in all aspects of ART is a critical factor contributing to patient adherence. The partnership developed between patients and health facilities and facility outreach workers can help improve patient retention.

ponents include: increasing access to ARVs and other medications, improving the physical infrastructure of laboratories and facilities, ensuring a consistent supply of quality drugs and commodities, building personnel capacity to manage ART programs and nutritional and psychosocial counseling of patients before and throughout treatment. The opposite page explains in-depth the critical components of USAID's ART programs. This brief describes these essential elements of effective ART programs, with special attention to the challenges of human resources, infrastructure capacity building, and support for patients during treatment, and looks more closely at USAID-supported programs in Zambia, Nigeria, and South Africa that are meeting these challenges.

Zambia Frontline Perspective: A Detailed Look at How USAID Supports an Innovative ART Adherence Program

HIV/AIDS is a major threat to Zambians, with an estimated 1.2 million people infected nationwide. In Zambia, the government has implemented a policy of providing free ART in order to reduce the impact of HIV and help sustain the livelihoods of thousands of households. Increased access to ART is helping reduce death rates from HIV/AIDS, but the lack of qualified staff to ensure that treatment regimens are carefully followed is a serious obstacle. Attrition of health workers is also high in Zambia. While the World Health Organization and Zambian Ministry of Health (MOH) recommend staff-to-population ratios of 1:5,000 and 1:700 for doctors and nurses, respectively, in Zambia these ratios are 1:17,589 and 1:8,064. With more than 250,000 people eligible for treatment, there is a great need for increasing human resources and improving infrastructure.

The USAID-supported Zambia Prevention, Care and Treatment Partnership (ZPCT) program strengthens delivery of ART services by improving the capacity of individuals to provide services; providing crucial renovations to laboratories, facilities, and equipment; providing travel reimbursement to workers; and delivering medical equipment and supplies. These activities boost the morale of overstretched workers and provide laboratories and pharmacies the renovations needed to provide quality services. USAID's ZPCT program also supports ART outreach services to rural health centers and strengthens referral networks for lab samples. Between October 2004 and September 2008, ART services increased from 10 sites serving 1,670 clients to 96 sites serving 62,128 clients.

With a shortage of health workers, the ZPCT also has developed an innovative strategy of training community volunteers to provide adherence support and strengthen adherence counseling at the health facility and community levels. New research carried out by Family Health International and the MOH has shown the ZPCT's strategy to be an effective, low-cost way to achieve high-quality

results that may help bridge the human resources gap. This strategy enables the health system to continue to provide quality ART to a larger number of patients while easing the workload for facility-based health workers.

The research measured the effectiveness of shifting adherence counseling tasks from health care workers to community volunteers, called adherence support workers, or ASWs, at five selected ART sites. The ASWs, who worked alongside doctors and nurses and were supervised by a professional health care worker, conducted community visits to track down patients who had missed their clinic appointments and provided patients with educational and psychosocial support, referrals, and other encouragement to improve adherence. The research findings suggested that using adherence support workers helped reduce waiting times and reduced loss-to-follow-up (that is, patients who no longer come for services, no longer take the prescribed treatment, and cannot be contacted by the program) from 15 percent to 0 percent. The authors suggested that the ASWs, who are mostly HIV positive themselves, were in a better position than health care workers to provide empathetic and emotional support, as well as needed community follow-up.

Seeing Results: Other Examples of USAID ART Programs

Nigeria: USAID is implementing the largest comprehensive HIV/AIDS prevention, care, and treatment project ever implemented in a single developing country. The Global HIV/AIDS Initiative Nigeria (GHAIN) program, funded by the Emergency Plan, is rapidly strengthening and expanding a wide range of HIV/AIDS services, including ART. GHAIN works closely with facilities to determine their capacity and infrastructure needs and improve ART service delivery. As of August 2008, the program has supported 98 comprehensive ART sites, with more than 54,000 people receiving ART, and has trained more than 2,500 individuals in ART management, including pediatric ART.

South Africa: In South Africa, which has the largest number of HIV-positive people in the world, the epidemic has placed an enormous strain on the health system and on communities. In 2004, USAID brokered a partnership to provide technical assistance to local nongovernmental organizations that carry out capacity-building activities with public facilities and other treatment sites to train health care providers in administering ARVs and full treatment services. This partnership has created a sustainable means for providing services, and now the majority of implementing partners are South African organizations. Treatment has expanded from 15 sites serving more than 30,000 HIV-positive patients in 2004 to 1,500 sites serving more than 305,000 patients by March 2008.

1 Ojha V. and Pradhan B. The Macro-Economic and Sectoral Impact of HIV and AIDS in India, 2006. A CGE Analysis. United Nations Development Program (2006).
2 Belle, C., Devarajan, S., Gersbach, H. (2002). Long Run Economic Costs of AIDS: Theory and an Application to South Africa. World Bank; UNAIDS (2002).