Delivering Antiretroviral Therapy in Resource-Constrained Settings
LESSONS FROM GHANA, KENYA AND RWANDA
Robert Ritzenthaler
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ACKNOWLEDGMENTS

Family Health International (FHI) is proud to present Delivering Antiretroviral Therapy in Resource-Constrained Settings: Lessons from Ghana, Kenya and Rwanda. This document is intended for governments, development partners and public and private health facilities seeking to provide ART as part of comprehensive care and support for people living with HIV/AIDS.

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ACRONYMS

ART .................................................. Antiretroviral therapy
ARV .................................................. Antiretroviral
BCC .................................................. Behavior-change communication
CCC .................................................. Comprehensive Care Center
COC .................................................. Continuum of care
COPE ............................................... Coast People Living with HIV/AIDS
COPHIA ............................................. Community-Based Prevention, Care and Support Project
CPGH ............................................... Coast Provincial General Hospital
DAART .............................................. Directly administered antiretroviral therapy
DFID ............................................... Department for International Development (UK)
DOT .................................................. Directly observed therapy
ERB .................................................. Ethical review board
ERC .................................................. Ethics and review committee
FHI .................................................. Family Health International
HMIS ............................................... Health management information system
ICRH .................................................. International Centre for Reproductive Health
IEC .................................................. Information, education, communication
IMPACT ........................................... Implementing AIDS Prevention and Care Project
IRB .................................................. Institutional review board
MTCT ............................................... Mother-to-child transmission
<table>
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<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>NASCOP</td>
<td>National AIDS and STD Control Programme</td>
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<tr>
<td>OR</td>
<td>Operations research</td>
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<tr>
<td>PLHA</td>
<td>People living with HIV/AIDS</td>
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<tr>
<td>PMTCT</td>
<td>Prevention of mother-to-child transmission</td>
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<tr>
<td>RPM+</td>
<td>Rational Pharmaceutical Management Plus</td>
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<tr>
<td>SOP</td>
<td>Standard operating procedure</td>
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<tr>
<td>STI</td>
<td>Sexually transmitted infection</td>
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<tr>
<td>TRAC</td>
<td>Treatment and Research AIDS Center</td>
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<tr>
<td>TRIPS</td>
<td>Trade-related Intellectual Property Rights</td>
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<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>USAID</td>
<td>U.S. Agency for International Development</td>
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At Family Health International’s April 2000 Board meeting, the late Dr. David Barry and other Board members made an impassioned plea for FHI to take up the cause of expanding antiretroviral therapy (ART) to treat HIV/AIDS in developing countries. FHI had strong experience in HIV prevention and care, they argued, and was positioned perfectly to bring ART to the global South. Dr. Barry, co-inventor of AZT, believed success would do more than bring hope to communities facing the full force of the epidemic; it would demonstrate to the international community that life-prolonging ART could be delivered safely and effectively in resource-constrained settings. The Board was supportive and agreed to back the ambitious initiative. They believed the high price of antiretroviral medications — still a prohibitive factor in expanding treatment — would eventually drop to a level where ART services could be provided affordably and sustainably in the developing world. They also believed FHI’s involvement would help leverage resources from the donor community.

Three months later a watershed event catalyzed FHI’s ART initiative. The XIIIth International AIDS Conference in Durban, South Africa, focused the world’s attention on the devastating effects of the epidemic and on the urgent need for affordable treatment. The historic conference, the first of the biennial gatherings to be held in the global South, was a flashpoint for protests against the high cost of AIDS drugs, including the ARV combinations that have prolonged so many lives in the developed world. The impression the conference made on policymakers and world opinion, and the momentum it gave to subsequent advocacy efforts, had far-reaching implications for the international community and for FHI’s programs.

In response to continued advocacy and the emergence of cheaper generic versions of ARV drugs, pharmaceutical companies began to offer the medicines at dramatically reduced prices and sometimes as donations to developing country governments and programs. As the cost of the treatments dropped, FHI took the
opportunity to make its care and support effort as comprehensive as its prevention programs. FHI staff sought to create a seamless continuum of care in which all needed HIV services, including psychosocial support, would be available through a closely linked referral network. It called for integration of ART into a comprehensive package of services that includes HIV testing and counseling, prevention of mother-to-child transmission (PMTCT), diagnosis and treatment of sexually transmitted infections (STI), clinical management of opportunistic infections and other illnesses, nutrition, home-based care and palliative care.

In October 2001, the Board allocated US$1 million in corporate funds to develop ART “learning sites” in Ghana, believing that progress would spur donor involvement. The funds covered all aspects of program development — from assessments to clinical training to purchase of initial drug supplies. At the same time, the U.S. Agency for International Development (USAID) was exploring the possibility of operations research on how best to introduce ART in Africa. In July 2002, USAID announced it would support the learning sites in Ghana and integrate ART into Implementing AIDS Prevention and Care (IMPACT) programs in Kenya and Rwanda. The three countries became the core of the FHI-USAID treatment and care initiative. FHI used its own resources to procure initial drug supplies for the Kenya and Rwanda programs. This helped leverage funds not only from USAID, but also from the British Department for International Development (DFID) and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Once providers had been trained, referral networks had been established and patients had been identified and counseled, the learning sites were ready to begin delivering ART. On Feb. 27, 2003, four HIV-positive women — so ill from AIDS-related diseases they were unable to work — began treatment with ARV drugs at the Biryogo Medical and Social Center in Kigali, Rwanda. “I can come back to work now that I feel strong again, starting maybe two days a week and then increasing the number of days depending on my strength,” says Eliza, one of the first four patients. “I want to advise other people who have AIDS not to despair, but to be strong and to have hope.”
With funding from USAID and DFID, FHI and its partners have provided comprehensive HIV services, including treatment, to thousands of people. The learning sites in Ghana, Kenya and Rwanda have become a model for USAID-funded treatment programs in Cambodia, the Dominican Republic, Namibia, Tanzania and Vietnam. But difficult challenges remain, particularly in scaling up services to meet the tremendous demand. Planners and providers are learning valuable lessons to help meet these challenges. In the process, true to Dr. Barry's vision, they are demonstrating that life-prolonging ARV drugs can be delivered safely and effectively even in the poorest settings.
Introduction
INTRODUCTION

At the United Nations General Assembly Special Session on HIV/AIDS, held in June 2001, the global community cited ART as a key component of effective HIV/AIDS programs. In their Declaration of Commitment, heads of state from 189 countries affirmed that “prevention, care, support and treatment for those infected and affected by HIV/AIDS are mutually reinforcing elements of an effective response and must be integrated in a comprehensive approach to combat the epidemic.”

Tragically, only a small fraction of the estimated 40 million people living with HIV worldwide has access to the full range of services, including treatment. In Africa, home to approximately 26 million HIV-infected people, only 8 percent of the more than 4 million people clinically eligible for ART (ages 15–49) has access to it.1 Delivering ART in these settings presents significant challenges related to drug supply, health infrastructure, provider availability and capacity, equitable service provision, and drug adherence, toxicity and resistance.

To address these challenges, FHI, USAID and their partners developed ART learning sites in Ghana, Kenya and Rwanda. These countries were identified because of their strong government commitment to provide and sustain HIV treatment, their well-established national AIDS programs and the presence of ongoing IMPACT prevention and care interventions. The objectives were to:

• Improve the capacity of clinics, laboratories and pharmacies in selected health facilities to provide comprehensive HIV services, including treatment;
• Strengthen referral networks to link ART delivery with other care and support services across a continuum of care between health facilities and communities;

• Educate communities, including people living with HIV/AIDS (PLHA), about HIV disease, the need for prevention and treatment of opportunistic infections, when to seek care and the benefits and limitations of ART;

• Provide ART to an initial cadre of patients, ensuring drug adherence, proper management of side effects and toxicity, and regular monitoring and follow-up; strengthen commodity management, including the drug supply chain;

• Explore selected operations research questions, particularly related to adherence and cost;

• Gather and distill lessons to guide service expansion.

In 2002, FHI worked closely with national, provincial, district and municipal leaders, health providers, community-based organizations and PLHA to conduct assessments, develop and refine treatment guidelines and protocols, build capacity and infrastructure, establish linkages and prepare communities for the introduction of ART. Technical partners included the Institute for Tropical Medicine, Antwerp, and Makerere School of Medicine (clinical training); Management Sciences for Health/Rational Pharmaceutical Management Plus (commodities; laboratory and pharmacy strengthening); and the Population Council/Horizons (operations research).

In 2003, ART learning sites were launched at Atua Government Hospital, Korle-Bu Teaching Hospital and St. Martins de Porres Hospital in Ghana; at Coast Provincial General Hospital (CPGH) in Kenya; and at Biryogo Medical and Social Center (health center) and Kabgayi District Hospital in Rwanda. At each site, ART was introduced as an integral component of comprehensive care and support for HIV-infected patients and their families. In 2004, additional sites opened at hospitals and health centers throughout each country. The sites,
operating with USAID assistance in Kenya and Rwanda and with DFID assistance in Ghana, are part of closely linked referral networks within defined geographic areas, such as districts or municipalities. By the end of April 2005, more than 5,800 new patients had initiated ART through this treatment and care initiative.

In the two years since the initial learning sites were launched, FHI and its partners have learned valuable lessons that can guide development and expansion of ART services in Africa and other regions. This document presents many of these, along with strategies, challenges and key recommendations. Comments by national and community leaders, providers and patients appear throughout the text to give readers a sense of the programs as they progressed.

Throughout the text, “lessons learned” refers to experience that implementers consider valuable for countries initiating ART programs. We recognize that this term is often used loosely in the public health literature, sometimes referring to genuine, new insights, but often validating or reinforcing existing best practices. However, the programs described in this document were launched at a time when extensive ART provision was considered infeasible in resource-constrained settings. There were few models to follow — none for programs involving the public sector and attempting to link communities with facility-based efforts. Thus, “lessons learned” applies most closely to the material contained herein.

The document is intended for governments, development partners and public and private health facilities seeking to integrate ART into existing HIV services. The lessons may not have direct relevance to all health facilities providing or planning to provide ART; they should be used or adapted depending on the epidemiological, political, social, cultural and economic context of each setting.

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The document is divided into nine chapters, each addressing an essential element of an effective ART program:

Chapter 1. Country Preparedness
Chapter 2. Community Preparedness
Chapter 3. Site Preparedness
Chapter 4. Referral Systems and Linkages
Chapter 5. Patient Preparation and Adherence
Chapter 6. Health Management Information Systems
Chapter 7. Scale-up
Chapter 8. Patient Response to ART
Chapter 9. Operations Research

FHI staff hope this document will contribute in a meaningful way as national programs and global initiatives — such as the President’s Emergency Plan for AIDS Relief, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the World Health Organization 3 by 5 Initiative — make new resources available for HIV treatment.
1

Country Preparedness
CHAPTER 1: COUNTRY PREPAREDNESS

This Chapter covers:

- Commitment and participation;
- National ART guidelines and drug selection;
- Roles and mechanisms for participation and feedback.

In principle, government leaders in Ghana, Kenya and Rwanda were eager to integrate treatment into existing HIV services. They recognized that expanding access beyond the privileged few had great potential benefits for individuals, families and overall social and economic development. But they also recognized the myriad challenges and complexities associated with treatment: How would their health systems — already fragile and overburdened — cope with the introduction of ART? What drugs would be procured? How much would they cost and who would pay for them? Where would services be located? Who would be eligible to receive them? What other interventions would be needed to support patients on treatment? How would they be linked? How would adherence and drug resistance be monitored? Leaders needed to consider these questions and prepare accordingly before treatment could be introduced in a safe, effective and equitable manner.

FHI assisted this decision-making process. At the national level, this entailed fostering the commitment and participation of government AIDS commissions, ministries of health, umbrella groups for PLHA and other key actors. It was also necessary to develop or refine national ART policies and treatment guidelines, and select first- and second-line drug regimens most appropriate to the local context. Another major task was defining the roles of donors, government authorities at all levels, and technical partners. And it was critical to establish mechanisms — task forces, steering committees and the like — to elicit and manage broad participation. The
intent was to integrate treatment programs within national, provincial, district and municipal structures to increase the potential for sustained, long-term continuity of services rather than to establish vertical ART projects operated from the outside with defined start and end dates.

COMMITMENT AND PARTICIPATION

By 2001–2002, many leading officials in Ghana, Kenya and Rwanda were already committed to introducing ART as part of comprehensive HIV prevention, care and support. The challenge was to develop concrete plans, build consensus, and then secure commitment and participation to put plans into action. To assist in this effort, FHI staff met frequently with relevant authorities, facilitated communication across agencies, and helped organize national meetings on key topics related to ART. (Chapter 2 describes a parallel process at the community level.) These exchanges garnered buy-in and helped crystallize a unique vision for ART delivery in each country.

Ghana

In September 2001, FHI staff met individually with directors of the Ghana AIDS Commission, the Ghana Health Services, the Ministry of Health and the National AIDS Control Program to exchange ideas about HIV treatment and develop a vision for ART learning sites. (Leaders had expressed initial interest through Dr. Fred Sai, AIDS advisor to President John Agyekum Kufuor and a member of the FHI Board.) The directors shared concerns, suggested strategies and identified stakeholders that must be involved at various levels. The discussion with Dr. Kwaku Yeboah, then director of the National AIDS Control Program, was particularly fruitful. He identified specific issues to be considered before planning could proceed in earnest, such as the cost of ARV drugs and attendant services, clinical criteria for initiating ART in Ghana (CD4 count, viral load, clinical signs) and means of monitoring patient response and drug resistance. Dr. Yeboah also proposed the facilities that would become the first learning sites in the country: Atua Government Hospital and St. Martins de Porres Hospital in Manya Krobo District, Eastern Region.
Following the initial meetings, FHI presented concepts for ART learning sites to the National Tuberculosis Program, the Noguchi Memorial Medical Research Center, the Public Health Reference Laboratory and the Reproductive Health Unit/Ministry of Health. Officials at these institutions affirmed the need to expand comprehensive HIV services in Ghana and pledged to support the ART program. For example, the Public Health Reference Laboratory offered to provide tuberculosis microscopy; Noguchi offered to test for CD4 levels and viral load and to expand HIV testing and counseling services. Staff also met independently with UNICEF, USAID, the World Bank and other funders to see how ongoing programs could support and link with ART provision. Representatives asked questions, particularly about drug and laboratory costs, but were generally enthusiastic. UNICEF, which was preparing to pilot PMTCT interventions at Atua and St. Martins hospitals, agreed to link with the ART program as a collaborating partner.

Over the ensuing months FHI continued to meet with key actors to secure commitment and participation. In November 2001, staff organized a national workshop to formalize buy-in and elicit further questions, suggestions and discussion. During the workshop, leaders of government AIDS agencies and potential implementers agreed on program components, general areas of responsibility and policy questions for further study. By February 2002, ART planning was well underway: an ART program staff, hired by FHI, was in place and subcontracts with partners were in force. At a ceremony to launch program development in Manya and Yilo Krobo — attended by 3,000 community members — the Minister of Health, Dr. Kwaku Afriyie, publicly declared his support for the initiative.

**Kenya**

In February 2001, the Ministry of Health published the first edition of *Guidelines to Antiretroviral Drug Therapy in Kenya*, which underscored the government’s commitment to delivering ART as part of comprehensive care and support for PLHA. In the foreword, Dr. Richard Muga, director of Medical Services, states, “With advancing technology, new powerful antiretroviral drug regimens have become available and now form a part...
of the total continuum of care of HIV/AIDS patients . . . Availability of antiretroviral drugs to Kenyans who need them is the subject of debate, but no doubt the government will soon put in place a legal framework to increase access to these drugs.”

Dr. Kenneth Chebet, then director of the National AIDS and STD Control Programme (NASCOP), was a primary author of the guidelines. Soon after publication, he and colleagues within the Ministry of Health asked USAID to help integrate ART into existing HIV services. With input from FHI, Dr. Chebet and USAID identified Mombasa, Coast Province, as an ideal setting for ART learning sites. There, through IMPACT and other projects, USAID already was funding a range of interventions that could support and link with ART services: peer education, HIV testing and counseling, STI treatment, home-based care, and preventive therapy and treatment for opportunistic infections. Kenyan officials believed lessons learned in Mombasa could inform public health policy, spur greater donor investment in treatment and guide expansion of ART services throughout the country.

