

TECHNICAL ISSUE BRIEF COMPREHENSIVE ANTIRETROVIRAL THERAPY PROGRAMS: SAVING LIVES AND PREVENTING NEW INFECTIONS

Antiretroviral Therapy: **Benefiting Individuals and Communities**

As part of its broad effort to fight the global pandemic of HIV and AIDS, the U.S. Agency for International Development (US-AID) is committed to the support of antiretroviral therapy (ART) programs, which provide lifesaving antiretroviral drugs (ARVs) to patients living with HIV.

Antiretroviral drugs arrest the replication of the HIV virus inside a person infected with HIV, affording the body's immune system time to recover and rebuild itself. While not curative, these medicines are dramatically powerful, with studies suggesting that HIV-positive patients in resource-limited settings can achieve near-normal life expectancies when taking ART (Mills, 2011). In addition, by lowering the amount of HIV virus in the body, ARVs help reduce the chance that an HIV-positive individual transmits the infection to an HIV-negative partner (Cohen, 2011).

USAID has been a key implementing agency for HIV treatment under the U.S. President's Emergency Plan for AIDS Relief (PEP-FAR) since its inception in 2003. At the end of September 2012, over 5.1 million people were supported on ART under PEPFAR (PEPFAR, 2012), accounting for a significant proportion of the 8 million people receiving treatment in low and middle income countries (UNAIDS, 2011). While USAID has played a critical role in ensuring that ARVs can reach the patients who need them, 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 also works broadly to establish a comprehensive approach to ART provision – including support for lifelong adherence, treatment of comorbid illnesses and integration of HIV treatment services with other services designed to meet the medical, psychosocial and socioeconomic needs of patients living with HIV.



ART outreach at the Mahatma Gandhi Clinic

The striking power of ART programs to improve the health of persons living with HIV provides important benefits for both the individual and the broader community. In addition to reducing onward HIV transmission, enabling patients to live longer maintains the integrity of families, societies and economies, particularly in severely affected countries. HIV-positive people on ART are able to maintain their health and their productivity - they are able to find and keep jobs and to continue to earn an income, provide for their children and pass on knowledge to future generations. Pregnant mothers receiving treatment substantially reduce the risk of passing the virus to their babies and are able to remain healthy enough to care for their children, reducing rates of orphanhood (Anema, 2011). By demonstrating that HIV-positive individuals can continue to lead healthy, productive and fulfilling lives, ART programs help reduce the stigma associated with HIV disease. This, in turn, encourages greater uptake of testing and encourages other individuals to seek care sooner.

Antiretroviral drugs are just one aspect – albeit an important one – of a comprehensive HIV and AIDS treatment, care and support program that includes meeting the medical, psychological and socioeconomic needs of those affected by the virus or the disease. USAID-supported ART programs focus on three key priorities:

- I. Improving ACCESS to ART for Individuals Living with HIV
- 2. Improving the **QUALITY** of ART Services
- 3. Fostering **SUSTAINABILITY** of Lifelong HIV Treatment Services

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DELIVERING ANTIRETROVIRALS SWIFTLY, SAFELY, AND EFFECTIVELY: SCMS PROJECT MARKS SEVENTH YEAR



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

October 2012 marked the seventh 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 and AIDS. In fact, since the beginning of the project, SCMS has delivered just over \$1.4 billion in HIV and AIDS commodities. In FY 2012, SCMS purchased pharmaceuticals in 25 countries, managing more than \$430 million worth of procurement worldwide. This effort made it possible to procure enough antiretroviral medications for more than 2.5 million patients. To date, more than 98 percent of ARVs purchased through SCMS are generics, amounting to savings of approximately \$700 million from the cost of equivalent branded drugs - savings that can be used to fund treatment for even more patients.

Additionally, when implemented in a thoughtful, comprehensive manner, ART programs have the ability to strengthen local health systems. Many health care delivery systems in resource-limited settings are designed for acute, time-limited care (e.g., helping expectant mothers through pregnancy, treating infectious diseases). Because HIV is a lifelong, manageable chronic illness, USAID treatment programs are investing in capacity building for comprehensive chronic health services designed to support individuals across time. The training USAID provides to health providers and the improvements it brings to laboratory services, pharmacies, logistics, commodity management and health information systems benefits patients and helps institutionalize the practices necessary not only for quality lifelong HIV care but also for treatment of noncommunicable chronic diseases.

Providing Quality Medicines for People Living with and Affected by HIV and AIDS

USAID plays a critical role in U.S. Government efforts to procure, distribute and manage ARV stocks throughout PEPFAR supported countries. In 2005, USAID established the Supply Chain Management System (SCMS) project, which provides a reliable, efficient and secure supply of ARVs and diagnostic supplies for ART programs in PEPFAR-supported countries. Created to ensure reliable availability of essential HIV commodities and to strengthen national supply chains in resource-limited settings, SCMS has been an important catalyst in the significant decrease in ARV prices, which has fueled the expansion of ART programs. Through the use of pooled procurement and generic licensing of ARVs, prices have fallen from approximately \$1,500 per patient per year in 2003 to about \$133 per patient per year in 2013 (SCMS, 2013).

