

PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

DREAM

AN INTEGRATED FAITH-BASED INITIATIVE TO TREAT HIV/AIDS IN MOZAMBIQUE

CASE STUDY



World Health
Organization



Community of
SANT' EGIDIO

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BACKGROUND

Drug Resources Enhancement against AIDS and Malnutrition (DREAM) was created by the Community of Sant'Egidio to fight AIDS in sub-Saharan Africa. The project takes a holistic approach, combining Highly Active Anti-Retroviral Therapy (HAART) with the treatment of malnutrition, tuberculosis, malaria, and sexually transmitted diseases. It also strongly emphasizes health education at all levels. DREAM aims to achieve its goals in line with the gold standard for HIV treatment and care.

DREAM was launched in Mozambique in March 2002, following two years of groundwork. However, the idea for the project was born in 1998 when the Sant'Egidio Community—a Christian movement founded in Rome in the late 1960s that has a strong base in Africa—decided to fight the devastating impact of HIV/AIDS.

Box 1. Drawing on experience in ending conflict in Mozambique

Sant'Egidio's previous experience in dealing with deadly conflict in Africa greatly helped in initiating the war against HIV. The community was the leading mediator in the peace process to end the civil war in Mozambique. An agreement to end that war was, in fact, signed at the Sant'Egidio headquarters in Rome following two and a half years of intense negotiations.

Mozambique is a country with almost 19 million people, of whom about half are younger than 18 years of age. It is estimated that, in 2003, about 1.3 million adults and children were living with HIV. Of those, about half were women of reproductive age (15-49 years). In 2002, in the capital city Maputo, approximately 15% of young women aged 15-24 were infected with HIV. In the absence of interventions, about a third of infants born to women with HIV will become infected with the virus. Therefore, programmes for the control of the HIV epidemic must focus on young people, in particular, women of reproductive age.

In addition to HIV/AIDS, Mozambique is burdened by illnesses such as malaria, tuberculosis and cholera. Malnutrition is common; about 14% of infants have below average birth weight and a quarter of children under five years of age are moderately to severely underweight. The impact of these problems is further aggravated by poor access to health facilities. In Mozambique, only 50% of the population receives care provided by a health facility and less than half of



women benefit from assistance at birth. Given that about two thirds of the population live in rural areas, community care and mobile health care play a central role in improving access to health facilities.

The National Plan to Fight AIDS illustrates the impact of the disease in Mozambique. The education sector has been seriously affected by a drop in the number of skilled teachers, who are dying as a consequence of AIDS. Between 1995 and 1998, the proportion of skilled teachers among the total number of teachers dropped by 68%, to 7%. Due to the shortage of personnel, about a third of Mozambican children have no access to education.

OBJECTIVES

General objective: delivery of a public health intervention

Within the framework of the national health system, the DREAM project aims to introduce the essential components of an integrated strategy for the prevention and treatment of HIV/AIDS. The project is intended to serve as a model for a wide-ranging scale-up of the response to the epidemic.

The main objective will be achieved through the establishment of services providing diagnosis and comprehensive treatment. The prevention of HIV transmission in the general population and of mother-to-child transmission through Community Care and Home Care services (CCHC) and Mother and Child Prevention and Care (MCPC), respectively, are additional key components of the programme.

THE PROJECT

Philosophy

DREAM aimed to resolve a paradox. Effective treatment for AIDS with HAART has long been available in countries where HIV prevalence is below 1%. However, in countries carrying the largest burden of the epidemic and where adult infection rates have reached levels above 20%, the large majority of infected people have no access to treatment. Nevertheless, the correct and effective treatment of HIV requires a comprehensive and multi-dimensional approach and cannot be achieved by merely distributing drugs to patients who qualify for treatment. Diagnostics, strategies that

assure adherence to treatment, trained personnel, mechanisms for monitoring opportunistic infections and conditions that manifest or co-exist with HIV infection, including malaria, tuberculosis, sexually transmitted diseases and malnutrition, are also required.

As a response to the complex tasks ahead, the health system has been organized around the following principles:

1. Relieve hospital structures of some patient load. Use of large hospital centres is limited and a strong focus is placed on local centres able to reach out to the periphery.
2. Capacity-building, for doctors, nurses, medical and laboratory technicians, is needed. The aim is to take advantage of existing human resources, and thereby to improve access to services and clinical monitoring of patients.
3. Maximize the potential of communications and transport, and introduce specific software for the purpose of management, communication, monitoring, training and epidemiological information. Such technologies improve the network of services provided and capacity to keep track of patients.

