

Improving adherence to highly active anti-retroviral therapy in Africa: the DREAM programme in Mozambique

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Abstract

Ensuring high levels of adherence to highly active anti-retroviral therapy (HAART) is a priority in treating people living with AIDS. This study reports the rates of adherence of patients served by DREAM (Drug Resource Enhancement against AIDS and Malnutrition) in the city of Matola, Mozambique. DREAM, an innovative programme tailored for Africa, was implemented by the Community of Sant'Egidio in August 2001. DREAM provides patients with anti-retroviral drugs and laboratory tests at no charge, and is based on a particular strategy of health education and organization of services designed for a population that is predominantly poor and has a low level of formal education. This study analyzes the adherence of 154 patients over a period of 6 months. In evaluating adherence, two indicators were used: (1) the percentage of appointments kept for check-ups, tests and the collection of medicine, and (2) the overall change in the patients' blood chemistry over the 6-month

period. Of the 154 patients, 127 (82.5%) kept more than 90% of their appointments. Adherence to the programme was further confirmed by a relevant increase of hemoglobin levels and CD4 counts, and a significant decrease in the viral loads among the 154 patients.

Introduction

Full adherence to highly active anti-retroviral therapy (HAART) is a major priority in the treatment of people with HIV to avoid the development of resistance to anti-retroviral drugs, virological failure and higher mortality rates, as multiple studies have shown (Chesney *et al.*, 1999; Paterson *et al.*, 2000). While full adherence to anti-retroviral therapy has not been completely achieved even in developed Western countries, high adherence is a crucial goal in sub-Saharan Africa, which has been hit by a catastrophic pandemic of HIV infection and where treatment often is a privilege of the elite.

Few rigorous evaluations of the efficacy of adherence interventions have been conducted. A recent review of reports on general adherence interventions found only 19 studies measuring adherence and treatment outcome over a period of at least 6 months. These studies were conducted mainly in Western countries, whereas little is known about adherence to anti-retroviral therapy in Africa (Meichembaum *et al.*, 1997; Eron *et al.*, 2000; Golin *et al.*, 2002; Tuldràand *et al.*, 2003).

Several factors specific to Africa lead to an assumption of low adherence on the continent, particularly because of the high cost of medicines and the lack of health infrastructure. Other relevant

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factors include poverty, lack of education, social instability, the lack of physicians, as well as poor roads and a lack of transportation, as cited in studies focused on resource-poor settings, including sub-Saharan Africa, in general (Farmer, 2001; Harries *et al.*, 2001; WHO, 2002), and Senegal, in particular (Laurent *et al.*, 2002). This study analyzes adherence to HAART within the Drug Resource Enhancement against AIDS and Malnutrition (DREAM) programme begun in August 2001 by the Community of Sant'Egidio, an international non-governmental organization. By December 2004, DREAM had reached 15 000 people in Mozambique with the Voluntary Counseling and Testing (VCT) protocol; 9000 people were being monitored and 4000 people were enrolled in HAART.

DREAM's strategy for attaining high levels of adherence to HAART

The principal goal of the DREAM programme is to attain a high level of patient adherence to all components of the therapy, promoting the patients' full participation in improving their health. The working methodology of DREAM is aimed at overcoming cultural, linguistic and social barriers present in the areas of sub-Saharan Africa where the programme is operational, both to increase people's awareness, and to increase their ability to take action and promote their own health.

The intervention model follows principles of health promotion and basic health-care assistance using the framework of health-care planning called 'PRECEDE to PROCEED' (Green, 1991). First, the needs of the population in terms of organization of services, health education and support were studied. The second phase coincided with the launching of the programme, when the identified elements were implemented and the results were monitored and evaluated. The elements that comprise the DREAM model are summarized in Table I and are divided into three categories: predisposing factors, enabling factors and reinforcing factors. Detailed descriptions of the programme have been published in book form by the Sant'Egidio Community (Emberti Gialloreti *et al.*, 2001; Liotta *et al.*, 2001; Marazzi *et al.*, 2003).