In September 2001, the Ministry of Health, USAID, FHI and the U.S. Centers for Disease Control and Prevention convened a technical and consultative meeting to discuss ART in Kenya and build consensus on the way forward. The meeting brought together an array of government officials (including the Minister of Health), public and private health providers, NGOs, PLHA, donors and other stakeholders. Following presentations on ART for the public and private sectors, participants discussed the complexities of HIV treatment, challenges unique to the Kenyan context and strategies to overcome perceived barriers. The meeting reinforced commitment to expand ART access in Kenya and secured broad participation in this effort. A key outcome was creation of a national ARV Task Force that would set standards, revise national guidelines, involve relevant training institutions, select drug regimens and recommend ART interventions to the Ministry of Health. At the inaugural Task Force meeting in February 2002, FHI — secretariat of the newly established body — presented a proposal for Mombasa ART sites (CPGH, Port Reitz District Hospital, Magongo Health Center and
Mkomani-Bomu Clinic). Members, including Dr. Chebet of NASCOP and Dr. Joshua Ngelu of the National AIDS Control Council, endorsed the proposal. They submitted it to Dr. Muga, Director of Medical Services, who formally approved the initiative.

**Rwanda**

In June 2002, the Ministry of Health issued the first edition of its *Guide to Use of Antiretroviral Medications for Adults and Children*. The guide, developed with input from the World Health Organization (WHO), expressed the government’s desire to increase the range and quality of HIV services, including treatment, delivered at public health facilities. In the foreword, then Minister of Health, Dr. Ezéchias Rwabuhibi, states, “This national guide represents an important step on the road to wider distribution of antiretrovirals in Rwanda . . . The guide responds to a request by the Ministry of Health to improve the capabilities of health providers and the quality of care in providing antiretroviral therapy.”

In 2001–2002, IMPACT was working with district hospitals and health centers in Rwanda to assure a basic package of HIV services for PLHA and their families. This package included HIV testing and counseling, PMTCT and services to prevent and treat opportunistic infections. In developing these services, IMPACT and partners were also laying the groundwork for introducing ART, which could be linked with facility- and community-based interventions along the continuum of care. Around this time, USAID officials in Washington — cognizant of falling ARV drug prices — were assessing strategies to integrate treatment into IMPACT and other programs. USAID and FHI concluded that Rwanda, like Ghana and Kenya, was an excellent candidate for ART learning sites: It had government commitment to provide and sustain HIV treatment, a well-established national AIDS program and ongoing IMPACT prevention and care interventions.

In consultation with USAID, FHI developed a proposal to introduce ART at two Rwandan health facilities (with others to follow): the Biryogo Medical and Social Center in Kigali and Kabgayi District Hospital. Biryogo was already providing medical, nutritional, educational, housing and economic support.
USAID Announces Introductory Antiretroviral Treatment Sites

Barcelona, Spain — The U.S. Agency for International Development announced today that it has started antiretroviral treatment programs for HIV-infected people in Ghana, Kenya and Rwanda. These are the first U.S. government-funded programs in these countries to provide comprehensive antiretroviral treatment for people living with HIV and AIDS.

The announcement was made at a press conference at the XIV International AIDS Conference in Barcelona, Spain. Representatives of the governments of Ghana, Kenya and Rwanda were in attendance.

“These antiretroviral treatment sites are an important first step in providing comprehensive care to the people who need it most,” said Dr. Paul DeLay, USAID’s senior HIV/AIDS advisor…
NATIONAL ART GUIDELINES AND DRUG SELECTION

In 2001–2002, the governments of Ghana, Kenya and Rwanda published national ART guidelines to complement guidelines on STI diagnosis and treatment, HIV testing and counseling, management of opportunistic infections, and other elements of comprehensive care and support. The ART guidelines, based on WHO recommendations, promoted a standardized approach to rapid scale up and addressed criteria for therapy initiation and exclusion, first- and second-line drug regimens, clinical and laboratory monitoring, drug procurement, storage and distribution, and a host of related issues. But treatment guidelines need to be updated as new knowledge and therapies become available. They also must be refined to reflect the realities of settings where treatment is to be provided. FHI facilitated this process as ART program planning was getting underway. All programs essentially followed WHO guidelines for first-line regimens. (Clinical and social criteria are discussed further in Chapter 5.)

**Ghana**

In February 2002, the National AIDS Control Program and FHI organized a Patient Management and Antiretroviral Therapy Workshop, which brought together staff from the Food and Drug Board, the Ghana AIDS Commission, Ghana Health Services, the National Tuberculosis Program, the University of Ghana Medical School and Akuse, Atua, Komfo Anokye, Korle-Bu, Kumasi and St. Martins hospitals. The purpose of the workshop was to clarify ART policies in Ghana and examine issues affecting patient care. Participants explored a range of treatment-related topics, including regimen selection, patient monitoring, and drug logistics and management. Technical experts from FHI, the Institute for Tropical Medicine, Antwerp, and Makerere University, Kampala, shared experiences in clinical management of HIV and described health system requirements for comprehensive care and support. They offered feedback on Ghana’s existing ART guidelines and facilitated a session to update and contextualize them. Recommendations informed design of the learning sites and became part of revised national guidelines.
Kenya

As described on page 20, the Kenyan government established a national ARV Task Force at a technical and consultative meeting in September 2001. The Task Force was mandated to "guide the Government of Kenya on the most rational approach for the introduction and implementation of antiretroviral therapy in both the private and public sectors." As part of its mandate, the Task Force was asked to formulate a national ART program strategy, covering such issues as regimen selection, training, monitoring, minimum requirements for treatment centers, and distribution of centers. It was also directed to further develop or adapt the *Guidelines to Antiretroviral Drug Therapy in Kenya*, using models from WHO and the Joint United National Programme on AIDS (UNAIDS). FHI, secretariat of the Task Force, has been a key technical resource. At monthly Task Force meetings, which commenced in February 2002, FHI has advised members on a host of treatment-related topics, including patient eligibility and drug selection. Suggestions informed ART program planning and were incorporated into the national guidelines.

Rwanda

In November 2002, an FHI team visited the Biryogo Medical and Social Center and Kabgayi District Hospital to assess their preparedness for ART service delivery. The team examined the quality and accessibility of existing HIV services, human resource and infrastructure capacity (including pharmacy and laboratory), training needs, current practices in clinical management of HIV, and data collection and management systems. The team also reviewed Rwanda’s *Guide to Use of Antiretroviral Medications for Adults and Children* — published the previous June — and considered its relevance to the planned learning sites. The team identified an important gap in the guidelines. Considering the low rate of contraceptive use in Rwanda, the original guidelines did not adequately address ART in women of reproductive age. Efavirenz was recommended as part of the first-line regimen for all patients. As this drug is known to cause birth defects in primates, the first-line regimen was modified to substitute Nevirapine for Efavirenz in all women of reproductive age. Although Nevirapine was being provided free to Rwanda for PMTCT programs, the government was not yet purchasing Nevirapine.
for use in ART services. FHI assisted the non-profit company CAMERWA — the only entity authorized to import and distribute ARV medication in Rwanda — in obtaining preferential pricing for Nevirapine from Boehringer Ingelheim.

ROLES AND MECHANISMS FOR PARTICIPATION AND FEEDBACK

Introducing treatment as part of integrated programs that could be sustained over the long term has required the involvement of many actors: government leaders at all levels; academic institutions; international partners in country; health providers; community-based organizations; PLHA groups; donors; and technical partners. (The role of community groups is described in Chapter 2.) These actors have stepped in as needed to develop and refine treatment guidelines and protocols, conduct community and site assessments, build capacity and infrastructure, strengthen referral systems, prepare communities for treatment, and provide ART and related services. Broad participation has enhanced sustainability of the programs. But it has also created challenges, particularly maintaining clarity on roles and responsibilities and avoiding duplication of effort. As an element of “country preparedness,” FHI and partners defined managerial roles and established mechanisms for participation and feedback. These range from formal committees in Kenya to ad hoc but frequent meetings in Ghana and Rwanda both at the national and community/site level.

Ghana

FHI developed the ART program with the District Health Management Team in Manya Krobo, in consultation with the Ghana AIDS Commission, the Ministry of Health, the National AIDS Control Program and traditional Krobo leadership (see Chapter 2). During initial planning in 2001, many donors were still reluctant to support ART services. In October 2001, FHI agreed to provide $1 million in corporate seed funds. In June 2002, USAID began supporting the program through IMPACT, as announced at the XIV International AIDS Conference the following month. DFID began funding the program in August 2003 and has been its primary financial supporter. FHI is responsible for overall implementation of the program and liaises directly with national, regional and district bodies.
The structure of the Ghana program staff has facilitated participation and feedback. Managers based in Accra communicate regularly with counterparts at the Ghana AIDS Commission, the Ministry of Health and the National AIDS Control Program (though no formal committees have been established). Clinical and program staff based in Manya Krobo work closely with the District Health Management Team, the UNAIDS-funded District Response Initiative (the government’s AIDS coordinating agency at the district level), health facilities, NGOs and other stakeholders. FHI takes part in monthly meetings between facility staff and partner NGOs to maintain clear lines of communication and inform both community education and mobilization efforts, as well as service delivery.

Kenya

The Mombasa program was established as part of provincial and district health services, under the auspices of NASCOP, the Ministry of Health and the national ARV Task Force. USAID, primary financial supporter of the learning sites through IMPACT, also has been a key decision-maker on aspects of the program. Day-to-day oversight rests with a group of three technical advisory partners — FHI (IMPACT), MSH (RPM+) and the Population Council (Horizons). Though there is some overlap, FHI is essentially responsible for developing ART services, creating demand and monitoring and evaluating the program. MSH oversees procurement, storage and distribution of test kits, pharmaceuticals and other biomedical commodities, as well as strengthening of pharmacies and laboratories (staff training, development of standard operating procedures, quality assurance mechanisms). The Population Council, with the International Centre for Reproductive Health, leads operations research and cost analyses. An FHI senior technical officer was appointed program coordinator and focal point for all issues germane to the ART sites. To bring government resources to bear, the Ministry of Health placed a staff person in Mombasa to serve as the coordinator’s counterpart. During the initial stages of program implementation, the Technical Advisory Partners met monthly to guide program development; these meetings were phased out as the program coordinator and his counterpart assumed leadership.

To facilitate participation and feedback, IMPACT, the provincial medical officer and local health authorities established three major committees (facility ART teams are described in Chapter 3):
Steering Committee: The committee’s role is to monitor overall implementation of the Mombasa ART program. Founding members included approximately 20 national, provincial, district and community stakeholders, as well as representatives from USAID and the technical advisory partners. The committee addresses barriers to service provision and expansion, fosters a climate conducive to comprehensive care and support for PLHA, determines cost-sharing mechanisms and levels, ensures coordination and collaboration among stakeholders, monitors progress and makes recommendations to improve the program. The committee, which meets twice annually, has a mix of medical and non-medical members. Since its inception, it has driven community involvement in the program (see Chapter 2).

Scientific Committee: The committee’s role is to establish and maintain a realistic, minimum framework for administering, monitoring and evaluating ART services in Mombasa. Staff from CPGH, the Ministry of Health, NASCOP, the technical advisory partners and other agencies were founding members. In line with the Guidelines to Antiretroviral Drug Therapy in Kenya, the committee determines patient eligibility criteria and first- and second-line drug regimens. Among its other responsibilities, it establishes quality assurance mechanisms, counsels health professionals on management of difficult cases, ensures effective and appropriate use of data, and advises the Steering Committee, national ARV Task Force and Ministry of Health. The committee meets quarterly.

Operational/Management Committee: The committee’s role is to ensure open communication, clearly defined work plans and synchronized action to meet program objectives. The committee, chaired by the FHI program coordinator, reviews standard operating procedures (SOPs), clinical algorithms and other relevant guidelines, supervises health providers at their sites, identifies and responds immediately to problems, ensures a minimum standard for data management at health facilities, and updates the Steering and Scientific committees on program progress. Issues that cannot be resolved by the Operational/Management Committee are referred to the U.S. offices of FHI, MSH or the Population Council, or to the Cognizant Technical Officers of IMPACT, RPM+ or Horizons. The committee meets as often as needed, but not less than monthly.
Rwanda

In developing the Rwanda program, FHI worked closely with the Ministry of Health (including the Secretary of State for HIV/AIDS and TRAC), provincial, district and diocese health directors, and medical directors of the participating facilities. USAID, the main financial supporter of the learning sites, is involved in all major decisions related to the program. As in Ghana and Kenya, FHI is responsible for overall implementation and communicates regularly with national, provincial and district officials. The Rwanda office hired a physician to serve as program coordinator under direct supervision of its senior technical advisor in Kigali. The coordinator provides ongoing clinical and technical assistance at the learning sites and works closely with the medical teams. Though FHI and partners did not establish formal committees (other than eligibility committees at the sites), staff report regularly to the Ministry of Health and USAID.

LESSONS LEARNED

Gather policymakers to crystallize a vision for ART services.

National leaders recognize the potential benefits of HIV treatment to individuals, families and overall social and economic development. But there is a gulf between the theoretical desire to provide ART and actual commitment — including budget line items — to make it happen. Even in countries where ART policies are in place, policymakers from multiple agencies need to discuss and debate the way forward. Will ART enhance or undermine prevention efforts? Should ART take precedence over immunization, malaria or other national priorities? If so, who should pay for ART services? Where should they be located? Who will have authority over them? What about other essential clinical HIV interventions, such as management of opportunistic infections, preventive therapies, palliation? Assembling policymakers to tackle such issues as a group — rather than circulating and re-circulating documents — accelerates decision-making. Events such as the February 2002 ARV Task Force meeting in Nairobi cultivated agreement on ART policies, guidelines and protocols, and on the location of ART sites. Through this process, key government “champions” emerged to smooth the way for program implementation.
Review national ART guidelines, including recommended drug regimens, as a first order of business.

Care and treatment guidelines — including those relating to ART — generally reflect the knowledge and treatments available around the time of publication, and therefore require periodic review and updating. Are the ARV drugs recommended in the guidelines the most appropriate for the country context? Is the regimen the most effective choice, based on recent scientific research? Are the most appropriate drugs registered in the country? Can the program afford the most effective drugs? Do donors or the host government restrict certain drug formulations? Or generic or branded drugs? Are there barriers to import, such as excessive value added taxes? Addressing such questions early — when integrating ART into existing HIV care and support services — is critical. Delaying the process can delay procurement, which has life-or-death implications for people with late-stage AIDS. With assistance from FHI, policymakers in Ghana, Kenya and Rwanda reviewed current guidelines, identified weaknesses and made revisions for ART sites. It is best to select regimens based on scientific data, adapt from international guidelines and then undertake a process to register the most appropriate drugs for that setting.

Share success stories.

Funding treatment as part of comprehensive care and support for PLHA is a significant, often controversial step. ART competes with other national and donor priorities and — unlike immunization or treatment for tuberculosis — must be provided for the duration of patients' lives. Indeed, integrating ART into existing services has been hotly debated within donor agencies, government bodies and communities. Thus, it is important to gather and share success stories to show that ART can be delivered safely and effectively in resource-constrained settings. When funding agencies see the human, societal and economic benefits of treatment — people returning to work, sending their children to school, raising them to adulthood — they are more likely to
sustain and expand support for ART programs. Success stories disseminated through newspapers, television and other media have helped the governments of Ghana, Kenya and Rwanda leverage funding from the World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and other sources.
Community Preparedness
CHAPTER 2. COMMUNITY PREPAREDNESS

This Chapter covers:

- Formative research in the community;
- Stakeholder involvement, including PLHA;
- Community education.

