As HIV treatment programs are implemented across the developing world, increasing numbers of HIV-infected persons are being treated with highly active antiretroviral therapy (HAART). For these people, the challenge has changed from gaining access to life-saving treatment to taking it correctly and consistently in order to realize the rewards of improved health status, and reduced morbidity and mortality from HIV. To achieve these health goals patients are required to take greater than 95 percent of their medications. Adherence to HAART is a challenge and various interventions to promote adherence are being developed and tested.

In Kenya, researchers from the Horizons Program and the International Center for Reproductive Health, in collaboration with Coast Province General Hospital (CPGH), Mkomani Bomu Clinic, and Port Reitz District Hospital (PRDH), have developed a health-facility based, directly administered antiretroviral therapy (DAART) strategy to promote adherence. The strategy builds on formative research findings from health workers and HIV-positive clients of HIV/AIDS care services. It also reflects field experiences in promoting adherence to medications to treat tuberculosis (TB) through directly observed therapy (DOT).

A six-month evaluation of the DAART strategy shows that a significantly higher proportion of patients exposed to DAART consistently achieved greater than 95 percent adherence compared to those receiving standard care (Sarna et al. 2005). This paper describes the DAART strategy, its successes and challenges, and client feedback on the intervention.

The DAART Intervention

DAART was developed as a facility-based intervention to promote adherence to HAART in Mombasa, Kenya. The intervention was designed to provide support to patients, foster responsible treatment-taking behavior, and enable close supervision of the patient during the first few months of initiating HAART. Because health workers observe patients taking only some doses of medication, DAART is more a behavioral intervention to build confidence and self-efficacy rather than a policing activity that ensures 100 percent patient compliance with treatment.

All patients who initiate treatment with HAART through the public sector do so at hospitals that are designated as treatment sites, which are equipped with trained physicians and laboratory facilities. Subsequently, clients visit these treatment sites every month for treatment follow-up and to receive formal treatment-related adherence counseling by trained adherence counselors.
This study required patients in the DAART group to visit a health facility, designated as an observation site, to collect medications two days a week (Monday and Thursday) and take one dose of medication in the presence of a DAART observer. The duration of the DAART intervention was fixed at approximately six months (24 weeks) to coincide with the short-course TB treatment provided at health facilities. Like all patients receiving HAART, DAART patients were also required to attend monthly medical follow-up visits, which included a consultation with a doctor and laboratory checkups, at the study's designated treatment sites: CPGH, Mkomani Bomu Clinic, and PRDH.

The DAART observation sites were selected to cover the entire district, thus facilitating patient access. The facilities included the three treatment sites (CPGH, Mkomani Bomu clinic, and PRDH) plus three additional peripheral health centers (Bamburi Health Center in Kisauni, Likoni Health Center in Likoni, and Magongo Health Center in Changamwe). Of these six sites for DAART observation, patients were allowed to choose one; however, they were allowed to change sites if needed.

**DAART Observers**

DAART observers were health workers, mostly nurses, who worked at the health centers. DAART observation was done in a room that was always accessible, so that observation was possible even early in the morning or late in the evening for clients who were employed. A convenient place for observation was a room close to the maternity clinic or a casualty room because these facilities are always open and staffed at all times. VCT rooms were also selected as places for observation. More than one DAART observer was trained at each observation site to cover for the other if needed. DAART observers were in regular contact with adherence nurses at the treatment sites.

**Dispensing ARV Medications**

At the time the intervention was initiated, medications were very expensive brandname drugs that were in short supply, and the issue of drug safety was of great concern as was the need for rigorous accounting of the drugs used for research purposes. Medications were pre-packed at CPGH specifically for each client and transported to DAART observation sites where they were stored for patient use. Sealed pre-packed bottles of medications were transported to the observation site and stored in a locked cupboard on site that was accessible only to specifically designated health workers. Pharmacy rooms were reinforced with grills and cupboards. With expanding access and rolling out of antiretroviral therapy programs in Kenya, the medications can now be dispensed directly from pharmacies at observation sites, just like any other medications, thus obviating the need to pre-package and transport these drugs.
Tracing Defaulters