Predisposing factors

The predisposing factors make the programme possible and predispose the patient to a high level of adherence. The most important element in this group is offering the anti-retroviral drugs and those needed to fight opportunistic infections *free of charge*. Another important factor is that DREAM was conceived as a *programme that would collaborate with the public health system*. The role of *local health-care personnel* is crucial, not only for communicating with the patients in their own language, but also for understanding the mentality of the local population.

Most of the elements included in predisposing factors relate to health education. To identify the steps needed to increase understanding and modify negative beliefs and behaviors, DREAM used three common theoretical reference models: the Social Cognitive Theory, the Health Belief Model and the Information–Motivation–Behavioral Skills Model (Becker, 1974; Bandura, 1986; Fisher, 1992). All three models emphasize that successful interventions address the entire network of cognitive, emotional, behavioral and social factors present. Before beginning DREAM, surveys were taken and focus groups were organized to evaluate the knowledge, beliefs and behaviors of patients and health professionals regarding AIDS. The social stigma faced by HIV-positive patients was also studied through the convocation of focus groups representing different sectors of society in Matola: politicians, members of civic associations, representatives of local schools and health-care professionals. The discussions, led by a health-education expert, revealed a particular burden born by women, who risk being abandoned by their husbands on the mere suspicion of being HIV-positive. Another indication of the social stigma lies in the number of suicides committed by people with HIV/AIDS. In Matola alone, the local newspaper reported 16 cases of suicide in 2003 of people with AIDS.

Finding effective ways to overcome the stigma and fear attached to being HIV positive, and the resulting reluctance of people to be tested and/or treated, is ongoing. Monthly meetings are held with

Table I. Elements of the DREAM programme

Predisposing factors	Enabling factors	Reinforcing factors
1. Free diagnosis and HAART treatment	9. Computerization	16. Nutritional support
2. Integration, collaboration with the national health system	10. Using team work model with a coordinator and differentiation of roles	17. Health education leaflets
3. Employing local health workers	11. Home assistance for fragile cases	18. Telephone calls to remind patients of appointments
Health education items	12. Local activists	19. Patient–care provider relationship marked by courtesy.
<i>Increasing patient knowledge about the disease and treatment</i>	13. Involvement of the family in the patient’s treatment programme	20. Different colored cards for the patients according to the type of appointment (medical check-up, blood test, collection of medicine, nutritional support)
4. HIV pre-test counseling	14. Integration of the day hospital and laboratory	21. Choosing the simplest form of treatment possible
<i>Changing patient beliefs, attitudes and behavior</i>	15. Offering service 8 hours a day, 5 days a week	22. Tri-combination therapy in only one pill
5. HIV Post-test counseling		23. Illustrations showing how to take the medicine
6. Group health education classes in the waiting room		24. Results-based incentive programme for local staff
7. Strong doctor–patient relationship		
<i>Increasing staff knowledge, awareness; reviewing their relationship with patients, increasing trust in the programme</i>		
8. Specific training about adherence strategies		

about 30 HIV-positive activists—both men and women—who are receiving treatment through DREAM and who are trained to encourage other patients to follow the programme closely.

Once the attitudes, knowledge and social situation of the local population were examined, a detailed educational strategy was developed, articulating specific interventions throughout the programme both the patients and health-care workers follow.

The VCT protocol is composed of *pre-HIV test counseling*, the test and *post-test counseling*. The pre-test counseling, offered by a specially trained worker, was developed to help the patients understand the HIV test and to assure them that if they test positive, they will be treated and the treatment will be free of charge. The post-test counseling is a crucial moment for the health worker to identify the problems the person may have in discovering he or she is seropositive, for helping the person understand that it is possible to live with the illness, for reinforcing self-esteem, and for building confidence in the therapy and in the programme staff.