Community institutions — local governments, traditional leadership, churches and mosques, schools, media and the like — are tremendously influential in shaping attitudes and norms, including those related to treatment-seeking behavior. Many cultural traditions, beliefs and practices promote health and well-being, while others inhibit people from accessing the information, services and support they need to live full, healthy lives. In the context of HIV/AIDS, negative perceptions among family members, neighbors, health workers and others can lead PLHA to discontinue medical and psychosocial services or refuse to seek them. Where stigma and discrimination are pervasive, PLHA who are clinically eligible to participate in ART programs may find it difficult to meet social criteria, such as willingness to visit a health facility regularly, be contacted at home or disclose HIV-positive status to a relative or friend who can support adherence to medications.

When planning the ART programs in Ghana, Kenya and Rwanda, FHI and partners recognized that long-term, sustained ART provision would not be possible without the support and participation of communities. Thus, preparing communities for ART introduction was a key component of the programs, carried out concurrently with work at the national level. In addition to assessing and addressing stigma and discrimination, the programs educated communities about the benefits and limitations of ART, the challenges associated with

3 In this guide, "community" refers to the catchment area of each ART learning site.
HIV treatment, and the criteria that would guide patient selection. Community leaders, including representa-
tives of PLHA groups, played an important role in formative assessments and planning activities, and joined
the steering committees formed to guide program implementation, monitoring and evaluation. Community
groups continue to provide services that make safe, effective ART delivery possible.

FORMATIVE RESEARCH IN THE COMMUNITY

FHI and partners conducted formative research, including focus group discussions with PLHA, at prospective
learning sites in Ghana, Kenya and Rwanda. In Ghana, the first country to become part of the treatment and
care initiative, FHI reached beyond the confines of health facilities to conduct extensive formative research
in the community. The research — carried out during January-September 2002 in Ghana’s Manya and Yilo
Krobo districts — focused on:

- Community knowledge of HIV/AIDS;
- Beliefs and behaviors around general health issues;
- Availability, accessibility and use of HIV testing and counseling services;
- Knowledge and perceptions of mother-to-child transmission (MTCT) and ways to prevent it;
- Preferences for testing and counseling and services to prevent MTCT;
- Perceptions of HIV/AIDS services;
- Health worker attitudes and behavior.

In investigating issues related to these topics, FHI facilitated 50 focus group discussions, 10 in-depth interviews
and a quantitative survey. Participants represented a broad cross-section of the community: antenatal clinic
attendees, breastfeeding and non-breastfeeding mothers, doctors, nurses, other health workers, HIV testing
counselors, in- and out-of-school youth, maternal and child health clinic attendees, PLHA, traditional birth
attendants, traditional leaders and truck drivers.
Except for health workers and antenatal clinic attendees with some knowledge of drugs to prevent MTCT, participants were generally unaware of HIV treatment. Some cited lack of treatment as an obstacle to HIV testing and counseling, expressing that without treatment there is no reason to know one's sero-status. After learning about ART during focus groups, participants expressed preferences for service delivery points in the community, with confidentiality a key concern. Some preferred that assemblymen or peer educators dispense the drugs, while others preferred the hospital setting.

A key finding was that stigmatizing behavior of health workers and others in the community inhibit people from seeking HIV services, such as testing and counseling. Following the formative research, FHI convened 60 staff from facilities in Manya and Yilo Krobo, including two prospective ART learning sites (Atua Government Hospital and St. Martins de Porres Hospital) and several health centers. Facilitators played audiotapes of PLHA criticizing the way they were treated by health workers. In general, health workers recognized the legitimacy of client expectations and complaints. They acknowledged that confidentiality was an issue and that staff had on occasion revealed clients' HIV test results without authorization. Some health workers were unaware their behavior unintentionally revealed a client’s sero-status. They attributed much of their behavior to lack of understanding and pledged to address patient concerns.

Voices from the Community: Formative Research in Ghana

Some people don’t believe the disease exists. Even if they believe, some people feel they are invincible or immune from infection.
—Youth on perceptions of HIV/AIDS

I think Parliament should make a law that anybody in the hospital who reveals anybody’s result should lose either his job or entitlement so that everyone will be serious about it.
—Adult male on confidentiality

We heard there is free testing but we don’t know where to go or where they do it. We are not aware of any free test.
—Adult female on HIV testing and counseling

When people see one person go for testing, they can even insult your family that you are all immoral people.
—Antenatal clinic attendee on HIV-related stigma

If we know that there is medicine that can prolong our lives, then we can go for a test.
—Adult male on availability of HIV treatment

I thought I was doing a good job all this time, but after the seminar I realized some of the things I did rather offended the clients.
—Health worker on provider-patient interaction
These and other findings highlighted the importance of community-specific information in designing, implementing and promoting HIV/AIDS services. Program planners have used the findings to guide advocacy and sensitization activities, develop communication messages and improve services. Formative research in Ghana, Kenya and Rwanda has helped program staff understand issues related to service utilization, improve health worker-patient interaction, and design services that respond to the needs of users and the communities where they live.

**STAKEHOLDER INVOLVEMENT, INCLUDING PLHA**

### Ghana

The effort to involve community stakeholders in the Ghana ART program began with a November 2001 visit to Nene Sakitey II, the Paramount Chief of Manya Krobo. Sakitey has a deep understanding of HIV/AIDS and its impact in Ghana’s Eastern Region, but was concerned about community acceptance of ART services and local capacity to deliver them. FHI underscored its commitment to patient confidentiality and presented the criteria for patient selection, noting that most PLHA will not yet be eligible for ART. Sakitey agreed to support the program and became an advocate for HIV treatment in Manya and Yilo Krobo.

Immediately following the meeting with Sakitey, FHI convened a community gathering at the headquarters of the Queenmothers Association, a traditional group that provides services for vulnerable people in the area, including orphans. A representative of the District Response Initiative said it was an “honor” to be part of this groundbreaking initiative for both Ghana...
and Africa. Participants were generally enthusiastic about the ART program, but voiced concern that drug prices would be out of reach for most community residents. They also were fearful that limited drug supplies would lead to corruption and a disruptive black market.

Following the initial discussions, FHI and the District Health Management Team continued to meet with and involve local stakeholders, including traditional and religious leaders, health workers, youth groups and unions. Besides the participating health facilities, formal community partners included CEFRIEND (IEC on HIV and STDs), the Klo Drivers Alliance, the Manya Krobo Youth Club, PHLAB, the Queenmothers Association and the Youngsters Peer Education Project. Program staff organized workshops to share technical strategies on ART, solicit ideas on program design, define roles and build capacity to carry out assigned tasks. In addition to implementing elements of the program — such as referrals and home visits — local partners fostered support for HIV services among their constituents and addressed widespread stigma and discrimination. Stakeholders meet regularly with health staff to identify and address obstacles to services.

Because HIV-related stigma and discrimination are pervasive in Manya and Yilo Krobo, engaging PLHA in significant ways during the initial program phases was difficult. Many were simply too worried about negative reaction. In some cases, it was necessary to bring in PLHA from Accra to participate in aspects of the program. But local PLHA participated extensively in the formative research described above, albeit in a confidential manner, and helped develop community education and communication activities. In addition, a PLHA group based at St. Martins de Porres Hospital made suggestions on program design and implementation.

Kenya

According to the coordinator of the Kenya ART program, “By design, the community was involved from the beginning.” In April 2002, staff convened a planning workshop to present program objectives to local health and political authorities and obtain their input and buy-in. Through the ART planning process, FHI cemented its existing relationships with the Ministry of Health (which provided a provincial coordinator for the program), the Provincial Medical Office and district and municipal leaders. The provincial medical officer, the
district medical officer and representatives from the Public Health Department, the Kenya Medical Association and the Pharmaceutical Society of Kenya were founding members of the Steering Committee described in Chapter 1.

Coast People Living with HIV/AIDS (COPE), based in Mombasa, was asked to represent the PLHA community during all phases of the ART program (a COPE member serves on the Steering Committee). Since there are few formal PLHA groups in Coast Province, FHI also elicited PLHA input through two national groups: the National AIDS Control Council and the Constituency AIDS Committee. Through these bodies, PLHA helped assess existing ART access and use in Mombasa and contributed ideas on interventions needed to expand access through the learning sites. The association with COPE has evolved since ART services were launched at CPGH. During clinical hours at the Comprehensive Care Center (CCC) — part of the hospital’s out-patient department that provides HIV care and support services — association members serve as volunteer peer counselors to educate and support ART patients and their families. They also facilitate linkage with home-based care for patients who require additional assistance meeting daily needs and adhering to medications.

The ART program involved a range of other HIV/AIDS organizations in Mombasa. For example, it engaged home-based care trainers affiliated with the Community-Based Prevention, Care and Support (COPHIA) Project, managed by Pathfinder International. The trainers, in turn, informed community health workers and caregivers about the ART program, securing their support and participation. COPHIA serves on the Steering and Scientific committees. Despite successes involving stakeholders in Mombasa, there is room for improvement. The COPE representative on the Steering Committee found the structure “useful” but urged inclusion of “technically informed PLHA.” He also recommended that Steering and Scientific committee meetings be held regularly, rather than only as needed. Most staff at the CCC were not knowledgeable about the committees, their responsibilities or their composition.
Rwanda

In preparing to introduce ART in Rwanda, FHI focused most of its efforts on the initial learning sites — Biruyo Medical and Social Center in Kigali and Kabgai District Hospital — rather than the communities. This was possible because, to a certain extent, existing services at the facilities (PLHA support, preventive therapy for tuberculosis) had already “prepared” the communities. However, program planners clearly defined patient selection criteria for community members who visited the facilities (through posters, for instance). Because of close collaboration between the facilities and local PLHA groups, program planners believed — correctly — that information about the ART program would flow to the communities. For example, Biruyo maintains close ties with Ihumure, a PLHA group that provides home-based care and psychosocial support to HIV-infected individuals and their families in nearby neighborhoods. Program staff also communicated closely with local political and religious leaders, including the Archbishop of Kigali — the highest ranking Catholic official in Rwanda — who has authority over Biruyo. Providing accurate information about ART through these channels fostered acceptance of the eligibility criteria and, in the process, helped avoid an overwhelming influx of patients seeking treatment.

Since ART services were launched in Rwanda, community members have become more deeply involved in the program by supporting friends and family members on ART. For example, to meet the social eligibility criteria, each patient is encouraged to select a treatment supporter — a marraine or parrain — who participates in pre-treatment adherence counseling with the patient to facilitate adherence. In the event the patient is unable to communicate difficulties, such as side effects or illness, to health staff, the treatment supporter does this on his or her behalf.

COMMUNITY EDUCATION

Formative research revealed varying levels of knowledge about HIV/AIDS and ART. Some people in the target communities had never heard of HIV treatment, while others had heard about it but had inaccurate information (“treatment” versus “cure”). Many believed incorrectly that all PLHA would be eligible for treatment.
In 2003, as the IMPACT Project and Coast Provincial General Hospital were introducing ART as part of comprehensive HIV care and support, it became clear that ART literacy materials were needed to help people on treatment adhere to their complex drug regimens. Formative research among community members, including people living with HIV, revealed serious gaps in knowledge not only about ART and associated side effects, but also about the basics of HIV and AIDS. In addition, the research revealed stigmatizing attitudes among clinicians, which could further inhibit patients from adhering to their medications.

With a grant from Pfizer, IMPACT began developing ART literacy materials for the Mombasa program (these have since been adapted for use in Eritrea, Ghana, Guyana, Malawi, South Africa and other countries). These included brochures and flip charts with local images and analogies. USAID and Kenya’s National AIDS and STI Control Programme provided additional funding to create the materials, which are geared to both literate and low-literate audiences. Coast People Living with HIV and AIDS (COPE), the largest PLHA association in the province, provided technical input at each stage to ensure the materials were on target and resonated with the intended audiences.

Others were skeptical about imported ARV drugs, concerned about patient confidentiality, and unaware of existing testing and counseling services. Research also revealed high levels of stigma and discrimination, even among health workers, which was inhibiting people from seeking or continuing services. Education and communication were needed to foster a climate in which clinically eligible PLHA could meet social criteria (such as disclosure), initiate treatment and adhere to medications.

Through its IMPACT programs in Africa, FHI had already developed behavior-change communication (BCC) materials that could be used or adapted to facilitate ART services in the target communities. These included brochures, guides, comic books, posters, videos, music cassettes and public service announcements that communicate the basics of HIV, address stigma and discrimination, and promote existing services. Many of these materials were created with input from the PLHA groups that would be instrumental in implement-
ing the ART programs. IMPACT had also established peer networks that could be tapped to disseminate ART information at workplaces, churches and mosques, schools and youth centers, police and military installations and other locations.

Yet there was still a need to design education interventions specifically for the ART programs. In May 2002, FHI sponsored a BCC strategy workshop for NGO partners in Ghana’s Manya and Yilo Krobo districts. In the ensuing months, the NGOs launched peer education and community outreach activities, organized dramas and rallies, and conducted home visits to PLHA. For example, by September 2002, 34 peer educators with the Manya Krobo Drivers Union had reached 5,000 drivers with information about AIDS and the planned ART program. They also distributed 12,000 condoms and reinforced HIV prevention messages. In Kenya, peer educators trained by IMPACT incorporated ART messages into their programs. Members of COPE visited schools, religious groups and other organizations to speak about prevention and living with HIV.

Each program also developed local-language materials to enhance patient-provider interaction. The materials, geared toward low-literate and illiterate audiences, as well as providers, describe ARV drugs and essential aspects of treatment, such as adherence and side effects. Importantly, they also underscore the importance of HIV prevention, communicating that people on ARV drugs are still capable of passing the virus to others. In Rwanda, FHI conducted formative research with ART patients in the private sector, as well as with patients on preventive therapy for tuberculosis and other opportunistic infections, to develop a range of educational materials. These materials have been adopted by the Ministry of Health and carry its logo. (Further discussion of patient preparation is provided in Chapter 5.)
LESSONS LEARNED

Work with local stakeholders and community members, including PLHA groups, to design, support and evaluate clinic and community services.

To most people in the target communities, treating HIV as a chronic condition was a relatively new concept. As a result, rumors and misinformation about ART began to circulate along with word of the planned programs. Some community members drew little distinction between HIV “treatment” and “cure.” Many thought all HIV-positive people would be eligible for treatment. Others were suspicious of ARV drugs, concerned how patient data might be used and, where stigma and discrimination were pervasive, troubled that limited resources would be used to treat people who were HIV-infected. It was imperative that program staff gather local stakeholders — PLHA, district and municipal officials, traditional leaders, health workers, media and others — to discuss ART, explain the planned interventions, forge partnerships and develop plans for joint action. Participation on steering committees generated support among stakeholders, increased their knowledge of HIV treatment, and empowered them to become advocates in the community. It also enabled the programs to tap into their networks. For example, PLHA involved in the program could communicate eligibility criteria to the broader PLHA community, religious leaders could address stigma and discrimination among their congregations, and NGOs providing home-based care could refer clients to ART learning sites. Regular meetings between community groups and health staff enabled community groups to zero in on misinformation in the community and providers to improve attitudes and service delivery overall. Some community groups required significant capacity building to become effective partners, while some providers required reflection to decrease their stigmatizing behaviors. Program planners should not assume a strong knowledge base and effective counseling and teaching skills. In Kenya, the program strengthened the counseling skills of PLHA before they began supporting ART patients at CPGH.
Manage expectations in the community.

Mobilizing community organizations, including PLHA groups, was an important step in ART planning and implementation. Their involvement helped correct misconceptions about ARV drugs — for example, that they are a treatment, not a cure — and helped reinforce overall HIV prevention, care and support messages in the community. But their involvement also created challenges. For example, like many others, PLHA involved in program development were anxious to begin treatment. Many of them expected that ART would be provided immediately and that they would be the preferred recipients. For example, members of Ihamure lobbied for preferential access to ART. Some PLHA expected implementers to provide housing, clothing and food, which were beyond the purview of the programs. It was vital to reinforce that establishing safe and effective ART services takes time, that ART must be delivered in an equitable and transparent manner, and that the programs can refer patients for material support but not provide it directly. Meeting the multiple needs of PLHA — the essence of comprehensive HIV care and support — requires collaboration of many organizations and groups, health facilities and community-based services. Community groups tapped to implement program components — home-based care, peer education and the like — at times saw each other as competitors rather than partners. Who would take the lead in advocacy? Who would take the lead in home-based care? To foster a spirit of collaboration, program staff worked with stakeholders at initial planning meetings to define roles and create realistic expectations regarding funding. Conflicts arose despite these efforts, requiring staff and community groups to revisit and clarify roles and responsibilities.

