

How AIDS Funding Strengthens Health Systems: Progress in Pharmaceutical Management

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Abstract: In recent years, new global initiatives responding to the AIDS crisis have dramatically affected—and often significantly improved—how developing countries procure, distribute, and manage pharmaceuticals. A number of developments related to treatment scale-up, initially focused on AIDS-related products, have created frameworks for widening access to medicines for other diseases that disproportionately impact countries with limited resources and for strengthening health systems overall. Examples of such systems strengthening have come in the areas of drug development and pricing; policy and regulation; pharmaceutical procurement, distribution, and use; and management systems, such as for health information and human resources. For example, a hospital in South Africa developed new tools to decentralize provision of antiretroviral therapy to local clinics—bringing treatment closer to patients and shifting responsibility from scarce pharmacists to lower level pharmacy staff. Successful, the system was expanded to patients with other chronic conditions, such as mental illness. Progress toward universal access to HIV prevention, treatment, care, and support will continue the push to strengthen pharmaceutical sectors that serve not only HIV-related needs but *all* health needs; health experts can likely take these achievements further to maximize their expansion into the wider health system.

Key Words: health systems, HIV/AIDS, HIV/AIDS global initiatives, pharmaceuticals

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The last half dozen years have seen the commitment of vast resources to respond to the HIV epidemic in developing countries with fragile health systems, especially by the Global Fund to Fight AIDS, Tuberculosis and Malaria and the United States President's Emergency Plan for AIDS Relief (PEPFAR). Clinical management of HIV infection requires health systems that support chronic disease management, and thus presents an opportunity to use these investments to support wider health

sector needs. A United Nations Millennium Project task force concluded that global programs cannot successfully address individual diseases until more resources are devoted to strengthening entire health systems and that the effectiveness of a health system can be measured by the consistent availability of medicines.¹

These new funding sources have had a significant effect on drug and commodity procurement, distribution, and pharmacy management systems in countries heavily affected by HIV. The Global Fund alone has approved grants for more than US \$15.5 billion—almost 60% allocated to HIV response and nearly 50% for medicines and commodities.² Other new drug procurement and distribution initiatives have drastically changed the global pharmaceutical landscape through their mandates to increase access to medicines; for example, substantial price reductions have been leveraged by committing predictable resources to achieve economies of scale (UNITAID); helping countries plan procurement and increase supply efficiencies (the US Agency for International Development-funded Supply Chain Management System); and negotiating prices with suppliers of antiretroviral (ARV) medicines and diagnostics (Clinton HIV/AIDS Initiative and others).

HIV-related drug procurement and supply chain management are seldom entirely vertical (ie, separate from overall national procurement and distribution systems). Efforts to increase access to HIV-related commodities and medicines, arguably, have had positive system-wide effects on drug development, quality assurance, and pricing at global and regional levels and on procurement, distribution, and dispensing at country level.

PHARMACEUTICAL DEVELOPMENT, QUALITY, AND PRICING

At the global level, efforts to increase access to HIV treatment have focused on ensuring that high-quality medicines are affordable and that drug research focuses on products (including heat-stable combination formulations) that meet needs in resource-limited settings. A number of developments, whose initial focus was on HIV-related products, have created frameworks that set precedence for widening access to high-quality medicines for other diseases that disproportionately impact resource-limited countries. Examples of those developments follow.

Pharmaceutical Quality

The World Health Organization (WHO) set up the Prequalification Programme in 2001 to facilitate access to quality-assured medicines for HIV, malaria, and tuberculosis.³

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The WHO assessment teams work with regulators from both developing and industrialized countries to ensure that the process is transparent and trusted by the end users. The Prequalification Programme is particularly important as an arbiter of quality assurance for generic products such as 3-drug combination ARVs that are not registered in countries with stringent drug regulatory agencies due to patent protection or marketing arrangements in those countries. In addition, the project's focus on quality improvement has strengthened regulatory authorities and increased manufacturer vigilance in producing countries such as India and South Africa.

Pharmaceutical Access

The WHO Prequalification Programme, the US Food and Drug Administration Fast Track Approval Process,⁴ and other mechanisms for quality assurance of AIDS medicines have dramatically lowered the cost of AIDS treatment by enabling generic procurement with the billions of dollars being spent by PEPFAR, the Global Fund, and other funders. During its first 3 years of operation, for example, more than 90% of ARV purchases by the Supply Chain Management System project were generic products, which saved the US government US \$364 million over the cost of equivalent branded products.⁵

Despite such advances, patent protection continues to influence both pharmaceutical development and pharmaceutical prices. As resource-limited countries have joined the World Trade Organization (WTO), they are bound by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). During the 1990s, there was concern about access to antiretroviral therapy (ART) in developing countries, and, in particular, how patent protection would affect the availability of generic equivalents. Access to treatment advocacy prompted the Declaration on TRIPS and Public Health at the WTO Ministerial Conference in Doha, Qatar, in November 2001, which clearly defines the flexibilities available to developing country members to ensure that TRIPS is “interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.” In practice, however, application of the TRIPS agreement continues to restrict generic competition and raises prices for priority public health products such as new first-line and second-line ARVs.