A nurse and an activist lead *group health education classes* for patients enrolled in the programme as they await their day’s appointments.

The sessions promote discussion, help patients overcome any resistance or fears they may have about the programme and resolve relationship problems with the staff. The sessions include basic information about the pathology, therapy and importance of adherence. While the patients’ specific questions and concerns may dictate the content of any given session, the classes are often based on a health education manual developed by the Community of Sant’Egidio, called *How’s Your Health?* The manual, a basic health and hygiene text, is suitable for the general population, including those who have a low level of formal education or are illiterate. The amount of written text has been kept to a minimum and each point is explained with illustrations. The topics covered in the manual (and, therefore, in the waiting room sessions) include how infectious diseases are transmitted, methods for controlling disease-carrying insects and rodents, personal hygiene, the importance of clean water and a healthy diet, and the proper use of a thermometer, pharmaceuticals, syringes and disinfectants.

The presence of the activists shows patients the effectiveness of the programme itself. In a situation where stigma is a serious factor, the example of the

activists is particularly effective because they are the most authentic demonstration that AIDS is not a death sentence.

For a high level of adherence, a *close relationship between the doctor (or clinic director) and the patient* is particularly important. The *training of the social and health-care staff* before the programme is established and continuing as the programme operates contributes to adherence. The nurse in charge of the pharmacy gives the patients the drugs prescribed by the doctor, checks that the patient has taken the medicines regularly in the preceding month and, if the patient has skipped taking any of the pills, finds out why. This information is reported both to the team coordinator as well as to the doctor, ensuring the physician has an accurate understanding of the patient's adherence and can take action when necessary. The team coordinator must have a precise understanding of the patient's level of adherence to know when other measures, such as home assistance, are required.

Enabling factors

The enabling factors are designed to help patients express their hopes and difficulties, promote their own health, and remove environmental, social or linguistic obstacles to full adherence. The *computerization* of the DREAM centers allows both a rapid and effective system of transporting data as well as the constant monitoring of the patients. The *composition of the staff* also is important. The team includes the doctor, nurse, home-care assistant, the laboratory technician and the coordinator, who organizes the work of the team, but also guides the patient through all the phases of the diagnostic/therapeutic regime and monitors the patient's adherence.

An element that simultaneously increases and monitors adherence is offering the *patient assistance at home*. Home care is provided to those patients who are particularly fragile: the elderly and the very young, those living alone, and those who have other health problems or lack self-sufficiency, such as the handicapped, those who have neurological problems or who are following a special regime after being released from hospital.

DREAM involves the *patient's entire family*, which in most cases is a precious resource and important support, in the diagnostic/therapeutic programme.

An organizational element that increases the patients' trust in the programme is the *strict integration of the various DREAM centers* (particularly the day hospitals and maternity clinics) *with the molecular biology laboratory*. The close working relationship and the rapid completion of the clinical analyses (the lymphocyte CD4 counts can be obtained within seven days and the viral load determined within 20 days) guarantees a limited waiting period, and contributes to the general organization and good functioning of the centers, at the same time increasing the patient's trust in the team and, therefore, adherence to the programme. The *extended operating hours of the DREAM centers* facilitates the access of patients, particularly those who live far from the centers.

Reinforcing factors

The reinforcing factors were identified both during the programme's planning phase as well as after its establishment. These elements were introduced to increase adherence, especially among the more fragile patients and those who tend to miss appointments. *Nutritional support* is offered to the patient according to his/her nutritional status, which is measured periodically using the body mass index (BMI). The food package delivered monthly also contains provisions for the patient's family. A typical package for a family of six contains 6 kg of grain flour, 4 kg of rice, 4 kg of legumes (beans, peas and soy), 2 kg of peanuts, 2 l of whole UHT milk and 2 l of vegetable oil. Nutritional support increases the patient's adherence by demonstrating concern for his/her overall health and well-being.