Balance consensus-building with timely roll out of services.

Involving a range of local stakeholders in ART planning and implementation has enhanced program coverage and innovation, and given community groups a sense of ownership. But developing and launching ART services was slowed when it “became necessary” to consult community groups because they are partners, not
because they have knowledge on a particular issue. Recognizing that time is precious for people with late-stage AIDS, the ART programs have sought to balance participation with timely launch of services. This can be a difficult balance to strike, given that ART, particularly site selection, is a sensitive topic that requires significant discussion with stakeholders. But there need not be a committee for every issue; it is possible to build broad consensus on overall goals and objectives, and then move quickly with selected partners on individual aspects of the program.
Site Preparedness
CHAPTER 3. SITE PREPAREDNESS

This Chapter covers:

- Site selection;
- Site assessments;
- Site preparedness (clinical, laboratory, pharmacy).

Ghana, Kenya and Rwanda were identified as candidates for ART sites because of their strong government commitment to provide and sustain treatment, their well-established national AIDS programs and the presence of ongoing IMPACT prevention and care interventions. In these countries, it was necessary to determine first the most appropriate regions, districts and municipalities for ART, and next the most suitable hospitals and health centers to provide it. Following rapid assessments by FHI, government leaders selected sites based on community need, existence of other HIV services (testing and counseling, preventive therapy and treatment for opportunistic infections, home-based care), capacity to deliver ART, level of infrastructure, and local willingness to participate in a treatment initiative. Subsequently, program staff and partners conducted in-depth assessments to begin preparing sites (clinics, laboratories, pharmacies) to deliver comprehensive HIV services, including treatment, in line with national and international guidelines.4 (Referral systems, patient preparation and information systems are discussed in Chapters 4–6.)

4 Pre-existing cost-sharing systems apply to the ART programs. In Kenya and Rwanda, ARV drugs are provided free of charge. In Ghana, patients pay a subsidized US$5 fee per month, which covers ARV drugs, laboratory costs and treatment of opportunistic infections. Waiver systems apply to all eligible patients unable to meet the costs associated with treatment.
SITE SELECTION

Ghana

As described in Chapter 1, Dr. Kwaku Yeboah, while serving as director of the National AIDS Control Program, recommended that initial ART sites be established at Atua Government Hospital and St. Martins de Porres Hospital (a mission facility) in Manya Krobo District, Eastern Region. These hospitals serve 220,000 people. In 2001, HIV prevalence estimates in the district were as high as 14 percent — significantly higher than the country’s overall prevalence estimate of 3 percent. At the time of site selection, neither hospital was offering specialized HIV services, though UNICEF and the Noguchi Memorial Medical Research Center were planning to pilot PMTCT at both institutions (Noguchi was also operating mobile HIV testing and counseling services in Manya Krobo). Atua and St. Martins did not have existing IMPACT-supported HIV services, as did initial sites in Kenya and Rwanda; but they had the basic infrastructure and leadership needed to become effective ART learning sites. FHI and partners believed building ART services from the ground up would be instructive for AIDS programmers in resource-constrained settings.

Kenya

Dr. Kenneth Chebet, then director of NASCOP, and colleagues within the Ministry of Health recommended CPGH in Mombasa as the initial ART learning site (see Chapter 1). The hospital, the second largest in Kenya, is a tertiary referral hospital for Coast Province serving a population of about 2.5 million. The facility is an important training center for medical personnel and functions as the core health facility in the province. In 2000–2001, an estimated 10 to 15 percent of women attending the hospital’s antenatal clinic were HIV-positive. At the time of site selection, the hospital’s HIV clinic — staffed by a full-time medical doctor, two registered clinical officers, five nurses and a part-time nutritionist — was providing ambulatory services to referred and self-referred PLHA. The clinic was linked with two IMPACT-supported testing and counseling centers and with the COPHIA home-based care project. The hospital laboratory was conducting HIV testing, diagnosing some opportunistic infections and performing full blood counts and liver function tests.
Based on a proposal from FHI, Dr. Ezéchias Rwabuhiihi, then Minister of Health, approved the establishment of ART sites at Biryogo Medical and Social Center and Kabgayi District Hospital. The goal was to develop models for comprehensive HIV services at two levels of the health system: a community health center (Biryogo) and a peripheral health district (Kabgayi).

Biryogo Medical and Social Center, a mission health facility, serves an estimated 46,000 people in one of the poorest sections of Kigali City. At the time of site selection, Biryogo was providing medical, educational, nutritional, economic and housing support for PLHA and their families, as well as IMPACT-supported HIV testing and counseling and PMTCT services. The area surrounding Biryogo has been one of the hardest hit by AIDS in the country. In 2001, Biryogo’s testing and counseling center reported HIV prevalence rates of 28 percent for women and 17 percent for men. Biryogo works closely with Ihumure, a local PLHA association, which operates an income-generating program for its members and provides home-based care and psychosocial support. Building capacity at Biryogo would enable PLHA to access comprehensive care and support in the community where they live, rather than at one of the city hospitals.

Kabgayi Health District comprises Kabgayi District Hospital and 24 health centers serving approximately 600,000 people. At the time of site selection, the hospital (a mission facility) was providing IMPACT-supported HIV testing and counseling services, as well as preventive therapy for tuberculosis and other opportunistic infections. From August 2000 through December 2001, the hospital’s testing and counseling center reported HIV prevalence rates of 12.9 percent for women and 8.2 percent for men. In June 2002, the hospital launched PMTCT services with the antenatal clinic at neighboring Kabgayi Health Center. The hospital offers nutritional counseling for PLHA and has close ties with Duteraninkunga, a local PLHA group, which, like Ihumure in Kigali, provides home-based care and psychosocial support. Augmenting HIV services at Kabgayi would help meet the needs of PLHA living outside Kigali City.
SITE ASSESSMENTS

Once sites were selected, teams \(^5\) conducted in-depth assessments to determine the availability and quality of service components essential to safe and effective use of ART, identify opportunities for strengthening and improvement, and collect baseline data for program monitoring and evaluation. The teams collected information on:

- Human resource capacity (staff number and level of training in HIV and related conditions);
- Physical infrastructure and supplies (including laboratory);
- Availability and use of clinical guidelines/protocols;
- Current HIV clinical management practices;
- Types of services provided to PLHA;
- Pharmaceutical management systems;
- Capacity and functionality of health information systems.

Teams assessed Atua and St. Martins hospitals in February 2002; CPGH, Port Reitz District Hospital, Magongo Health Center and Mkomani-Bomu Clinic in September 2002 (services would eventually be expanded to the latter three sites); and Biryogo Medical and Social Center and Kabgayi District Hospital in November 2002. The teams used several methods to conduct the assessments: in-depth one-on-one interviews with health care providers (medical doctors, clinical officers, nurses, counselors, pharmacists and laboratory technicians); semi-structured interviews with relevant HIV specialists and community leaders; client exit interviews; focus group discussions with PLHA groups; medical record review; observation of health workers caring for patients; and physical inspection of facilities. (For Kenya and Rwanda, FHI developed standardized data collection tools for structured interviews.) Based on the findings, program staff and partners developed implementation plans to prepare the sites for ART service delivery.

\(^5\) FHI, MSH and the Population Council were equal partners in the Mombasa site assessments.
SITE PREPAREDNESS: CLINICAL SERVICES

By the time ART was introduced, all sites were offering a complement of HIV prevention and care services. As mentioned above, HIV testing and counseling, PMTCT, preventive therapy and treatment for opportunistic infections, nutritional support, and linkages with home-based care were already available at the Kenya and Rwanda sites when they were selected. In Ghana, Atua and St. Martins hospitals needed to develop a basic framework of HIV services — including testing and counseling — prior to provision of ART.

In all three countries, the ART programs renovated service delivery space. In Ghana, health staff created space for HIV testing and counseling, PMTCT and ART services, recognizing the need for confidentiality. The CCC at CPGH in Mombasa, which began enrolling patients one month before launch of ART, combined expanded HIV-related services in one location to make them more accessible. The CCC is particularly well-equipped to address the needs of PLHA. In addition to testing and counseling, nutritional support, preventive therapy and treatment for opportunistic infections, the CCC houses HIV triage, the tuberculosis clinic, the STI clinic, the skin clinic and PLHA support services. Triage (“assess, assist and direct”) and close links among these units ensure easy patient flow, rapid file and record retrieval and easy referral. According to a CCC staff member, renovation of the hospital created a “welcoming” climate for patients and their supporters, as well as a functional and comfortable working environment for the staff.

Training of health workers was another critical need identified in the site assessments. In 2002–2003, FHI facilitated training on HIV prevention, management of HIV disease, dimensions of ART, adherence counseling, nutrition and other relevant topics (laboratory and pharmacy training are described later in this Chapter). The Institute for Tropical Medicine, Makerere University and Mildmay International were key partners in training efforts, as were experts from national AIDS bodies, medical schools and other country institutions. Trainings included health workers from beyond the initial learning sites, recognizing that the ART programs would
expand to other facilities in the country. Staff at the ART sites recognized the need for regular in-service training and mentoring to update them on HIV-related information and clinical practices. Training of new staff is an ongoing necessity because of staff attrition and relocation.

In Ghana, the first training activity was a workshop on HIV testing and counseling (May 2002). The workshop and subsequent refresher courses covered a range of salient topics, such as pre- and post-test counseling, design of counseling rooms, record-keeping and confidentiality. Over the following months, the program trained a core group of doctors, nurses, pharmacists and laboratory technicians in general HIV programming, comprehensive HIV care and management of opportunistic infections, with a brief introduction to ART. When drugs became available, FHI offered an intensive three-day course on ART, using its HIV/AIDS Care and Treatment manual for the first time. (The manual has since been translated into French.) Program staff also organized intensive adherence training for nurses/counselors, physicians and dispensing pharmacy technicians, as well as training on stigma and discrimination for all health staff. Initially, the FHI program coordinator — a physician experienced in HIV treatment — closely supervised clinicians to build their confidence and assist with difficult issues. The program provides supplemental training in the evenings so as to not disrupt daytime services.

In Kenya, multiple cadres — prescribers, nurses, laboratory staff, medical records staff, pharmacy staff — attended selected training sessions jointly, such as those on HIV epidemiology, prevention and comprehensive programming (April 2003). Health staff also attended break-out sessions tailored to their individual duties. For example, medical records staff were trained to better manage HIV patient data, patient flow and confidentiality issues. The Horizons Project conducted intensive adherence training for nurses in preparing for operations research on ART (see Chapter 9). Throughout, training sessions underscored the importance of confidentiality and the negative impact of stigma and discrimination on treatment-seeking behavior. As in Ghana, formative research revealed stigmatizing attitudes and practices among health workers.

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6 Clinicians at the Institute for Tropical Medicine in Antwerp and at FHI in Arlington, Va., serve as “electronic mentors” to assist Rwandan clinicians on difficult cases.
In Rwanda, training for physicians (November 2002–February 2003) focused on ART and HIV disease management, including opportunistic infections. A separate course for nurses and social workers included content on adherence counseling, nutrition and psychosocial aspects of HIV. At Biryogo Medical and Social Center, FHI seconded a physician with experience in HIV treatment to help provide ART. Expansion at this site has been rapid, with 138 patients on treatment within nine months of start-up (with one defaulter and no cases of treatment failure).

In each country, program staff and partners developed clinical care protocols for ART — based on national guidelines — to establish standards and guide service delivery. This was not done to create new or parallel procedures, but rather to integrate the ART programs into existing public frameworks, thereby fostering acceptance of the new services and ensuring quality. In Kenya, FHI, MSH, the Population Council and staff at CPGH developed SOPs for the Mombasa sites. The SOPs, approved by the Scientific Committee and pre-tested at the CCC, are a valuable tool in assuring the uniformity and quality of ART services. Ongoing supervision and mentoring are required to integrate protocols into routine clinical practice. According to the coordinator of the Mombasa ART program:

> At this early stage of implementation, the capacity to adhere to the protocols and the actual performance of procedures and practices has been slow to build up... This requires that staff are closely observed, closely monitored and closely supported to adjust to the requirements of the new protocols. It has taken time to enculture these standards. This process is ongoing....

The SOPs are being adapted for HIV programs outside Kenya, including the Nigeria, Tanzania and Zambia programs funded by the U.S. President’s Emergency Plan for AIDS Relief.

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7 Initially, FHI organized ART training through the Institute of Tropical Medicine, Antwerp; the Ministry of Health has taken charge of training and now organizes 10-day training sessions for clinical staff who will work at centrally located scale-up sites.
LESSONS LEARNED: CLINICAL SERVICES

Take steps to minimize attrition of health staff.

Introducing ART as part of comprehensive HIV care and support strengthens service delivery and promotes a continuum of care for patients. But increasing numbers of ART patients create challenges for already overburdened health staff, resulting in decreased morale and motivation. Attrition is soon to follow. To maintain a motivated, competent staff, it is important to address the professional and financial needs of health workers. This may be beyond the purview of donor-funded development programs; advocacy with government budget authorities is an option. Other steps include special educational opportunities for staff working with HIV patients, clinical consultation, positive supervisor feedback and data feedback on mechanisms that recognize progress in reaching more clients, saving more lives. Other incentives include attention to the HIV care needs of infected health providers and their families, and assistance with abstract-writing and presentation at national and international conferences.

Consider space as well as services.

Even a modest investment in upgrading the space for ART and other services can promote more efficient patient flow, confidentiality and a comfortable working environment for patients and staff. This is particularly important in settings where stigma and discrimination are prevalent. Focus group discussions in Manya Krobo and Mombasa revealed confidentiality as a major concern among community residents.

Provide continued mentoring and supervision to health workers with responsibility for complicated patient management.

SOPs or clinical care protocols, including those defining the schedule for patient visits and laboratory testing, promote effective clinical management and monitoring of ART patients. In addition, opportunities for case consultation with experienced ART clinicians can be extremely beneficial in building the capacity of providers to manage patients while improving patient care. Case consultation sessions are especially useful when they include the entire team caring for HIV patients. The sessions can be held weekly or monthly on the weekend, with lunch. This also helps with staff motivation.
While building capacity on ART management, programs should also strengthen clinical practice in managing HIV disease overall, particularly diagnosis and management of opportunistic infections and other HIV-related conditions. It is best for HIV specialists from countries or settings similar to the local context to conduct training. Experience from “developed” countries is valuable, but practicing the science of HIV/ART is strongly impacted by local factors, traditions and belief systems.

**SITE PREPAREDNESS: LABORATORY SERVICES**

Diagnosing HIV, initiating ART, monitoring patient responses and assessing resistance patterns all depend on high-quality laboratory services. Based on site assessment data, program staff and partners strengthened laboratory services at all ART learning sites by procuring and installing (or repairing) equipment. FHI’s program coordinator in Mombasa found “it is necessary that the infrastructure for monitoring (of HIV disease) is in place. Tracking the progress of people on treatment is critical to the intervention. On-site capacity to do this is important not only to build the site itself but to be convenient to the patient and provider.” An important aspect of laboratory capacity building is that its benefits are not limited to patients with HIV. Many of the tests are also critical to managing patients with renal and hepatic diseases, among others.

**Ghana**

Building laboratory capacity was a key objective at Atua and St. Martins hospitals. Program staff believed it would enhance patient convenience, heighten safety in handling samples and, thus, strengthen quality assurance if laboratory testing for most ART-related assays could be performed on site.

The Public Health Reference Laboratory in Accra assessed laboratory services at Atua and St. Martins hospitals prior to the launch of ART. Based on the assessment, FHI procured a hematology analyzer, microscopes and other basic laboratory materials, while damaged chemistry equipment was repaired. As a result, test results could be obtained more rapidly and the program was spared the expense of transporting specimens to
other facilities. In selecting new equipment, program staff and partners considered in-country servicing capabilities. Other considerations included need for minimal training to process samples and lack of restrictions on reagent brands, which expanded options and reduced costs.