A system for tracing defaulters was easily put in place because Mombasa already has a well-established home-based care system with a cadre of volunteer community health workers (CHWs) who provide care and support to HIV-infected persons in the community. Most health centers already had strong links with local CHWs, and this link was strengthened by expanding the duties of the CHWs to include verifying the addresses of patients once they started HAART and tracing any patients who missed appointments. CHWs also delivered medications to the homes of clients who were too sick to visit the observation sites; a limit of three visits by CHWs for this purpose was permitted, following which clients were expected to visit the hospital. CHWs were provided a token allowance of 1,000 Kenyan shillings per month (approximately US$13.50) plus matatu (local transportation) expenses of 50 Kenyan shillings per tracing (approximately US$0.65). CHWs were also called upon to trace patients from the non-DAART arm who failed to keep their clinic appointments.

Patient Experiences with DAART

Patients participating in the DAART intervention were interviewed at the end of 24 weeks to explore their views about DAART, reasons for missed visits, and satisfaction with DAART services. A total of 116 patients were enrolled in the DAART intervention; 94 persons were interviewed after they had completed approximately six months of DAART. Service data on the DAART intervention was also collected to evaluate the intervention. Findings from the patient interviews and the service statistics are presented below.

Clients preferred to use treatment sites as DAART observation sites, as well as sites close to their homes.

Patients were allowed to select a DAART observation site of their choice out of six possible sites. Sixty percent of patients who initiated DAART (72/116) selected a treatment site as their DAART observation site: 41 patients used CPGH, 27 used Bomu, and 4 used PRDH. Forty percent selected peripheral sites for DAART: 11 patients were followed at Likoni, 16 at Bamburi, and 17 at Magongo Health Centers.

Patients were asked to provide reasons why they selected a particular DAART observation site; multiple responses were permitted. The most commonly cited reasons were the site's proximity to their home (69 persons), the quality of health care at that site (16 persons), a recommendation by a health worker (15 persons), familiarity with the center (12 persons), and the site's proximity to their workplace (10 persons). Convenience, confidentiality, knowing a health worker on site, sympathetic staff, and financial reasons were mentioned by 12 persons altogether.
The majority of patients made 90 percent or more of expected DAART visits.

The DAART intervention required patients to make a total of 48 visits over 24 weeks of follow-up to DAART observation sites to pick up their medication and be observed taking a dose. Arrangements were made to provide medications to patients who wanted to travel out of Mombasa.

Service data from DAART sites show that 59 percent of DAART patients who completed 24 weeks of follow-up (n = 94) were able to attend 90 percent or more of DAART visits, 16 percent attended between 80 to 89 percent of required visits, 20 percent attended between 50 to 79 percent of the visits, and 4 percent attended less than half of the visits.

On self-report, 62 percent of patients reported attending 100 percent of DAART visits. Among those who missed visits, reasons cited were traveling away from home (n = 12), being too sick to attend (n = 8), transportation problems (n = 4), other commitments like a job (n = 4), and DAART observation not available on holidays (n = 2).

"I missed visits as I had gone for a funeral for one week, hence missed two days but I had carried enough medicine since I had told the nurse."  
35-year-old female patient

"It was public holiday and also I didn't go once. The tracer brought for me drugs at home."  
36-year-old female patient

"I was sick for only two days."  
40-year-old male patient

Interestingly, fewer DAART patients reported missing their monthly follow-up visit to the treatment sites compared to non-DAART patients. Eighty-two percent (n = 77) of patients in the DAART arm said they attended all six monthly visits compared to 37 percent (n = 36) of non-DAART patients.

Most clients had no transportation problems getting to the treatment and observation sites.

At the start of the DAART intervention, transportation issues were expected to be a major hurdle for patients. Three quarters (71/94) of DAART patients reported using matatus to reach the observation site. Nearly a quarter (21/94) walked to the DAART observation clinic, and two percent (2/94) used a bicycle.