Further reinforcement comes in the form of *pamphlets* distributed to the patients to facilitate their understanding and help them remember specific information about the programme, the therapy, etc. These small pamphlets are designed for individuals with a low level of formal education, relying on clear drawings and a minimum amount of text. *Telephone calls* (where a fixed or cellular

phone is available), including to relatives or neighbors, and *home visits* to remind patients of appointments have been shown to be extremely useful in maintaining a high level of adherence. The *courtesy of members of the social health-care team* toward the patients and their family is an irrevocable part of the DREAM programme as well as being indispensable for increasing the patient's trust in the staff and their willingness to precisely follow the instructions received.

Another important aspect is the *organization of appointments* and respect for the schedule on the patients' part. This is decisive for the proper functioning of the centers, as well as for therapeutic success. Patients are given different colored cards to help them remember different appointments—for analyses, doctor's visits, picking up their medication. The DREAM programme also seeks the most effective, but also the *simplest therapeutic protocol* for each patient. DREAM has assured that the *tritherapy, using generic drugs, is available in a single pill*. Along with a small bag with a 30-day supply of pills, the patients also are given an *illustrated card* showing the moment during the day when the pills are to be taken. Another aspect of improving the quality of services offered to the patients is the *proper recognition, including economically* of the work performed by the staff. The local personnel are offered various incentives on the basis of the quality and quantity of work performed.

Population and methods

This is an observational, retrospective study conducted with 154 HIV-infected patients enrolled in HAART and treated at a day hospital in Matola, Mozambique. The city of about 700 000 residents was formed over the past 30 years in a rural area near Maputo, the capital. The residents, most of whom are poor, migrated to the area to flee fighting during the civil war and or after natural disasters such as flooding struck their homes. The population, therefore, includes members of various ethnic and linguistic groups coming from different parts of Mozambique.

Of the 154 patients, 89 were female and 65 male. The average age was 36.2 years (SD 9.4 years). Only two of the patients had a university degree; 40.3% had at least 5 years of schooling, 38.3% had some schooling, although less than 5 years, and 20.1% were illiterate. About 53% of the patients lived more than 15 km from the day hospital and 26.9% lived at least 3 km from the day hospital. About 70% of the patients used public transport to reach the day hospital, 20% had their own transportation and 10% came on foot.

Anti-retroviral drugs were administered free of charge according to specific protocols. The most common combinations were AZT + 3TC + NVP or d4t + 3TC + NVP. In the DREAM protocol, the decision to begin therapy depends first of all on the CD4 count. If a patient's CD4 count is less than 200 cells/mm³, therapy is begun. When the CD4 count is between 200 and 350 cells/mm³, the decision to initiate therapy depends on the viral load; therapy is begun if the viral load is greater than 55 000 copies/ml. For patients with a CD4 count between 350 and 500 cells/mm³, the DREAM protocol calls for the patient to come regularly to the day hospital for check-ups, which include blood tests every 3 months (hemochromo and CD4) and monitoring of the BMI. When the CD4 count is above 500 cells/mm³, the follow-up consists in conducting the tests every 6 months rather than every 3 months. Therapy is initiated when a patient's CD4 count is above 350 cells/mm³ only in exceptional cases when other negative factors are present, such as low BMI or the patient presents symptoms of opportunistic infections.

All patients in this study were receiving first-line therapy. Patients were checked routinely for adherence to the treatment, as well as for toxicity, effectiveness and possible development of drug resistance. The 6-month period of adherence assessment began on 1 January 2003 with all 154. For adult subjects who already had been following a standard HAART regime for at least 6 months, DREAM's diagnostic and therapeutic protocol envisioned a total of 10 appointments in the 6 months covered by the study for medical visits, blood tests, medications and nutritional support. To evaluate adherence to the HAART therapy, the

study chose to examine the level of adherence of the entire group, analyzing four indicators:

- (1) The total number of appointments kept for medical check-ups, blood tests and medicine collection (an appointment was considered kept if the patient arrived as scheduled or within 7 days of the originally scheduled appointment spontaneously or after having received a telephone call or home visit).
- (2) Hemoglobin levels at time 0 and time 1 (after 6 months).
- (3) CD4 counts at time 0 and at time 1 (after 6 months).
- (4) Viral load levels at time 0 and time 1 (after 6 months).