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 and AIDS medicines and diagnostic supplies at the best value for PEPFAR 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 decision-making
- 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 and AIDS.

Components of USAID's HIV and AIDS Antiretroviral Therapy Programs

There are many complex issues related to delivering quality ART clinical services in resource-constrained settings. USAID has been a leader in adapting to local challenges and context, providing support directly to patients and health workers when necessary, as well as simultaneously building the capacity of national health systems.

Infrastructure for ART Services: USAID has supported substantial health facility infrastructure improvements, including building or repairing facilities and electrical systems, installing communications and information systems for record keeping and supporting facility supervision and management. USAID has also improved and updated laboratories and commodity warehouses and applied innovative use of technology to better manage data within health facilities. Going forward, USAID will assist with essential infrastructure for ART services with a particular eye to improving both the quality and efficiency of health care in the countries in which we work.

Support for Patient Linkage, Adherence and Retention:

A large component of USAID support for ART programs is ensuring that patients are linked to services and adhere to therapy once enrolled. When a person tests positive for HIV, it is essential for that person to begin ART as soon as eligible according to the country's guidelines for eligibility for ART. Earlier treatment, as close to eligibility as possible, provides a chance for better health outcomes, including morbidity and longevity. It is also widely recognized that once viral suppression is achieved through correct use of ARVs, the risk of transmission of the virus to a sexual partner is greatly reduced. USAID is promoting models of service delivery that increase the likelihood of successful referral from testing to care, earlier treatment and adherence to ART. Adherence to ART is important for the long-term health of HIV-positive patients, as poor adherence can lead to treatment resistance, increased rates of HIV transmission and poorer health outcomes. USAIDsupported ART programs provide support through adherence counseling, patient tracing for missed appointments, nutritional support and use of mobile technology to provide adherence and appointment reminders.

Support for Robust Monitoring and Evaluation Systems: In order to guide the planning and management of ART programs, USAID provides support for monitoring and evaluation (M&E) activities at all levels of the health system — national, subnational and at individual health facilities. USAID staff and implementing partners continue to work with national counterparts to develop, revise and implement information systems for both facility-level ART programs and community-based ART programs. The data provided from these systems allow national governments and USAID partners to examine key indicators, such as retention rates from ART clinics, and allow for continuous program improvement.

Innovative Models for Service Delivery: While most ART programs are facility-based clinical service platforms, USAID-supported ART programs employ models of ART service delivery in line with the needs of the local population and host government. Innovative approaches have included patient support groups, the use of "expert patients" and community health workers and mobile outreach clinics. Task-sharing strategies that allow for nurse-initiated ART have helped avert human resource bottlenecks that could limit access to lifesaving medicines. The use of text message (SMS) reminders helps support patient adherence and retention in care.

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. USAID programs provide extensive support to strengthen the procurement, supply, storage and distribution systems for drugs, while simultaneously improving the logistics information management systems to adequately forecast and manage supplies at the clinic level.

Support for National Policies and **Guidelines:** USAID supports the development and improvement of national-level ART delivery policies, guidelines and standards. At the global level, this includes working with manufacturers and the U.S. Food and Drug Administration to facilitate a fast-track approval process to review and approve appropriate high-quality ARVs. At national levels, this includes support for regulatory frameworks and development and revision of clinical guidelines. At the facility and community levels, this includes support for training and education to improve the quality of ART services.

Continuous Quality and Performance Improvement: USAID supports the institution-alization of quality improvement practices that ultimately underpin better health outcomes and the reduction of morbidity, mortality and transmission of HIV at the community level. Funding is provided to assist host country governments to (I) ensure compliance of nationally accepted guidelines and standards in the continuum of care from testing through adherence, (2) maximize resources and avoid waste, (3) ensure that appropriate skills and resources are available, (4) improve patient-centered services, (5) promote access of services in an equitable way, and (6) maximize the use of evidence-based quality improvement practices.

Capacity Building for Sustainability: Understanding that the long-term goal for USAID support for HIV treatment programs is to ensure that the high-quality, effective comprehensive programs can be sustainably transitioned to host-country governments (and in some cases, private sector stakeholders), USAID has ensured that capacity building efforts are integrated into the workplans of all implementing partners. This includes support for human resource development (including training, retention and production of health care workers), supply chain management and logistics and capacity building at the national and subnational levels (e.g., districts) to ensure proper oversight and support for treatment programs within host-country governments.

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Since its inception, saving lives and improving broader health outcomes have been goals at the very core of PEPFAR. The release of the Obama Administration's PEPFAR Blueprint: Creating an AIDS-free Generation last November strongly reaffirmed the United States'

commitment to such goals. Over the past decade, USAID has developed collaborative networks that provide technical support, strengthen host country management and build robust leadership and capacity in communities affected by HIV and AIDS around the world. Through collaboration with partner country governments and implementing partners, USAID is on track to assist the PEPFAR goal of supporting ART for 6 million people by the end of FY 2013. Our support for HIV treatment services remains a central part of our efforts to turn the tide on the HIV epidemic – improving patient health while reducing transmission and building stronger health systems.

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