The program deferred procuring CD4 and viral load testing equipment, as it was not cost-effective for a small hospital setting. For CD4 count — a baseline eligibility criterion for ART — protocol at Atua and St. Martins included on-site blood draw and transport of sample to Noguchi in Accra. Results are available at the originating laboratory hospital within 72 hours. Viral load, measured if treatment failure is suspected, is managed according to the same protocol. FHI and partners trained laboratory staff at the sites to collect and process samples for viral load testing.

The program also procured a water storage tank to relieve chronic water shortages at the hospitals and purchased generators to stabilize electrical power; previously, frequent power outages were shutting down automated laboratory equipment.

Kenya

The ART program at CPGH was integrated into the existing laboratory system, so start-up was relatively easy, as no special registers or procedures were needed. But many components of the laboratory system were weak or stressed by the existing workload, and the absorptive capacity to support program expansion was rapidly exhausted. The program made interim arrangements to contract out CD4/CD8 testing to a local facility until an appropriate machine could be procured. FHI procured a Partec CyFlow CD4/CD8 machine per government policy in early 2003. Because of a change in policy and consequent procurement of a FACSCount device, CPGH found itself with two CD4/CD8 machines; this enabled the laboratory to support roll-out of ART services throughout the province.
Lack of human resources at CPGH — compounded by an increasing workload from all areas of the hospital, equipment breakdowns and lack of automation — quickly constrained scale-up of the ART program. While building the skills of laboratory staff, CD₄/CD₈ testing had a considerable impact on laboratory workload. Hematology and biochemistry testing also impact workload. Certain tests are mandatory for all ART patients and are used to monitor treatment efficacy/adverse effects.

To train laboratory staff, the RPM+ Project developed a five-day multidisciplinary workshop on HIV and ART management, combined with duty-specific training to address priority topics. This was followed by monthly modular training to build skills and strengthen good laboratory practice. Laboratory staff also needed to learn basic computer skills to improve efficiency in performing CD₄/CD₈ counting with the Partec CyFlow machine.

Interventions to strengthen the reliability and timeliness of testing concentrated on renewing awareness and improving adherence to laboratory practices and standards. Daily quality control checks and routine machine calibrations, together with streamlining specimen collection and flow and strengthening record-keeping, have made it easy to follow all samples — not only ART patient samples — from collection to receipt of test results. Hospital staff viewed this as a major achievement. According to one staff member, “Samples no longer get lost like previously; it is easy to pinpoint the exact place where the problem occurred.”

Improving record-keeping, taking standard precautions (gloves, for instance), developing request and reporting forms with normal values for Kenyans, setting up accident and incident records, and establishing a post-exposure prophylaxis protocol were also priority activities. SOPs developed under the program were particularly useful in monitoring adherence to agreed-upon practices and in guiding new staff. Strengthening inventory management systems to address frequent reagent stock-outs included developing inventory stock cards and increasing buffer stocks.
Rwanda

At each ART site, FHI procured a hematology machine for automated measurement of red blood count, white blood count and platelets, and a semi-automated clinical chemistry spectrophotometer for analyzing basic metabolic and hepatic blood parameters. The program also procured reagents for assays required according to the ART monitoring protocol. The laboratory technician seconded by FHI to the National Reference Laboratory in Kigali trained facility staff on the new lab instruments.

Upgrading the laboratories had several benefits: convenient, on-site patient services; fewer specimens lost during transport to other facilities; and improved quality assurance. Non-HIV patients requiring basic laboratory tests can also access these services.

As part of protocol at the ART sites, CD4 testing is performed at the National Reference Laboratory, with blood samples transported from the ART sites daily if needed. Intermittent delays in test results have occurred due to maintenance of the national laboratory’s FACSCount equipment, as well as stock-out of reagents. To alleviate this problem, FHI procured new FACSCount equipment for the national laboratory. FHI has also assisted the laboratory in forecasting reagent stock requirements.

LESSONS LEARNED: LABORATORY SERVICES

Recognize that even a moderate investment in laboratory upgrading can prepare community health centers and district hospitals to conduct most tests for ART monitoring.

In resource-constrained settings, PLHA may have a variety of HIV-related conditions. Strong laboratory capacity at health facilities helps diagnose and treat these conditions prior to ART initiation, as well as distinguish between drug toxicity and treatment failure after treatment has started. With a moderate investment in laboratory upgrading, community health centers and district-level facilities can conduct most laboratory tests.
for ART monitoring. As part of program planning, it is crucial to develop an implementation plan to strengthen laboratory services. This helps staff prioritize issues and sensitize stakeholders to laboratory requirements. But basic requirements — uninterrupted electricity, consistent, clean water supply — must be met.

**Forecast ART program scale-up and prepare laboratory capacity accordingly.**

Though integrating ART into existing laboratory services may be relatively easy, it is important to ensure that laboratories can support scale-up. Components of the existing system may be weak or already stressed by the workload. In the push to start, stakeholders may overlook laboratory-related constraints to expansion, especially if there is much to address. Program planners need to anticipate equipment needs and address human resource constraints given that the workload of the laboratory will increases significantly with both routine and ad hoc testing required for those on ART. Trained personnel and procedures to ensure quality of results must be in place before launching ART services.

**Do not underestimate the complexity of the laboratory function.**

Unforeseen issues, be they technical or political, may arise when upgrading laboratory capacity, as evidenced by the dual CD4/CD8 machines at CPGH. Unanticipated costs to the patient and the laboratory might include identifying co-existing pathologies during laboratory screening, which requires further investigation before the patient can start ART. Also, as patients continue on ART, other pathologies may require further investigation and treatment, even as incidence of opportunistic infections decreases.

**SITE PREPAREDNESS: PHARMACY SERVICES**

**Ghana**

During the planning phase of the ART program, ARV procurement and distribution in Ghana occurred within the country’s established drug and commodity management system. ARVs were procured according to the existing tendering process.
Following an assessment of drug procurement by the DELIVER Project, managed by John Snow, Inc., the government established a separate supply chain for ARVs to:

- Reduce bottlenecks by supplying the ART sites directly from the Central Medical Stores;
- Bypass the weak national management information system, which could adversely affect availability of ARV stocks.

The separate ARV supply chain is an interim solution and will be integrated into the general procurement system as more sites begin providing ART in Ghana. Program staff encountered technicalities that delayed procurement of ARV drugs: WHO pre-qualification, donor requirements of branded versus generic drugs, compulsory licensing, issues affected by Trade-related Intellectual Property Rights (TRIPS), and government requirements to issue a time-consuming tender once funds were available for procurement and repeat these when new monies become available. Understanding these issues is essential to a secure, uninterrupted supply of ARV drugs for ART sites.

At the sites, FHI and partners selected drugs for first- and second-line regimens in accordance with Ghana’s national ART guidelines. But regimen selection was limited to one or two choices; there were few alternatives in the event of adverse drug reactions or toxicities to preserve drugs for future therapeutic options. After selecting these regimens, ART program staff realized that drugs for the alternate second-line regimen were not available in Ghana, requiring sustained efforts to expedite their procurement.

The ART program abided by existing procedures in managing ARV drug supplies at the sites. The program introduced Logistics Management Information System forms to track and maintain drug stocks. The program organized training in use of the forms, as well as broader training on ARV management for pharmacy staff. Pharmacy staff in Ghana, as in Kenya, also provide adherence counseling when educating patients about ARV drugs.
The ART program procures drugs from local suppliers in Nairobi at Accelerating Access Initiative prices and delivers them directly to the ART sites in Mombasa. This interim arrangement has allowed USAID to support procurement for program start-up but will be eliminated once responsibility for ARV procurement is transferred to the Ministry of Health.

The ART program was integrated into the CPGH pharmaceutical management system to foster sustainability and expansion. SOPs developed at the hospital are based on Ministry of Health facility forms and procedures, including those for pharmacies. The program developed patient-centered pharmacy records to assist in tracking supplies, quantification and monitoring for prescribing errors and patient adherence. Renovations at CPGH included installing secure cup-boards and procuring a refrigerator for selected second-line ARV drugs. The program also added dispensing booths to improve confidentiality in the outpatient pharmacy, and made available reference material on international and national guidelines for HIV management, including ART, opportunistic infections and drug information. Updating the materials is a continuing challenge.

To train pharmacy staff, RPM+ developed a five-day multidisciplinary workshop on HIV and ART management, combined with profession-specific training. As was the case for laboratory staff, initial training was followed by monthly modular training to build skills and improve performance. The multidisciplinary structure encouraged team building and helped staff understand each discipline’s role in the ART program.

Several issues continue to affect ARV drug management: complexity of quantifying drugs due to the erratic rate of scale-up, lack of a computerized pharmaceutical management system, short-dated stock and high temperatures in Mombasa. RPM+ continues to assist the pharmacy in quantifying needs, though software will be required over the long term to collect and aggregate patient data, monitor the speed of scale-up and fluctuations in dose/drug requirements for new patients, and quantify needs for consumption and scale-up. The ART program arranged with drug suppliers to exchange ARV drugs that cannot be used before the expiry date (stock must reach the company at least six months before expiry). The program established a well-functioning
system to track and exchange short-dated ARV stock. For several ARV products, storage temperature should not exceed 25°C; temperatures in the non-air-conditioned outpatient pharmacy often exceed 30°C. The approach has been to air-condition the bulk storage area and keep minimum stocks (up to a week) in the non-air-conditioned dispensary. The ART program established systems to monitor ARV eligibility, prescribing, dispensing and adherence as part of overall clinical management and rational drug use. Given that generic ARV drugs from the Kenyan government (cost shared by the patient) and branded drugs from PEPFAR (free to the patient) are provided at CPGH, the program implemented a “two cupboard” system, with dual storage, dispensing and record-keeping. Pharmacy staff perceive improvement in the quality of medication counseling — not only for ART patients but for other patients as well — as a major success. Staff reported they were applying their ART counseling training to patients taking diabetic or hypertensive medicine. Operationalizing the adverse drug reaction monitoring and reporting system has been a major challenge. Delay in defining roles and responsibilities for this important component has been a serious constraint.

**Rwanda**

FHI worked with CAMERWA to procure ARV drugs. Program staff and CAMERWA developed a process for forecasting, ordering and tracking ARV drugs to ensure that a three-month supply is in stock at CAMERWA at all times. This lead-time was defined based on experience ordering and obtaining ARV drugs from manufacturers. Each ART site maintains a comparable supply of ARV drugs to ensure patients have access to their needed supply.

The program implemented measures to guarantee secure storage of ARV drugs and prevent theft and diversion of supplies. These measures include locked cupboards and protocols that define staff access to the drugs. FHI and facility staff developed a system to maintain drug records, including stock control cards for individual drugs and an Excel software file to forecast needs and track distribution. These measures have ensured a sufficient supply of ARV drugs to meet patient needs.
LESSONS LEARNED: PHARMACY SERVICES

Take steps very early to ensure a secure, uninterrupted supply of ARV drugs.

Initial forecasting, identifying regimens, ensuring local registration, contacting local drug manufacturing representatives for preferential pricing decisions, and obtaining necessary USAID or other donor authorizations for procurement are extremely time consuming. Attention to drug procurement must come very early in the program and precede training and other program interventions. This is increasingly important as the lag time between ordering and receipt of product increases as pharmaceutical firms face exponential increases in ARV orders worldwide.

To guarantee drug supply and avoid stock-outs, it is essential to define protocols for drug forecasting, ordering, dispensing and tracking at both the national and health-facility levels. Pharmacy staff require training on ART, related protocols, functional record-keeping of drug procedures, and systems to minimize drug theft and diversion. Before an ART program begins, it is important to consider infrastructure needs, such as secure, air-conditioned storage space and confidential counseling areas. Records (bin cards, forms and patient records), labels and bottles/cartons are also essential to an effective pharmacy function.

Involve pharmacy staff at the site and national levels in identifying system strengths and weaknesses.

It is possible to integrate ART services into pharmaceutical management systems. But it is critical to understand each site, identify unique strengths and weaknesses, and then collaboratively develop a plan with clearly defined roles, responsibilities and timeframes. It is beneficial to involve different disciplines to build trust and foster understanding of professional roles across departments.

Develop a commodity management plan but be flexible.

It is critical to have a plan and a timeline, but also to adapt the plan as necessary. As suggested by a staff member at the CPGH pharmacy, “Follow the plan but be flexible — Don’t hurry. Don’t underestimate.” Another staff member advised program planners to “approach with an open mind — [the task] may be bigger or less
than expected.” Pharmacy staff recommend building numbers slowly but surely and not underestimating the required level of effort and commitment. “Everything is possible if there is commitment,” a staff member noted. “Don’t look (only) at the problems — look at the level of commitment to solve them.”
Referral Systems and Linkages
CHAPTER 4. REFERRAL SYSTEMS AND LINKAGES

This Chapter covers:

- Essential services for PLHA;
- Referrals and linkages within communities and with/within health facilities.

A functional referral system ensures early access to and communication between services to meet the diverse needs of PLHA and their households. This is the essence of the continuum of care. The services usually involve many providers and programs. Referrals strengthen coordination of services within a health facility and between a health facility and community-based services. For example, referrals can link HIV testing and counseling and outpatient department (OPD) clinical care services within a facility or strengthen ties between the facility, home-based care and PLHA groups. Functional referral systems involve communication between providers and agencies involved in patient care to maximize the quality and effectiveness of those services. Functional referral systems also help avoid duplication of services.

ESSENTIAL SERVICES FOR PLHA

Collaboration between services is essential to comprehensive care and support for PLHA. Primary services include: HIV testing and counseling; PMTCT; HIV clinical care; nutrition and food support; home-based care; palliative care; end-of-life care; psychosocial support, including PLHA groups; socioeconomic support; and human rights and legal support. ART patients require specific services to ensure medication efficacy, including adherence support and nutritional assistance. According to a program officer in Ghana:
Seeking the well-being of PLHA must be a concerted effort. The best way is for all "stakeholders" who provide the different needs of these people to work together. The existence of one and not the other service diminishes whatever effort would be put in place. This calls for intensive efforts of community mobilization getting everybody involved, understanding the needs of the PLHA and also identifying the groups that deliver or can [meet] their needs.

REFERRALS AND LINKAGES WITHIN COMMUNITIES AND HEALTH FACILITIES

During the start-up phase, the ART programs in Ghana, Kenya and Rwanda drew upon existing linkages with community and health services to meet immediate PLHA needs. In Ghana, FHI expanded IMPACT’s existing relationship with the Queenmothers Association to provide HIV testing and counseling, support orphans and offer skills training for PLHA. Staff have since developed links with a range of community groups (CEFRIEND, the Klo Drivers Alliance, the Manya Krobo Youth Club, the Youngsters Peer Education Project) to facilitate referral for HIV services. In Kenya, FHI had worked previously with COPE, which represents the PLHA community in Coast Province. COPE members now serve as volunteer peer counselors at the CCC to educate and support ART patients and their families. They also facilitate linkage with home-based care for patients who require additional assistance meeting daily needs and adhering to medications. In Rwanda, existing referral links between Biryogo Medical and Social Center and the Kigali Central Hospital have facilitated rapid patient hospitalization and access to acute medical care.

Though these linkages have been valuable, they have been informal. The ART programs are seeking to formalize linkages, though functional referral mechanisms do not yet exist at all sites. Where formal mechanisms do not exist, referrals are ad hoc and there is no systematic referral process with a coordination focal point, tracking system and documentation. A range of HIV-related care and support services is available at or linked to the ART sites. But lack of a formal referral system makes it difficult to coordinate services, assure patient access and identify service gaps.
In Kenya, establishing the CCC at CPGH brought together several HIV-related services at one location. In addition to testing and counseling, nutritional support, and preventive therapy and treatment for opportunistic infections, the CCC houses HIV triage, the tuberculosis clinic, the STI clinic, the skin clinic and PLHA support services. But the close proximity of these services did not always assure that referrals were systematically made. Staff recognized that there was no routine referral of tuberculosis patients for HIV testing and counseling, nor a mechanism for inpatients after discharge to pass through the CCC for follow-up. They also recognized that while parents of HIV-infected children are referred by the Family Care Center to the CCC, there was no documentation or tracking system for follow-up on services received. Staff have since been working to systematically ensure access to all needed services, understanding that the lack of a structured referral system hinders the continuum of care even within a hospital.