To strengthen our understanding of the factors leading to higher adherence, we conducted a qualitative study in January 2005; two health-care workers who had not previously known the patients asked them to list in order of priority the components of the DREAM programme they most appreciated. The interviews were conducted while the patients were waiting for their appointments at the day hospital in Matola.

Results

The results reported here refer to the level of adherence reached by the group of 154 patients as a whole.

As shown in Table II, during the 6-month period of study, 127 (82.5%) of the 154 patients kept more than 90% of the appointments called for by the protocol for medical visits, blood tests and picking up their medications, 20 (13%) kept 50–90% of their appointments, while seven (4.5%) kept fewer than 50% of the appointments.

The high level of respect for appointments at the day hospital was confirmed by and coincided with a relevant increase within the group of 154 patients of hemoglobin levels (Table III) and CD4 counts (Table IV), and with a lowering of the viral loads (Table V). The percentage of patients with a hemoglobin level under 8 g/100 cm³ decreased from 14.9 to 3.9%, while those with a hemoglobin level above

10 g/100 cm³ grew from 46.7 to 81.8%. The percentage of patients with a CD4 count below 200 cells/mm³ decreased from 83.1 to 29.2%, while those with a CD4 count above 500 cells/mm³ grew from 1.3 to 19.5%. The percentage of patients with a viral load above 100 000 copies/ml decreased from 31.8 to 4.5%, while those with a viral load less than 50 000 copies/ml grew from 55.8 to 91.6%.

In the follow-up study to identify the elements of the DREAM programme considered most important by the patients themselves, 189 HIV-positive patients receiving therapy were interviewed. The group included 135 of patients who were part of the original group of 154 referred to throughout this paper. (The remaining 19 patients were not interviewed simply because they did not have appointments on the days the interviewers were present). Forty-eight percent of the patients said what they appreciated most about DREAM was that they were healthier once they began therapy; however, since feeling better was not a specific component of the DREAM programme, those patients were asked to choose another factor as their first response.

The vast majority of the 189 patients in therapy (92%) listed the free testing, analyses and medicine as the most important component of DREAM.

Table II. Adherence to appointments among the 154 patients

Percentage of kept appointments	People [N (%)]
>90	127 (82.5)
50–90	20 (13)
<50	7 (4.5)
Total	154 (100)

Table III. Hemoglobin levels in the 154 patients at time T0 and T1 (0–6 months)

Hemoglobin (mg/ml)	No. of persons		Percentages	
	T0	T1	T0	T1
<8	23	6	14.9	3.9
8–10	59	22	38.3	14.3
>10	72	126	46.8	81.8
Total	154	154	100.0	100.0

Table IV. Levels of CD4 in the 154 patients at time T0 and T1 (0–6 months)

CD4	No. of persons		Percentages	
	T0	T1	T0	T1
0–49	40	2	26	1.3
50–99	27	12	17.5	7.8
100–149	26	15	16.9	9.7
150–199	35	16	22.7	10.4
200–499	24	79	15.6	51.3
500+	2	30	1.3	19.5
Total	154	154	100.0	100.0

Table V. Viral load levels in the 154 patients at time T0 and T1 (0–6 months)

Class	No. of persons		Percentages	
	T0	T1	T0	T1
<50000	86	141	55.8	91.6
50000–100000	19	6	12.3	3.9
>100000	49	7	31.8	4.5
Total	154	154	100.0	100.0

Eighty-six percent of the patients listed the free nutritional supplements for themselves and their family members as the second most important factor (of those who had listed nutritional support as the second factor, 98% had said the free medicine and testing was the most important factor). The 189 listed a variety of factors third: the home visits by activists (46%), a good relationship with the health-care workers (21%), home visits by DREAM staff (12%), nutritional support (9%), and the health education lessons and manual (8%).