Clients were asked if they had transportation problems; nearly three fourths (67/94) of clients reported having no problems. Of the 27 patients who reported transport difficulties, 18 reported financial constraints while seven patients reported non-availability of matatus due to strikes. A total of 21 clients were provided assistance with transportation amounting to 50 Kenyan shillings (approximately US$.65) per visit; 17 clients needed assistance for all visits. There was some overlap between genuine need and patients requesting assistance after hearing from others that assistance was being provided.

"Sometimes I could walk when I did not have fare."  
42-year-old female patient

"Sometimes I lacked bus fare but later fare was provided by researchers."  
40-year-old female patient

"I had problems once when the matatus went on strike."  
44-year-old male patient
Decentralizing the dispensing of ARV medications to health centers in the community would improve access for clients, facilitate the implementation of DAART, and reduce transportation problems.

**Community health workers played an important role in promoting patient adherence and their home visits were well accepted by clients.**

CHWs were linked to DAART observation sites to provide support with verifying addresses of patients, tracing defaulters, delivering medications to very sick clients, conducting unannounced pill counts, and collecting information about patients who died at home. Almost all clients (96 percent) reported home visits by CHWs; 42 percent of DAART clients reported more than three visits, 32 percent reported two to three visits, and 22 percent said they received one visit.

Data from service statistics show that a total of 378 home visits were undertaken by CHWs, an average of four visits per client over 24 weeks. In 43 percent of the visits, the CHW’s sole purpose was to take medications to the client.

Overall, home visits by the CHWs were well accepted:

- *No problem, I looked forward to her visits.*  
  33-year-old female patient

- *No problem, because I treated her like any other visitor, so nobody paid any attention.*  
  32-year-old female patient

Only one client reported being uncomfortable with tracer visits:

*My husband questioned me on why the CHW was visiting me since she is well known in my area. I preferred not to have her visit me again.*  
44-year-old female patient

**DAART health workers helped link clients with community support services.**

During clinic and home visits, health workers (DAART observers and CHWs) did more than just observe medication intake and promote adherence. Many took it upon themselves to play a larger role in providing social support to their clients. Twenty-six clients reported that health care workers provided them with information about community support services and linked them to PLHA groups, ten clients were linked to home-based care services, nine clients were linked to Catholic Relief Service’s food donation program, and three clients to church groups.

**Most clients had very positive opinions of the DAART intervention.**

When clients were asked what they liked about the DAART intervention, 87 percent of respondents reported finding DAART very helpful. Clients cited a variety of reasons, the most common being that DAART helped with taking medications (26/93) and offered helpful counseling and time to socialize with health workers (21/93). Other reasons were that DAART provided an opportunity to meet and share experiences with other HIV-positive persons receiving HAART (13/94), which happened spontaneously when patients were waiting to be observed, and that the treatment and observation sites were close to home (6/93). Some reported liking everything about DAART (7/93). Twelve clients (13 percent) reported not liking anything about DAART.
DAART has helped me take my drugs regularly. Besides, I was able to meet the doctor any time I wanted to [at the treatment site].

56-year-old male patient

Going helped me get advice on any medical condition I had. I would have liked to go on with the DAART program.

58-year-old male patient

It [centre] was near home so I could even walk when I didn't have fare.

36-year-old female patient

It reduced my anxiety about drugs. I got used to taking drugs. Also the drug dose timing; I was able to follow the time strictly.

33-year-old male patient

Met other people and made friends. Also heard other people's experience and shared mine.

59-year-old female patient

Clients were asked to report what they did not like about DAART. The most common answers were competing commitments (10/94) and that the duration of the program was too long (9/94). A few said that it was too time-consuming (4/94) and that health workers were not always available (3/94). Only one person cited transportation problems. It is interesting to note that 60 percent (56/94) of clients reported liking everything about DAART in response to this question.

[It was] tiring, was late to work.

28-year-old female patient

I wasted a lot of time. I could not do my personal work effectively.

39-year-old male patient

Fare was an issue sometimes, such that I could not come to the DAART site.

26-year-old male patient

Everything. It is expensive, cumbersome, people ask why I go to hospital every day. I didn't like it at all.