In Rwanda, the Social Services Unit at Biryogo Medical and Social Center has extensive experience meeting the needs of PLHA and their families, including psychosocial support, economic support (such as coverage of school fees for children in need) and food distribution. Service delivery is documented in the unit's records. A centralized tracking and recording system of referrals within the health center has been formalized. Biryogo maintains close collaboration with Ihumure, a local PLHA association, which operates an income-generating program for its members and provides home-based care and psychosocial support. A coordinated referral network for HIV-related care and support services has led to increased use of services.

**LESSON LEARNED**

**Formalize functional referral systems to meet patient and household needs.**

A functional, formal referral system is an integral component of comprehensive HIV services. Such a system fosters communication and coordination between care and support services, both within health facilities and between health facilities and community support agencies/groups. Conversely, an informal referral system does not ensure that the needs of PLHA, including those on ART, are systematically met across the continuum of care. Creating a directory of services available at health facilities and in the community is a first step in
educating providers and patients. A standard referral note or slip for patients to present at the referred site is a valuable tool. It assists patients and helps providers track services provided. Systems to track and document referrals strengthen coordination and overall PLHA care and support. Different institutions or programs providing various elements of comprehensive care need to meet regularly to discuss how to improve referral and monitoring, and ensure that the continuum is functioning. Formal meetings between these organizations at least every two months are critically important.
5

Patient Preparation and Adherence
CHAPTER 5. PATIENT PREPARATION AND ADHERENCE

This Chapter covers:

- Eligibility criteria and patient selection;
- Pre-treatment counseling, ongoing adherence counseling and adherence monitoring.

While clinical/biological data are key factors in initiating ART, patient motivation and ability to adhere to a complex medication regimen are essential for treatment success. In Ghana, Kenya and Rwanda, the ART programs developed protocols to prepare patients for ART and support their adherence after treatment has started (family planning and other relevant issues are also covered during counseling). Applying these protocols — with their similarities and variations across the countries — has provided valuable insights into patient preparation and adherence support. Notably, counseling has also underscored the importance of HIV prevention among people on ART. In all patient-provider sessions, counselors reinforce the message that people on ART are still able to pass the virus to others and must take precautionary measures.

ELIGIBILITY CRITERIA AND PATIENT SELECTION

All ART sites established eligibility, clinical/biological and social criteria. Clinical criteria, drawn from national guidelines and WHO recommendations, were similar across the countries: WHO clinical stage III or IV and CD4 count 250 or less in Ghana; WHO clinical stage III or IV and CD4 count 200 or less in Kenya; and WHO clinical stage III or IV and CD4 count 200 or less in Rwanda. In 2003, the Rwandan government raised the CD4 level to 350 or less (WHO clinical stage III), which has been adopted by the FHI-supported ART sites.

Certain social criteria were identical across the countries (residency in the catchment area, history of adherence to medications, attendance at pre-ART counseling sessions). Other social criteria varied. Sites in Ghana and Rwanda required disclosing one's HIV-positive status to a family member or friend; Kenya and Rwanda gave preference to health facility staff and their nuclear family members, including children, who meet the...
clinical criteria. The Ghana program requires one pre-treatment visit at the patient’s home by a health care worker to verify residence; the Rwanda program offers ART to clinically eligible PMTCT mothers who have successfully taken the Nevirapine dose.

The social criteria provoked debate. But there was general consensus that such delineations as residency and disclosure of HIV status were necessary in areas of high HIV prevalence and limited stocks of ARV drugs. In applying these criteria, the prevailing approach to promote equity has been explaining the criteria clearly and directly. The ART program in each country has disseminated criteria widely to ensure their transparency in the community. Looking into the future, the coordinator of the Ghana program noted, “When drugs are widely available and/or at market prices, social criteria may not be very necessary.” The situation in Ghana, Kenya and Rwanda is evolving in this direction as resources for treatment become more widely available.

The programs in Kenya and Rwanda have taken additional steps to ensure that patients meet clinical and social eligibility criteria. In Mombasa, the program established an Eligibility Subcommittee, composed of CPGH clinicians and a representative from the International Centre for Reproductive Health (ICRH), which is conducting operations research with the Horizons Project. In Rwanda, after completing the patient’s physical assessment, the ART physician refers the patient’s medical record to an on-site Eligibility Committee for final review. The committee, comprised at minimum of the physician, an ART nurse, a social worker and a representative from the facility administration, makes the final decision.

In Kenya, strict observation of eligibility criteria was not initially observed, resulting in initiation of ART in patients who were terminal and others who should have been deferred or whose care could have been managed differently. According to the program coordinator, “Compassion tended to override reason and observance of the criteria.” As a result, the Eligibility Subcommittee has reaffirmed that ART patients must comply with all criteria. To foster equity and transparency, some in Coast Province have suggested broadening committee membership to include non-clinical members. This is opposed by current members, who contend that a high level of technical knowledge is needed to select patients fairly and consult on difficult clinical cases.
PRE-TREATMENT COUNSELING, ONGOING ADHERENCE COUNSELING AND ADHERENCE MONITORING

Ghana

Adherence counselors are nurses who have received training in ART and general HIV management. Nurses complete a three-day training on ARV adherence counseling, followed by mentoring/supervision by the clinician-in-charge. Patients must complete at least one session of treatment adherence counseling before beginning ART. Two or three sessions are preferred, which most patients are able to attend. Interacting with patients during the counseling sessions enables counselors to assess readiness to begin treatment, which is confirmed by the clinician before ART is initiated.

Clinical care protocols mandate that patients disclose sero-positive status to a relative or friend and that this support person — “adherence monitor” — attend adherence counseling sessions. Counselors help patients develop a support system if they do not initially have an adherence monitor. A counselor visits the patient at home within the first week of treatment to assess how well she or he is handling the medications. Subsequently, counselors conduct periodic home visits to support ART patients.

Adherence monitoring is conducted at each clinical visit after the patient has started ART. The first visit occurs within two weeks of treatment initiation. The clinician assesses consistency of pill-taking in three ways: by patient self-report (number of pills missed since last visit); by pill count when the patient visits the facility; and by review of pharmacy records (whether ARV drugs were refilled on time). These findings are included in the patient’s clinical record.

During the first six months of services at the ART sites, treatment adherence was very high, even among patients with a low literacy level. Improving health status attests to patient adherence: Of patients who completed six months of treatment, the median increase in CD4 count was 126 and median weight gain was 7 kilograms. (See Chapter 8 for additional information on patient response.) Patient relatives deserve a large share of the credit for high adherence levels, according to clinicians. They have reminded patients to take...
medications at the proper times and prevented patients from taking herbal and other non-prescribed medications without prior discussion with clinicians. During the first six months, only one patient was unable to adhere to the medications, due to excessive alcohol use. In that case, treatment was stopped.

Kenya

Three nurses at the CCC conduct adherence counseling for ART patients. The medical officer and registered clinical officer also educate patients about ARV drugs and the importance of medication adherence. In addition, pharmacy staff counsel patients on medications in dispensing booths created for the ART program.

Adherence counselors reported “some resistance” to the three counseling sessions required before initiating ART. But counselors contend that most patients appreciate the information and support they receive during the sessions. Important aspects of pre-treatment counseling are required level of adherence when taking the medications, side effects associated with the drugs, and the need for ongoing prevention with sexual partners. Counselors follow procedures described in the SOPs.

Helping patients disclose sero-positive status to family members or others is a challenge, but it remains an important component of the counselor’s role. Counselors indicated that their training prepared them well to deal with this and other difficult issues. But they voiced concern about the growing numbers of ART patients, noting that counseling is time-consuming, should not be rushed, and may be extensive when disclosure issues are involved. They agreed that more counselors will be needed as more patients initiate ART. One of the ARTS program’s major contributions was development of low-literacy materials for providers and patients on ART. These are useful in patient education and adherence counseling.

Managing side effects is a critical topic during ongoing adherence counseling. Counselors identified the need to give patients clear, precise information on side effects and ways to manage them, in both English and Swahili. Counselors also requested pill samples for use as a visual aid when discussing each medication (name, dose, schedule).
During the first six months of ART services, adherence levels were high, with no patient default due to poor adherence. Of patients who completed six months of treatment, the median weight gain was 6 kilograms.

**Rwanda**

Nurses experienced in HIV care complete a two-day training in adherence counseling before conducting ART-related counseling sessions. Pre-treatment counseling strives to assess patient readiness to begin treatment, optimize ART adherence and prevent further HIV transmission and re-infection. Topics include: the goal of ART; the need for drug combinations; side effects and side-effect management; adverse effects; adherence strategies; follow-up clinical visits and laboratory testing; and preventions strategies. Patients receive ART-related materials in Kinyarwanda, including a card with a picture of each drug in the patient’s regime and the schedule for pill-taking.

Patients attend three to five information and adherence counseling sessions with a treatment supporter — a marraine or parrain — selected by the patient prior to ART initiation. A mini-directly observed therapy (DOT) strategy is applied to foster adherence at the beginning of treatment. Per this approach, patients attend the health facility in the morning, five days a week, to take their pills under nurse supervision. The evening and weekend doses are taken at home without supervision. The length of the mini-DOT intervention varies among health facilities, depending on distance that patients must travel to the facility. For patients at Biryogo Medical and Social Center, most of whom live in the surrounding neighborhood, the intervention continues for the first six weeks of treatment. At Kabgayi District Hospital, where patients have farther to travel, the intervention takes place for one week only. Patients who cannot easily travel back and forth during the week of mini-DOT are offered free lodging at the hospital.

Adherence monitoring continues at the facilities after treatment has started. At each clinical visit, the ART nurse reviews the patient’s report of drug adherence, noting missed doses since the last visit. The patient and the ART nurse discuss barriers to adherence and identify interventions to overcome them. The physician reinforces the importance of medication adherence during follow-up visits.
During the first six months of ART services, adherence levels were high, with no patient default due to poor adherence. Of patients who completed six months of treatment at the sites in Rwanda, the median increase in CD4 count was 91 and the average weight gain was 3 kilograms.

**LESSONS LEARNED**

**Educate communities about who needs and qualifies for ART to promote adherence and a sense of equity.**

Once PLHA recognize the benefits of ART, they are generally eager for treatment to begin. But not all PLHA need or are ready for ART, and there are limited treatment slots for those who are. This can create dissension over who does and does not received life-prolonging medications. Thus, it is critical to define clinical and social criteria and disseminate the criteria widely. Strict, transparent adherence to the criteria can minimize erosion of community support for ART.

**Tailor counseling and advice to individual patient needs, while encouraging the support of treatment “buddies.”**

Drug adherence is of paramount importance to ART success. Counselor training, protocols for pre-treatment and ongoing adherence counseling, and community support strategies are critical elements of an effective program. A patient-centered approach to adherence in which the patient is an active partner in his/her health care — including patient disclosure of sero-status and support of treatment “buddies” — can lead to high ART adherence levels. Counseling needs to assist patients in identifying what will work for them given their individual circumstances, including work schedules, family interactions, etc. If effective monitoring and support systems are in place, illiteracy has a minimal effect on adherence. It is also essential to reinforce prevention measures during counseling sessions, reminding patients that they can infect partners if precautionary measures are not taken.
6
Health Management Information Systems
CHAPTER 6. HEALTH MANAGEMENT INFORMATION SYSTEMS

This Chapter covers:

- Key considerations;
- Patient and program monitoring;
- HMIS development and integration.

It is widely recognized that timely and reliable information management is essential to effective HIV care and support programs, particularly those that provide ART. In Ghana, Kenya and Rwanda, such information has provided the ART programs with a basis for determining regimen acceptability (adverse clinical events, adverse drug reactions), durability (sustained viral suppression without drug resistance), accessibility (commodities management) and adherence. It has also provided the basis for assessing program operational and implementation performance on an ongoing basis.

Effective case management of ART patients requires “real time” longitudinal treatment history data, as well as aggregated data on all patients under treatment so that general patterns of response to treatment can be assessed in a timely fashion. FHI has developed recording and reporting protocols and basic database systems to address these needs, and these protocols appear to have been successfully implemented at the ART sites in Ghana, Kenya and Rwanda. Information on operational/implementation performance is gleaned from routine program records and reports, as well as periodic evaluative surveys of facilities and service providers.

In Ghana, program staff initially relied on hard-copy clinical forms for both patient and program monitoring. Staff subsequently developed an Access-based software program, compatible with other statistical packages, that can handle large numbers of patients. In Kenya, FHI has completed a computer-based ART system, which
contains SOPs with a series of clinical forms, registers and a tracking card system, complete with instructions for information management. The package also includes a reporting form with definitions of indicators and computer program software with a user’s manual. A paper-based system was introduced in all CCCs. Over the next six months, the computerized system will be introduced in provincial hospitals; by the end of 2005 the computerized system will be introduced in a number of high-volume health facilities at district hospitals. In Rwanda, facility staff complete forms to meet the reporting requirements of various entities (MOH, PEPFAR, USAID). The forms are filled out monthly and sent to FHI’s Kigali office, which has designed a database with standard key variables — CD4, ART regimen, weight, sex, ART regimen change, etc. The sites use either Excel or EPIINFO software, depending on available skills at the sites. FHI’s data entry officer supervises the sites and regularly brings patient and program data to the country office.

**KEY CONSIDERATIONS**

The ART programs have addressed numerous considerations and strategic decisions in facilitating information support for patient and program monitoring. One issue concerned the scope of the system and the need to balance information needs with available time, skills and human resources. Another issue was defining the functions to be covered by the HMIS. At minimum, the system needed to include recording, reporting, database systems and data analysis applications for case and program monitoring. Beyond this, decisions needed to be made as to whether the system should provide real-time access to patient records and databases, what level of telecommunications support would be required, and whether the system would attempt to link facility-based and non-facility based sources of care.

The level of technology also needed to be considered. Options ranged from simple paper-and-pencil systems to technology-driven systems. Technology can overcome some infrastructural limitations found in resource-constrained settings (lack of telephone service, for one) and thus improve program operational performance. But feasibility, sustainability, cost and compatibility with existing systems needed be carefully considered.
HMIS DEVELOPMENT AND INTEGRATION

The ART programs took several steps to develop and integrate HMIS for ART patient and program monitoring. The first step was to assess existing HMIS at each site to identify needs. This was done as part of the in-depth site assessment in each of the three countries. Factors considered were ways to integrate the HMIS for ART into the existing HIV service delivery and national HMIS infrastructure, anticipated scale-up of the ART programs, and available resources. These resources include:

- **Human resources** in terms of trained staff with expertise in information technology (IT), data entry, data management, quality control, data analysis and report writing.
- **Available equipment and supplies**, such as lockable file cabinets, microcomputers, printers, diskettes, surge protectors and backup power sources;
- **Logistical infrastructure**, such as electricity supply, data management/medical records room with air-conditioning;
- **Access to support services**, such as computer maintenance support.

A next step was to design patient enrollment and follow-up forms. Certain key components needed to be standardized across programs to allow for data pooling. Other components could be designed for specific settings. At the ART sites in Ghana, Kenya and Rwanda, patient data during a reporting quarter include:

- Number of patients started on ART;
- Number of new adverse clinical events;
- Number of new adverse drug reactions;
- Number of patients who changed regimen due to drug toxicity;
- Number of patients who changed regimen due to treatment failure;
- Number of patients who changed regimen due to adverse clinical event;
- Number of patients defaulting on ART;
- Number of patients who ceased treatment due to death.

It was important to strike a balance between the information absolutely necessary to evaluate clinical outcomes and the information the programs would ideally like to have. Staff also recognized the need to make the data required consistent with existing data requirements, to the degree possible.

Designing HMIS data flow and reporting infrastructure was another key activity. Issues included how hard-copy ART patient data would be collected, checked for completeness and accuracy, collated, stored and filed, and entered into a computer, preferably on-site (if computers were indeed available). Quality control was needed to ensure timely data entry. Procedures to protect patient confidentiality were developed to ensure patient identification information is not available to unauthorized individuals. ART program staff also defined key HMIS policies and procedures in SOPs maintained at the facility and updated regularly.