Drug and Vaccine Development

Expansion of efforts to ensure equitable access to ART, including coformulations designed to support adherence, has provided a public–private partnership model that fosters development and commercialization of drugs for other diseases that disproportionately affect poorer countries. Examples include the Drugs for Neglected Diseases Initiative, started by Médecins sans Frontières with the support of several ministries of health, research institutes, and pharmaceutical manufacturers, which initially focused on treatment for sleeping sickness, leishmaniasis, and Chagas disease and on inexpensive, fixed-dose combinations of antimalarials; the Medicines for Malaria venture, which is concerned with the discovery, development, and registration of new malaria medicines; and the Global Alliance for Tuberculosis Drug Development. Examples related to vaccine development

include the International AIDS Vaccine Initiative, the Malaria Vaccine Initiative, and the GAVT Alliance.

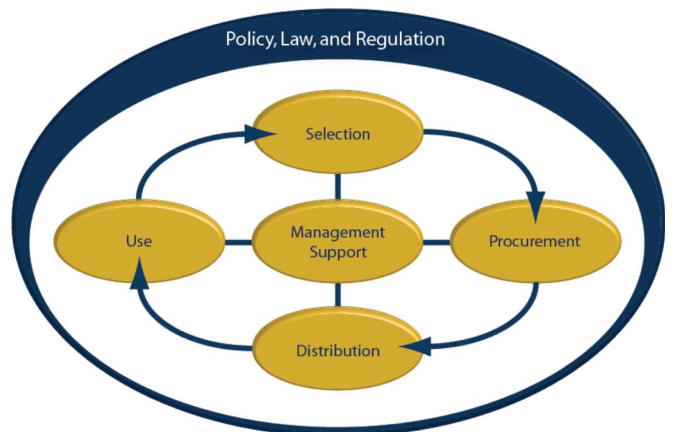
PHARMACEUTICAL PROCUREMENT, DISTRIBUTION, AND DISPENSING

Public sector supply systems, especially in Africa, have had to manage dramatically increased volumes of expensive medicines and commodities as HIV treatment has become more widely available. Decentralization of HIV treatment to the level of primary health center (PHC) means that pharmaceutical systems must now be able to deliver supplies to more service delivery points, across different sectors, and for more clients while the imperatives of HIV treatment accentuate the importance of preventing stockouts. With the expansion of HIV care, traditional “push” systems, where clinics receive a set quantity of drugs regardless of how much they dispense, are increasingly inappropriate.

The scale-up of HIV care programs is helping drive significant improvements in the scope and reliability of pharmaceutical and commodity procurement systems in developing countries. Support must address all components of the pharmaceutical management system: policy, law, and regulation; selection; procurement; distribution; use; and management systems.⁶

Policy, Law, and Regulation

Decentralizing HIV care to improve treatment access often requires legislative changes to enable health care staff other than pharmacists to dispense medicines (Fig. 1). In South Africa, the Department of Health permits patients who are stabilized on ART to be referred from hospitals to PHCs while maintaining a centralized dispensing unit at the hospital.⁷ Hospital pharmacy staff prepare prescriptions for delivery to the clinic closest to the patient, where pharmacy assistants or nurses dispense ARVs, review patients’ treatment progress, and return progress reports and uncollected medicine to the hospital. In one hospital and PHC network,



Pharmaceutical Management Framework
FIGURE 1. Policy and legislation support the pharmaceutical management framework.

this HIV-specific innovation has been expanded to provide long-term treatment for mental illnesses and other chronic conditions.

In some countries, the private sector is a key provider of HIV treatment. In Ethiopia, PEPFAR-funded technical support was used to advocate for the legislative change needed to allow the private sector to deliver ART services and then to help build the capacity of health care providers at private hospitals and community pharmacies to deliver ART.