Discussion

The results demonstrate that it is possible to achieve a high rate of adherence to HAART even in countries with limited resources. We would argue that the results are linked to the characteristics of DREAM and the procedures implemented. The dedication of time and resources to understanding and identifying what could be called the ‘African’

aspects of AIDS, both environmental and anthropological, appears to be vital. The availability of specially trained health-care workers who speak the local languages and work in public health institutions facilitates the involvement of the patients, motivating them to take responsibility for their care. The patients become more knowledgeable and can feel physically that adherence to HAART improves their state of health.

Three other fundamental elements contributed to the high rate of adherence:

- (1) That treatment is completely free and that it is available in a single pill.
- (2) The personalization of nutritional aid and other services (home assistance, the involvement of activists, etc.) to remove environmental obstacles to adherence.
- (3) Computerization to check adherence and intervene when necessary. The availability of complete and extensive information allowed staff to trace the patients and clarify difficulties or problems.

Obviously, adherence is an issue only where treatment is available. Studies demonstrate that it is possible to offer HAART while maintaining reasonable cost structures in poor countries (The Panos Institute, 2000). We believe DREAM offers excellent care at a sustainable cost and can be used as a model for treatment in other limited-resource settings. While the programme requires a significant initial investment (about US\$330 000) to set up the molecular biology laboratory, the costs for the tests and the anti-retroviral drugs are fairly low, particularly when compared to Europe and North America. The programme is stable, efficient and reproducible only with a properly equipped laboratory. Costs can be contained and even lowered through careful use of the reagents.

Laboratory costs associated with the diagnostic and therapeutic protocol used by DREAM run about US\$170 per year for every patient on anti-retroviral therapy and about US\$95 for monitoring HIV-positive patients not yet in HAART. The current annual cost for the generic anti-retroviral drugs is about US\$330 per patient. These costs do

not include the salaries paid to the staff. However, because DREAM is integrated into the public health-care system, the programme rarely has to pay a health-care worker a full salary; generally it is a matter of supplementing the salary paid by the state. Each patient-activist costs the programme only about US\$50 per month, but the activists are very important in promoting adherence among their peers. Where fully operational and with all components present, DREAM costs about US\$600 per patient per year (including the cost of the nutritional supplement packages), although a scaled-down model could be run at a cost of US\$400 per patient per year. In the reduced-cost programme, the patients are not offered assistance at home and the number of personnel is reduced, thereby increasing the amount of time each patient spends in the waiting room.

DREAM insists on a diagnostic protocol that includes the analysis of viral load in addition to CD4 counts. A programme that does not track viral loads will, over time, see an increase in the number of patients resistant to the drugs and, therefore, will require significantly more money for providing second-line therapy. The cost of providing nutritional support to the patient and his/her family usually does not burden the programme budget because of the recent WFP decision to provide that support to people with AIDS. Mozambique spends less than US\$50 per capita per year on its citizens' health and national spending across the continent rarely reaches US\$100. Clearly the US\$600 cost per patient of the DREAM programme is not sustainable by national health-care systems in sub-Saharan Africa. While one hopes that African nations can become self-sufficient in their battle against tuberculosis and malaria, it would be almost impossible for them to sustain the costs of fighting AIDS on their own. However, our experience is that funding to treat AIDS in sub-Saharan Africa is not lacking—money is arriving in substantial amounts. The problem lies in identifying effective programmes that will use the funds efficiently.

In conclusion, the high level of adherence achieved by patients in DREAM supports the programme's complex approach and confirms the fact

that high-quality service will lead to benefits that amply repay the costs. An investigation into the impact of the programme on preventing the spread of HIV has not yet been completed, but we expect to see positive results in this respect as well.

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