When designing an HMIS for ART, program planners considered the existing organizational structure and workforce capacity and mapped out key roles and responsibilities. Given the increased workload as increasing numbers of patients began treatment, it was necessary to train sufficient staff on HMIS issues and, with the ministry of health, identify dedicated staff to manage this function. At the CCC at CPGH, the sheer volume of records has affected data capture for national and program reporting needs. While the program developed tools to facilitate manual management of data (tally sheets, spreadsheets), the labor required for this effort has interfered with timely completion of reports.

Program staff and partners also sought to integrate HMIS with the Logistic Management Information Systems (LMIS) related to commodities management. Integration — as opposed to developing parallel MIS — enhances system efficiency, allows for validity checking across MIS as a form of quality control, and allows for more robust program costing projections.
LESSONS LEARNED

Demonstrate to providers the many benefits of effective HMIS—to patients and programs.

Many staff, especially physicians, consider HMIS more of a bureaucratic burden than a tool to facilitate safe and effective ART services, optimize best clinical practices and capture important lessons. Thus, it is important to reinforce the essential role of HMIS early and often. Data should be packaged in user-friendly formats that facilitate use in case and program management. Resources for HMIS must be included in program budgets so that adequate resources are brought to bear. It is also critical to achieve consensus on minimum “common denominator” HMIS indicators to avoid parallel HMIS and minimize additional workload for physicians and other providers.

Foster a culture of rigorous data collection, recognizing that this does not come naturally to most health staff.

Program management should foster a culture of rigorous data collection at ART sites. But there is a need to balance information collection requirements with workforce capacity in resource-constrained settings — without proper data design and management planning, data collection can quickly overwhelm staff assigned to the HMIS.

Use computer technology if possible.

Computerization is not mandatory for a well-functioning HMIS but has many advantages over pencil-and-paper methods. Computers can help manage patient-specific data for longitudinal patient monitoring and outcomes research (preferable where resources permit) and help summarize aggregate patient data for program management purposes. At this point, computers can enhance, not replace paper-based systems.

Integrate the national HMIS systems into clinic-level systems.

Avoid the creation of parallel and/or duplicative systems as much as possible by examining data needs and systems for the national-level HMIS and finding ways to integrate the systems at the data collection level.
HMIS staff need to collaborate with clinical staff for optimum data quality.

Data collected needs to be monitored regularly in terms of validity and completeness. HMIS staff need to work with clinical staff to improve weak areas. For example, if HMIS staff find that certain key data are not being collected by clinical staff, they need to have a mechanism for reporting back to the clinical staff. Or, if certain data are difficult to collect from other clinical areas, then HMIS and clinical staff can work together to devise new systems. In some cases formal collaborative relationships need to be created at the beginning of the program so that communication can occur in a comfortable environment.
7
Scale-up
Scaling up successful small-scale programs to regional and national levels has long been the goal of public health efforts against AIDS, especially in regions with significant HIV prevalence. Yet too often such expansion has been limited by competition for funding, lack of political support or absence of mechanisms for broader implementation. As a result, some valuable programs have failed to grow beyond the pilot stage. This changed dramatically with the advent of ART in developing countries. Once ART became available and affordable outside of the world’s wealthiest countries, planning for introducing and scaling up HIV treatment services became imperative.

**ART SCALE-UP**

Scale-up to new sites and within initial sites was a key consideration for FHI and partners when designing the ART programs in Ghana, Kenya and Rwanda. Since 2003, these programs have expanded dramatically. The strategy has been to:

- Initiate learning sites where program systems and design could be tested and lessons learned;
- Develop standards to guide all care and treatment activities and ensure strong program management at existing and new sites; continue “growing” initial sites through training and capacity building as new resources come on line;
• Use the sites as learning centers where physicians, nurses, laboratory technicians, pharmacists, counselors and other staff from new sites can observe and absorb effective clinical and management processes;
• Create rapid start-up teams of experienced clinical staff, monitoring and evaluation experts, laboratory technicians and others who can move on to help establish new sites and transfer skills.

In February 2003, Biryogo Medical and Social Center in Kigali became the first developing-country health facility to provide ART with USAID funding. In the two years since, the program has expanded beyond Biryogo and Kabgayi District Hospital to include 10 additional sites in Rwanda (see box on page 91). The Ghana ART program, launched in May 2003 at Atua and St. Martins hospitals, has grown to encompass four sites. The Kenya program, initiated in June 2003 at CPGH, was covering 12 sites as of June 2005.

In each country, follow-on sites were established comparatively quickly with the benefit of trained clinicians (who became trainers themselves), lessons learned and availability of standard materials, such as BCC materials, laboratory equipment and reagents. In Ghana, establishing structures at Atua and St. Martins took almost one year. Preparing subsequent sites, for example, Korle-Bu and Komfo Anokye, took between six weeks and three months. In Rwanda, initial sites have served as a training ground for physicians, nurses and social workers in such areas as client selection, client education, client flow, record-keeping, ART side effects and adherence. Given FHI’s deepening relationship with the MOH ART team in each country, program staff are able to obtain authorization for new sites quickly.

SITE SELECTION AND UPGRADING

Criteria for selecting the initial sites — particularly for pre-existing HIV services — also guide program expansion. Services such as HIV testing and counseling, and preventing and treating opportunistic infections, provide a natural entry point to ART. Facilities offering HIV services are also more likely to have functioning systems in place that can absorb an ART program, as well as clinical staff capable of learning new skills.
## Scale-up in Ghana, Kenya and Rwanda (as of June 2005)

<table>
<thead>
<tr>
<th>Location</th>
<th>ART Launch Date</th>
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<tbody>
<tr>
<td><strong>Ghana</strong></td>
<td></td>
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<tr>
<td>Atua Government Hospital*</td>
<td>May 2003</td>
</tr>
<tr>
<td>St. Martins de Porres Hospital*</td>
<td>May 2003</td>
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<tr>
<td>Korle-Bu Teaching Hospital</td>
<td>December 2003</td>
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<tr>
<td>Komfo Anoyke Teaching Hospital</td>
<td>February 2004</td>
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<tr>
<td><strong>Kenya</strong></td>
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<tr>
<td>Coast Provincial General Hospital*</td>
<td>June 2003</td>
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<tr>
<td>Rift Valley Prov. Gen. Hospital</td>
<td>July 2003</td>
</tr>
<tr>
<td>St. Mary's Mission Hospital</td>
<td>January 2004</td>
</tr>
<tr>
<td>Mkomani-Bomu Clinic</td>
<td>May 2004</td>
</tr>
<tr>
<td>Port Reitz District Hospital</td>
<td>July 2004</td>
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<tr>
<td>Malindi District Hospital</td>
<td>August 2004</td>
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<tr>
<td>Kakamega Prov. District Hospital</td>
<td>September 2004</td>
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<tr>
<td>Naivasha Sub-District Hospital</td>
<td>October 2004</td>
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<tr>
<td>Amurt Health Clinic</td>
<td>November 2004</td>
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<tr>
<td>Bungoma District Hospital</td>
<td>December 2004</td>
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<tr>
<td>Casino STI Clinic</td>
<td>January 2005</td>
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<tr>
<td><strong>Rwanda</strong></td>
<td></td>
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<tr>
<td>Biryogo Medical and Social Center*</td>
<td>February 2003</td>
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<tr>
<td>Kabgayi District Hospital*</td>
<td>August 2003</td>
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<tr>
<td>Kicukiro Health Center***</td>
<td>September 2003</td>
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<tr>
<td>Ruli District Hospital</td>
<td>December 2003</td>
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<td>Gikondo Health Center</td>
<td>May 2004</td>
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<tr>
<td>Masaka Health Center</td>
<td>June 2004</td>
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<td>Nyamata District Hospital</td>
<td>October 2004</td>
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<td>Remera-Rukoma District Hospital</td>
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<tr>
<td>Byumba District Hospital</td>
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<tr>
<td>Kigeme District Hospital</td>
<td>March 2005</td>
</tr>
<tr>
<td>Ruhango Health Center</td>
<td>April 2005</td>
</tr>
<tr>
<td>Gitewe District Hospital</td>
<td>May 2005</td>
</tr>
</tbody>
</table>

* Initial ART site (pilot phase)
** FHI is also supporting ART services at Kenyatta National Hospital in Nairobi.
*** In February 2005, after enrolling 453 patients at Kicukiro Health Center, the ART program transferred management of this site to Columbia University.
Expanding to sites with existing HIV programs has another advantage: local and regional authorities have at least some familiarity with program needs and have seen the benefits of supporting AIDS-related activities in their areas. They are more likely to understand ART and help win the support of the local population.

Once appropriate expansion sites are identified, FHI teams conduct in-depth assessments, collecting information on:

- Human resource capacity (number and level of training in HIV and related conditions);
- Physical infrastructure and supplies, including clinical, laboratory and pharmacy;
- Availability and use of clinical guidelines/protocols;
- Current HIV management practices;
- Types of services provided to PLHA;
- Pharmaceutical and laboratory management systems;
- Capacity and functionality of health information systems.

Based on the findings, FHI teams and facilities develop implementation plans and budgets to prepare sites for ART service delivery. This entails upgrading infrastructure (counseling and treatment rooms, laboratories, pharmacies), developing SOPs and protocols tailored to individual sites, training health workers, and integrating ART into HMIS. These efforts generally follow the process described in Chapter 3; with the benefit of lessons learned at the initial sites, preparation of expansion sites can occur relatively rapidly.

Preparing clinical, laboratory and pharmacy staff to take on the considerable demands of an ART program is a prime scale-up activity. While each country manages training somewhat differently, all have used the initial sites as training centers for health workers at expansion sites. In addition, experienced “start-up teams” and staff from established sites provide on-site training at expansion facilities. In Rwanda, where clinical staff
shortages are particularly acute, FHI has seconded staff clinicians to provide on-the-job training and provide services. Motivating clinical staff — often chronically overworked and underpaid — to take on these new responsibilities, which increase significantly when ART services begin, is also an important scale-up task. Access to clinical consultation, mentoring and continuing education have contributed to staff motivation, as well as increased capacity to provide ART services. In Kenya, for example, physicians and nurses receive additional ART training through a twinning arrangement with New York University.

**LESSONS LEARNED**

**Consider staff commitment when selecting expansion sites.**

Commitment of health workers is a key factor in selecting expansion sites. If staff are not motivated to do the extra work, there is little chance for success. It is important to develop human resource strategies to retain staff, especially physicians and nurses, who have a high attrition rate. Program planners must also temper the expectations of health workers, who may not fully appreciate the complexities of HIV treatment and may believe dispensing drugs is all that is required to implement a successful program. They must be prepared for a major influx of clients seeking ART and related services. It is important to seek agreement from the ministry of health to defer transfer of clinicians trained in ART to other health facilities, at least for a period of time.

**Train nurses to handle key ART tasks to relieve the burden on physicians.**

Integrating ART into existing services can add significantly to the workload at health facilities. Nurses are an indispensable resource in carrying out new responsibilities. In addition to patient triage and adherence counseling, nurses can assume broader clinical responsibilities with proper training, including coordinating care services, managing adverse drug effects and providing leadership for the HIV team, thereby freeing doctors to treat more patients or start ART at more than one clinic. To address nurse shortages, it helps to involve nurses at primary health facilities and with community-based services, who often have experience interacting
with and caring for PLHA. They can be trained to identify potential candidates for ART, manage side effects and make referrals. All cadres of health workers generally require hands-on training, in addition to classroom instruction, to prepare them for the rigors of an ART program.

**Involves stakeholders to reduce stigma and discrimination.**

As described in Chapter 2, community preparedness is essential to the success of an ART program. Early in the expansion process, it is critical to engage communities in the planning and design of services. Promoting local “ownership” of ART programs by, for example, engaging stakeholders in establishing eligibility criteria, increases local support. Indeed, stigma and discrimination often decrease in communities with ART programs. As more PLHA frequent health centers and hospitals, they get to know each other and become less afraid of identifying themselves as PLHA. They also interact increasingly with other patients who are not infected.
8

Patient Response to ART
CHAPTER 8. PATIENT RESPONSE TO ART

This Chapter covers:

- Patient characteristics;

By the end of April 2005, approximately 18,000 new patients were managed for HIV clinical care at FHI-supported sites in Ghana, Kenya and Rwanda. Of these patients, 5,805, or more than 30 percent of those in clinical care, initiated ART.

PATIENT CHARACTERISTICS

Women comprise the majority (62%) of ART patients in all three country programs. Through April 2005, female clients accounted for 59 percent of all patients who initiated ART through the Ghana program, 61 percent of all patients who initiated ART through the Kenya program, and 65 percent of all patients who initiated ART through the Rwanda program.

The median age of patients on treatment has been relatively uniform across the three countries—40 years in Ghana, 38 years in Kenya and 37 years in Rwanda. The vast majority of
patients on ART at the FHI-supported sites are adults. However, pediatric clinical care and treatment are expanding as focused efforts to implement the essential programmatic elements for treating children are intensified, including training of pediatricians and pediatric nurses, procurement of pediatric ARV formulations and the evolution of a family-centered model of care.

**SNAPSHOT OF PATIENT RESPONSE TO TREATMENT**

Through April 2005, patients on ART experienced 442 new adverse clinical events (“untoward medical occurrences”) and 667 new adverse drug reactions (“unintended responses”). Patients experienced side effects generally consistent with the drug regimens: high cases of peripheral neuropathy with the Stavudine regimen in Kenya and Rwanda; high cases of rash with the Nevirapine regimen in Kenya and Ghana; and high cases of severe anemia in Ghana where Combivir is included in the first-line regimen. Among patients who changed drug regimens because of adverse clinical or drug effects, 114 patients (60%) changed regimens because of toxicity, 23 (12%) switched because of treatment failure and 53 (28%) changed because of an adverse clinical event. At the end of April 2005, 187 children were on ART at the FHI-supported sites in the three countries. At the end of April 2005, 42 patients in the three countries had defaulted on treatment, and
228 had died. The default rate, representing less than 1 percent of those who started ART, suggests that patients are highly committed to treatment and that ART adherence protocols implemented at the FHI-supported sites are being rigorously observed. Deaths comprised approximately 4 percent of those on treatment, which may be associated with the advanced stage of a significant number of patients when treatment was initiated. For example, 15 percent of patients new to HIV clinical care in Ghana in 2004 were diagnosed at WHO Clinical Stage IV. In aggregating defaults and deaths across the three countries, more than 95 percent of patients who started ART continued on treatment.

Overall, immunologic (CD4 count) and clinical responses (weight gain, reduction in opportunistic infections) have been positive, and very few patients have discontinued treatment. FHI studied a subset of patients who had completed at least six months on ART to assess immunologic and clinical responses. In Ghana, the median CD4 count increased from 108 at baseline to 234; in Rwanda, the median CD4 increased from 134 to 225.

Clinical responses have also been encouraging. Median weight of patients increased from 51 to 58 kilograms in Ghana, from 56 to 62 kilograms in Kenya, and from 53 to 56 kilograms in Rwanda.
Beyond Statistics

Dominic, 39, receives ART at St. Martins de Porres Hospital in Manya Krobo District, Ghana.

I am a self-employed electrician, married to a beautiful trader and we have a 15-year-old son. I am a Krobo and live in the Yilo Krobo District… I will say that ARVs are very useful and they really work. I had lost weight and completely lost all my body hairs and hated looking in the mirror since I didn’t like how I looked. However, I now confidently admire myself in the mirror with great disbelief as I look at my figure after starting ARVs. I have put on weight and now have fresh dark hairs on my body. My wife [also HIV-positive] is always amazed about it, and she sometimes gets disappointed that she hasn’t started her drugs yet. The adherence counselor and, at times, the doctor visit us at home and this gives us a lot of joy knowing that they really do care for us. We know that we are not the only people infected with HIV in our town. We shall do everything it takes and look forward to better times in the future by taking my drugs and we will still be a happy couple.