Selection: Collecting and Using Pharmacovigilance Data

Few developing countries have well established systems for pharmacovigilance; however, national programs are increasingly strengthening their capacity to develop drug information and safety systems. Pharmacovigilance and drug information programs are important mechanisms to collect and disseminate information on the safety and effectiveness of medicines to inform decisions and improve treatment outcomes.⁸ In 2008, Namibia launched the Therapeutics Information and Pharmacovigilance Centre, which instituted an adverse drug reaction surveillance and reporting system for ARVs. In its first year of operation, the center's surveillance indicated that zidovudine-associated anemia was the most frequent ARV-related adverse effect (64% of reported reactions).⁹

Procurement: Promoting Regional Collaboration

Policymakers have been exploring ways to expand resources, such as regionalizing certain pharmaceutical management activities, sharing information, and adapting successful initiatives and tools for use in different settings. In 2004, the 14 member countries of the East, Central, and Southern Africa (ECSA) Health Community began investigating ways to work together to adapt their health system management strategies to address HIV scale-up challenges. They launched an advisory network known as the Regional Pharmaceutical Forum, which provides technical leadership and helps ECSA countries enable their policy environments and incorporate the best practices required to maximize access to HIV-related medicines and commodities. The ECSA Health Community has developed a strategy to pool procurement of HIV-related medicines and supplies to decrease members' pharmaceutical prices, starting with the creation of a business plan and a Web site to support coordinated informed buying. The Web site provides a database for members to monitor prices and share procurement and supplier information.

Distribution: Integrating Vertical Supply Systems

Before national HIV care programs, HIV-related supply systems proliferated to serve uncoordinated projects. These systems were set up in parallel to the primary pharmaceutical supply systems. As national AIDS programs manage and regulate the overall response to HIV, countries have increasingly integrated HIV-related commodities and

pharmaceuticals into the essential-medicines supply system. With this integration, improvements in HIV-related commodity distribution become embedded within and help strengthen existing pharmaceutical management systems.¹⁰

The Government of Rwanda created a mechanism for stakeholder collaboration to address multiple donor-specific ARV distribution systems that had been operating autonomously. The Coordinated Procurement and Distribution System optimized donor resources, simplified pharmaceutical management, and standardized ART and commodity selection across all external donor programs. CAMERWA, the national procurement agency, now uses "basket funding" with donors contributing funds, while various Coordinated Procurement and Distribution System committees comprising a wide range of stakeholders oversee product selection, procurement, and distribution.

USE: PROMOTING LIFELONG ADHERENCE TO TREATMENT

Because ART efficacy requires high levels of adherence over the long term, HIV-supported programs have helped build pharmacists' and pharmacy technicians' medicine counseling skills, which they can use with all patients. Effective and confidential medicine counseling is critical. Programs in countries such as Kenya and Ethiopia have stressed the importance of improving communication skills among ART dispensers and have designated or constructed private spaces, such as booths, for patient counseling. Pharmacy staff noted that better communication skills and other interventions to improve ART counseling end up benefiting all patients.¹¹ In addition, procurement and dispensing of 3-drug ARV fixed-dose combinations should contribute to adherence to treatment because pill count has consistently been found to be one of the strongest predictors of adherence.¹²

A lack of standardized definitions and tools for assessing and monitoring treatment has hampered programs providing adherence support. The International Network for the Rational Use of Drugs Initiative on Adherence to ARVs has developed standardized indicators and simple data collection methods to monitor adherence using information routinely available in HIV care clinics.¹³ Cell phone technology and community partnerships, which can be incorporated into wider health programs, have also been developed to support treatment adherence.

INTEGRATING PHARMACEUTICAL AND HEALTH INFORMATION SYSTEMS

A number of information systems have been developed to help pharmacy managers quantify ART use and the amount of needed inventory. Programs supported by PEPFAR and the Global Fund have implemented pharmaceutical management indicators to minimize stockouts. These have been incorporated into the monitoring and evaluation strategies of other public health programs, such as malaria initiatives, and the tools can be easily adapted for additional purposes.

BUILDING CAPACITY IN PHARMACEUTICAL MANAGEMENT

Task shifting to dispense ART has helped ease the pressure on HIV care programs. Severe shortages of pharmaceutical professionals have led to strengthening the capacity of local training institutions and use of other health cadres. Namibia has increased the capacity of its National Health Training Centre to enroll pharmacist assistants. In South Africa's Eastern Cape Province, PEPFAR funds have supported the development of a cadre of pharmacy assistants, who, as part of their training, are placed and mentored in PHCs, where they support multiple health programs.

CONCLUSIONS

Developing countries are seeing important improvements in their overall health systems resulting from the scale-up of HIV programs. Progress toward universal access to HIV prevention, treatment, care, and support continues to push health systems to provide HIV services and to strengthen pharmaceutical sectors that serve not only HIV-related needs but *all* health needs. As described, many HIV-related efforts and innovations in procurement and supply chain management have already illustrated their wide applicability to other health programs. However, public health experts, policymakers, and procurement and supply chain experts can likely further maximize the spillover of achievements in HIV programs to the wider health system.

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