48-year-old female

Clients did not specifically mention waiting time as something that they did not like about DAART. Clients reported waiting an average of 17.2 minutes (median 15 minutes) to be seen by a DAART observer.

When asked specifically about the duration of the DAART intervention and the twice-weekly visits to the health facility, 45 percent of clients said the duration was all right and a similar proportion (43 percent) reported that the duration was too long. Interestingly, 13 percent of clients reported that the duration was too short.

When asked how DAART could be improved, the suggestions focused on reducing the number of visits and shortening the program.

If they could make it once weekly it would be better. It is also good to have more than one health worker doing the observation.

32-year-old female patient
**DAART follow-up should be once a week; this is manageable for the employed people.**

39-year-old female patient

**Reduce the six months to at least three months because six months twice a week can really cause financial constraints on other individual obligations.**

46-year-old female patient

DAART health workers felt the program succeeded in helping patients adhere to HAART.

DAART observers, CHWs, and pharmacists also provided positive feedback about the program.

*DAART is very beneficial; we have been able to reach patients with difficulties with adherence. It assists the patients with low literacy level to adhere as they take quite some time to understand. Sometimes patients make very big mistakes at home and we get a chance to correct them before these mistakes go far.*

Pharmacy technologist, Bomu Clinic

*It has encouraged my patients to be open and they are doing very well now. DAART has improved the patients’ status and they can do their work without having to depend on their relatives. DAART has really helped the patients to remind them of their drug intake especially those patients with poor memory or those with an unsatisfactory social support system; it has helped the patients to swallow the drugs on time.*

DAART observer, Likoni Health Centre

*DAART should continue, to enable close follow-up of some of our patient who have problems taking their pills. It is very unfair to let a confused patient go home alone if for sure this patient has no one or may just have little children at home.*

DAART observer, Likoni Health Centre

Challenges highlighted included staff shortages (especially a problem when too many clients came in at the same time), the need for transportation allowance for very poor clients traveling long distances, and the cost in time and money for pharmacists at CPGH to pre-package the medication and send it out to the other sites to ensure a secure supply.

**Conclusions and Recommendations**

Although DAART was successfully incorporated into service delivery at peripheral health centers and was well accepted by clients and health workers, several challenges to implementation became apparent. These included the time and resources involved in pre-packaging the medication at CPGH to ensure drug security, staff shortages, and the costs of providing transportation to poor clients. Decentralizing the stocking and dispensing of antiretroviral (ARV) medications to peripheral sites in the community would normalize ARV delivery such that it would be like any other medication dispensed from peripheral health center pharmacies, thus doing away with pre-packaging. Widening the network of health facilities that provide DAART support would serve to distribute the staff workload over more sites and move DAART services closer to patients’ homes, thus reducing transportation problems. A shorter duration of DAART follow-up could reduce the costs to the health system and to clients and would increase the feasibility of the intervention, but would need to be evaluated.

DAART offers a unique opportunity for close monitoring of patients receiving HAART. DAART also serves to enhance links between health service delivery and community resource networks, thereby facilitating access to care and support for HIV-infected individuals. In view of the frequent occurrence of HIV/TB co-infection, DAART offers an opportunity to combine resources to improve treatment success rates for two serious illnesses. A combined DAART for HIV/TB co-infection should be evaluated.
Data collected at 48 and 96 weeks of follow-up will provide more information about the effectiveness of the DAART intervention in the long term in maintaining higher patient adherence after the end of the intervention, and thus provide more information for assessing its feasibility.

September 2005

Reference


Investigators for this study were Stanley Luchters of the International Centre for Reproductive Health, and Avina Sarna and Susan Kaai of Horizons/Population Council. Intervention and study partners include Horizons, ICRH, Coast Province General Hospital, Mkomani Nomu Clinic, Port Reitz District Hospital, FHI/IMPACT, MSH/RPM Plus, and Kenya Ministry of Health.

For more information on this study please contact Avina Sarna (asarna@pcindia.org) or Stanley Luchters (Stanley.Luchters@icrh.org)


This document may be reproduced in whole or in part without permission of Population Council provided full source citation is given and the reproduction is not for commercial purposes.