—Dominic

Eliza, 43, was one of the first people in the developing world to initiate ART with USAID funding. She receives treatment at the Biryogo Medical and Social Center in Kigali.

I’m ready for every occurrence, as long as I can increase my life by a few or many years, because my three young children need me. Even the ones who are married still need me. I just want to thank Biryogo [Medical and Social Center], which initiated this program of free medication. I can come back to work now that I feel strong again, starting maybe two days a week and then increasing the number of days depending on my strength. Also, I want to advise other people who have AIDS not to despair, but to be strong and have hope. If necessary I will give them testimony how the medication helped me. I will tell them that my life is going on, and how grateful I am toward Biryogo and toward God, who is working miracles for me.

—Eliza
For another major indicator of clinical response, the incidence of opportunistic infections, the percentage of patients on ART with candidiasis, chronic diarrhea, herpes zoster, Kaposi’s sarcoma and tuberculosis dropped sharply between baseline and the six-month clinical follow-up. The slight increases reported in cryptococcal meningitis and pneumonias are likely attributable to improved clinical diagnosis.

**LESSONS LEARNED**

*Analyze patient responses carefully to enhance case and program management.*

Routine collection and analysis of patient response data is essential to the effective management of ART patients and programs. For example, ARV drugs are ordered according to the patient’s regimen. Thus, it is imperative to know the proportion of patients still on a certain regimen, who changes one or more drugs, who ceases treatment, etc. It is also critical to know the type of side effects and drug toxicity experienced by patients in order to adjust ART educational sessions and materials. Further, when regimens fail it means resistance to certain drugs has developed. This leads providers to change to a more effective regimen, which has implications not only for the patient, but for program management as well (drug procurement, supply sources, costs, etc.).
**Foster strong interpersonal relationships between clients and service providers.**

Perhaps the most important factor contributing to high adherence rates has been the strong partnership that has developed between ART patients and service providers. This has been observed at all learning sites in Ghana, Kenya and Rwanda, where participating providers have proven both technically strong and compassionate. Nurses have also been very client-focused. In Ghana, for example, nurses make home visits when concerned about patients, even during off hours.

**Strengthen links between health facilities and community-based programs, including home-based care and PLHA support groups.**

In Ghana, Kenya and Rwanda, strong links between health facilities and community-based programs, particularly home-based care and PLHA support groups, have contributed to high ART adherence rates. Together, adherence counseling, SOPs (including the pre-treatment protocol), disclosure to a “buddy” and regular follow-up by home-based care and PLHA groups helped achieve an adherence rate of well over 95 percent through April 2005. Of the 5,805 new patients who initiated treatment during that period, only 42 defaulted or were lost to follow-up (226 patients ceased treatment due to death). As a result, immunologic and clinical responses have been impressive. Patients recognize the immense value of ART to their lives — and to the lives of their families — and will adhere to the medications with proper support.
9

Operations Research
CHAPTER 9. OPERATIONS RESEARCH

This Chapter covers:

- Operations research issues related to ART;
- Stakeholder involvement in research planning;
- Formative assessment and research design;
- Research initiation;
- Research and service integration.

OPERATIONS RESEARCH ISSUES RELATED TO ART

During planning of the Mombasa learning sites, USAID and FHI identified operations research (OR) as a key component of the program, to be carried out in tandem with ART service delivery. To manage the OR component, they turned to the Horizons Program of the Population Council, which already had formulated a list of priority research topics related to HIV treatment: health systems; adherence and sexual behavior; equity and accessibility; community involvement; cost and cost effectiveness; human rights; and stigma and discrimination. Horizons reviewed these topics, developed a set of potential OR questions for the planned sites (CPGH, Port Reitz District Hospital, and the Bomu and Magongo health centers) and enlisted the International Centre for Reproductive Health (ICRH), based in Mombasa, to conduct the research.

STAKEHOLDER INVOLVEMENT IN RESEARCH PLANNING

At the inaugural stakeholders meeting for the Mombasa ART program, convened in April 2002, OR was the subject of a special session. Horizons and ICRH led discussion of OR in the program setting, research methodologies and possible research topics for the planned sites. Stakeholders identified ART adherence as a critical
topic, given its role in treatment success and its potential bearing on the spread of resistant strains of HIV. They also cited cost and cost effectiveness, the relationship between ART and sexual behavior, the impact of ART on uptake of HIV testing and counseling, and the effect of stigma and discrimination on service delivery. Horizons and ICRH used this session as the basis for OR planning. The Scientific Committee established at the stakeholders meeting was tasked with reviewing and approving OR activities.

Following the April 2002 meeting, Horizons and ICRH continued to define the OR component with members of the Scientific Committee and others, including Ministry of Health officials and providers at the planned sites. Jointly, they decided to study the viability of a modified directly observed therapy (DOT) strategy to promote ART adherence. In the context of tuberculosis, DOT entails observing all dose-taking for the duration of treatment — six to nine months. This is impractical for ART, since multiple doses of medication must be taken for life. A modified strategy involves observing some doses every week for a fixed duration. Planners believed this could help ART patients through the initial period when they are at elevated risk of defaulting because of side effects, while fostering good drug-taking habits for long term.

A modified DOT or intensive follow-up strategy requires frequent contact between patients and health workers. This can be achieved in two ways: frequent patient visits to health facilities or frequent health worker visits to patients’ homes. The success of either approach depends on patient acceptability and health worker support. Is an intensive follow-up or modified DOT strategy acceptable to PLHA? Would PLHA prefer visiting health facilities or having health workers visit them at home?

**FORMATIVE ASSESSMENT AND RESEARCH DESIGN**

Prior to designing the OR study, Horizons and ICRH conducted formative research to elicit PLHA and health worker views on a modified DOT strategy for ART. Specifically, researchers sought to understand patient acceptability of facility- and home-based approaches, potential barriers to each, and issues related to disclosure and stigma. Researchers also explored the willingness of PLHA to discuss the economic impact of ART on the household.
Horizons and ICRH conducted the formative assessment in Mombasa during August 15–September 15, 2002. The Scientific Committee approved the protocol and data collection instruments. Data collection techniques included in-depth interviews, focus group discussions and key informant interviews among convenience samples of PLHA and health workers. Researchers interviewed 38 PLHA, 31 health workers from six facilities providing HIV/AIDS care services in Mombasa, and five key informants.

The formative assessment provided interesting findings. Contrary to expectations, there was an overall preference for facility-based follow-up. Findings highlighted the importance of confidentiality, quality of care and the need to feel in control as factors influencing PLHA preference for follow-up in health facilities. Health workers identified practical strategies to foster acceptability of frequent follow-up of PLHA on ART. The workers saw the assessment as consultative and participatory, which generated a sense of ownership.

Based on these findings, Horizons and ICRH designed an OR intervention study to test a directly administered ART (DAART) strategy to promote ART adherence. Nested observational studies on stigma and discrimination, high-risk behavior, and cost and economic impact were included. To ensure the study was integrated into service delivery, pharmacy services and patient preparation and follow-up, the research team finalized the design in partnership with provincial and municipal health officials, implementing partners, providers at the planned sites and community health workers. The research protocol was discussed with and approved by the Scientific Committee and the Provincial Medical Office.

The OR intervention study is a prospective randomized controlled study comparing DAART as a strategy to promote ART adherence (intervention group) with standard self-administration of ART (control group). Patients in both groups receive adherence counseling as part of standard care in an HIV treatment program. In the intervention group, patients are required to visit a facility-based DAART observation site close to their home twice a week for six months to collect medications and be observed taking doses. For routine treatment monitoring, these patients are required to visit the treatment site once a month, as are non-study patients. In the control group, patients visit the treatment site only once a month for routine monitoring.
To address barriers to frequent facility visits highlighted in the formative assessment, three strategically located satellite health facilities, one in each geographic zone, were included as observation sites. These were the Bamburi, Likoni and Mkomani health centers. These sites, plus the four ART learning sites (CPGH, Port Reitz District Hospital, and the Bomu and Magongo health centers), gave patients seven observation sites to choose from, enhancing convenience. The possibility of early opening hours at centers was added for employed patients. A tracer system using community health workers linked to health facilities was included to address patients unable to visit the health facility when unwell or defaulting. For the duration of the study, medications for patients in the DAART arm, to be collected by patients at the observation sites, are pre-packaged centrally at CPGH and delivered to the sites once a week.

RESEARCH INITIATION

Research projects require extensive planning, networking, partnerships, negotiations and timely intervention. While some aspects may take a relatively short time, others, such as getting required approvals, identifying human resource requirements, developing data collection tools and conducting training, may take much longer. Early planning and action is key.

Ethical Approvals

Prior to initiation, most research projects involving human subjects require approval from ethical review boards (ERB). Horizons submitted the proposal for the DAART intervention study to the Population Council’s Institutional Review Board (IRB), the Kenyatta National Hospital Ethics and Research Committee, and the Kenyan Ethics and Review Committee (ERC), as well as the Scientific Committee and the Provincial Medical Office. By August 2003, these bodies had approved the DAART intervention study, along with the nested studies on stigma and discrimination, high-risk behavior and cost and economic impact analyses. ART service delivery began at the end of June 2003.
**Human Resource Requirements**

Integrating research into service delivery requires carefully selecting a research team. While service delivery staff or health workers are suitable for certain types of related activities (access to clinical data, medical interventions), external research staff may be required for other research activities (evaluation, handling of such sensitive topics as sexual behavior, client satisfaction and stigma).

In the interest of capacity building, sustainability and research integration, adherence nurses were asked to collect data and information pertaining to adherence (baseline and follow-up adherence questionnaires). Research assistants/interviewers based at the learning sites were asked to collect data pertaining to client satisfaction, high-risk behavior, stigma and cost and economic impact. Health workers at the satellite observation sites — the Bamburi, Likoni and Mkomani health centers — were asked to collect DAART service statistics and data.

**Data Collection Tools and the Adherence Training Manual**

For the DAART intervention study, multiple data collection instruments are needed at different points of the research period. Horizons and ICRH developed data collection instruments in a phased manner; those required for research initiation were developed, adapted and piloted while the Kenyan ERC was still reviewing the study proposal. As a result, patient recruitment could begin quickly once approval was received. Data collection instruments to be applied at midterm and end of study were developed over the following months, based on initial research findings.

Because no formal training tool for adherence counseling was available, Horizons developed an *Adherence Training Manual* for adherence counselors, drawing on best practices from New York State medical services, University of Florida training programs, the World Health Organization HIV testing and counseling manual for Asia, and other resources. Horizons submitted the manual, along with checklists for use at the learning
sites, to the Scientific Committee for approval. A preliminary version of the manual was approved in time for a health worker training in April 2002. The training manual was revised and finalized following research initiation.

RESEARCH AND SERVICE INTEGRATION

In the ART program, OR had to be conducted within the existing health system and in tandem with service delivery. Thus, the OR study (adherence counseling and DAART) was developed alongside and in close collaboration with ART service planning. The study design is closely integrated with ART services (adherence counseling is an essential part of service delivery). Adherence nurses provide pre-treatment and ongoing counseling to all patients receiving ART, including those participating in the DAART study. The DAART study has also been linked into the program: Patients randomized to the DAART group are followed at health centers that serve as observation sites where patients collect their medications twice weekly. Pre-packaging of medications for patients in the DAART arm has been integrated into pharmacy functions and drug delivery and DAART observation integrated into health center functioning. During a recent review of the program, adherence nurses and pharmacy staff from CPGH expressed that the DAART study is fully integrated into service delivery and program implementation. A positive spin-off from DAART observation at peripheral health centers has been the initiative taken by the DAART teams to link with COPHIA food-donation programs that provide grain and oil rations as additional support for needy patients and their families.

KEY FINDINGS

Key findings to date include the following (final study results are expected in June 2006):

- Most clients disclosed their HIV status within the family but not in the community.
- Most clients were willing to take ARV drugs if available, but felt they did not need any help taking the medications.
- Health workers felt that follow-up at the clinic and at home would be acceptable to most clients, although they cited barriers to both options.
- Clients preferred facility-based to home-based follow-up.
- Clients see family members as important sources of assistance and support.
- Support groups were not well known by clients, but most were willing to have members visit them at home to help with taking medications.
- Most respondents were willing to pay for drugs but not for monitoring tests.

**LESSONS LEARNED**

*Include OR research in program planning.*

Including OR from the start of program planning has been instrumental in integrating research within program implementation. Early discussions on OR helped in refining the research design in the context of program implementation, in mobilizing resources to conduct research and in increasing acceptability among health workers, program planners and implementers.

*Involv[e] stakeholders.*

Stakeholder involvement is crucial to the acceptability and success of research programs. As numerous stakeholders may be active in the research area, it may be useful to set up smaller committees with key officials for effective processing and management of the research program. Including all stakeholders in an initial discussion, followed by closer interaction with smaller committees, played a major role in successfully initiating the research project in Mombasa. Constant updating and additional meetings with key members of the Scientific Committee, municipal health departments and hospital administrators was key to finalizing the research proposal and intervention.
Conduct formative research to guide study design.

Formative research on the acceptability of a modified DOT strategy to promote adherence was invaluable in finalizing the research study design and proposal. Formative assessment provided the research team with evidence-based information on acceptability and barriers, which facilitated the discussions on research design and proposal development with the Scientific Committee and program implementers.

Seek early approval of the Ethical Review Board.

ERB approval is required for any research involving human subjects. Obtaining ERB approvals is often a lengthy process as most boards have fixed dates for meetings. Erring on the side of caution and seeking ERB approvals early prevents delays later. Subsequent changes in the proposal can be submitted as protocol amendments.

Train health staff to collaborate in operations and applied research as well as provide services.

The quality and effectiveness of health interventions benefit from informed practice-to-research and research-to-practice initiatives. While clinical and other program staff are often far too busy to engage in research on a regular and systematic basis, their understanding of and participation in operational and applied research designed to inform program improvements are important if such research is to “make a difference” in programs. Training forms the backbone of interventions and research, impacting the quality of services delivered and research conducted. A key lesson learned in Mombasa was that training should be conducted as close to launch of the intervention as possible, with plans in place for “ongoing-need-based-incremental” training. In most OR projects, interventions go hand-in-hand with research, necessitating special or dual training for service delivery staff working in research. Staff should be appropriately trained and encouraged to participate in the work underway — especially testing new approaches, evaluating them and incorporating them into program activities.
References
REFERENCES


COVER PHOTOS  Top row, left to right: ART adherence counseling at Kabgayi District Hospital, Rwanda (Deborah Murray/FHI); Queen-mothers at ART program launch, Manya Krobo, Ghana, February 2002 (Trad Hatton/FHI); Women’s acute-care ward at St. Mary’s Hospital, Mumias, Kenya, September 2004 (Steve Taravella/FHI). Bottom and back: Traditional leaders at ART program launch, Manya Krobo, Ghana, February 2002 (Trad Hatton/FHI).

CHAPTER DIVIDER PHOTOS  Introduction: Queenmothers at ART program launch, Manya Krobo, Ghana, February 2002 (Trad Hatton/FHI); Chapter 2: Dr. Kwaku Afrisie, then Minister of Health, Ghana, at ART program launch, Manya Krobo, February 2002 (Trad Hatton/FHI); Chapter 3: Traditional leaders at ART program launch, Manya Krobo, Ghana, February 2002 (Trad Hatton/FHI); Chapter 5: Dr. Dominique Rwakunda, medical director, Kabgayi District Hospital, Rwanda, overseeing construction of the facility’s ART clinic, June 2003 (Robert Ritzenthaler/FHI); Chapter 4: Traditional leaders at ART program launch, Manya Krobo, Ghana, February 2002 (Trad Hatton/FHI); Chapter 6: ART register, Kenya ART program (Steve Taravella/FHI); Chapter 7: Comprehensive Care Center at Rift Valley Provincial General Hospital, Nakuru, Kenya, September 2004 (Steve Taravella/FHI); Chapter 8: ART patient at Biryogo Medical and Social Center, Kigali, Rwanda, June 2003 (Robert Ritzenthaler/FHI); Chapter 9: Women’s acute-care ward at St. Mary’s Hospital, Mumias, Kenya, September 2004 (Steve Taravella/FHI).
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