Elements

DREAM has chosen to invest in intensive short-term personnel training, followed by more prolonged in-service training with the support of expert personnel present at the workplace. Subsequently, community intervention models have been developed, such as outpatient care, community and home-based care. These do not require extensive resources and can be set up quickly. As a backup, a small number of high technology centres capable of supporting large areas (e.g. molecular biology laboratories) have been made available. A third step has been to invest heavily in providing access to treatment and clinical and laboratory monitoring for patients in remote locations. Centres that are within a radius of 150km of the city have been equipped so that they can offer the same qualitative level of treatment and monitoring as those closer to the city. Apart from equipment, transport of blood samples and periodic supervision by DREAM staff have been organized. The fourth step consists of the effective use of computer resources to guarantee both the best possible organization of work and even long-distance monitoring of various aspects of the programme. An efficient computer system also allows for additional support to clinical and diagnostic operations through the use of internet technologies. This can include second opinions from specialized European centres, tele-medicine, tele-diagnostics, and long-distance training.

Adherence to ARVs and follow-up of treatment are key to the effective use of HAART in large-scale public health settings. Therefore, DREAM provides the treatment package free to all patients. This is a crucial element; for many patients, even the cost of transport may prevent them from adhering to treatment. By eliminating the cost of treatment, high adherence rates have been achieved.

The elements of this comprehensive model may be duplicated to treat conditions other than AIDS, such as tuberculosis. Hence, the model may potentially serve as a blueprint for the development of broader health systems-response to HIV in resource-limited settings.

Box 2. Elements of the DREAM model for a health systems response to HIV

- optimal use of personnel
- intensive training
- scaling-back investment in institutional development and investing instead in a stronger field presence
- intensive use of technology and innovative methods in the fields of communication, informatics and diagnostics.

Programme acceptability and viability lie in providing free treatment and services, while at the same time ensuring the highest level of quality.

RESOURCES

Facilities

The DREAM project is fully integrated within the framework of the National Health System. Since August 2003, the DREAM project has been active in nine clinical centres distributed across the country. Another centre is planned to open in 2005. These clinics are supported by three molecular biology laboratories, run by the Community of Sant'Egidio, located in the country's three large reference hospitals (Table 1). All clinical centres are part of public institutions or privately owned structures included in the public health network, and they are qualified to provide antiretroviral treatment. The Community of Sant'Egidio relies on close collaboration with other organizations; in fact more than two thirds of DREAM centres are not run directly by the Community of Sant'Egidio. In these cases, the Community of Sant'Egidio guarantees supervision and training of personnel, as well as the provision of antiretrovirals.

Table 1. The Community of Sant’Egídio relies on close collaboration with other organizations

Geographic location	Hosting centre	Direction
Clinic services		
<i>Southern region</i>		
Maputo (capital city)	Benfica Health Centre Polana Caniço Health Centre Clinical Centre of Mahotas for children with neurological disorders Military Hospital of Maputo (beginning in 2005)	2 nongovernmental organizations: <ul style="list-style-type: none"> ▶ General Union of Cooperatives ▶ Association para la Salud Integral y el Desarrollo Humano (ASIDH) Sisters of St. John of God Ministry of Defense
Province of Maputo	General Hospital of Machava Matola II Health Centre	Community of Sant’Egídio
Province of Gaza: Chokwe City	Provincial Hospital for Tuberculosis	Daughters of Charity
<i>Central region</i>		
Outskirts of the city of Beira (provincial capital of Sofala)	Manga Chingussura Health Centre	Community of Sant’Egídio
Provincial capital of Zambezia	Quelimane Central Hospital	Dehoniani Fathers
<i>Northern Region</i>		
Nacala city (about 100 km from the regional capital Nampula)	Health Centre AKUMI (OI treatment started; ART beginning in 2005)	Vincentian Fathers
Laboratory services		
<i>Southern region</i>	Maputo Central Hospital	
<i>Central region</i>	Beira Central Hospital	Community of Sant’Egídio
<i>Northern Region</i>	Central Hospital of Nampula (services beginning early 2005)	

Staff

A minimum staff structure is uniform across all DREAM centres and consists of the following:

- ▶ **1 doctor or clinical officer:** direct follow-up of patients in the first four weeks, initiation of HAART, arrangements for follow-up
- ▶ **1 experienced nurse:** clinical monitoring of patients already on the programme, evaluation of results of initial tests, decision whether to admit patients, referral to a doctor of more complicated cases or those awaiting a decision about starting HAART
- ▶ **1 nurse** trained to deliver drugs and to monitor adherence to protocols
- ▶ **1 nurse** trained to take samples (this could be the same staff member who delivers drugs in smaller centres)
- ▶ **2-4 community members** to welcome patients, compile basic clinical information, deliver nutritional supplements, provide adherence support
- ▶ **1 centre coordinator** (not necessarily a health professional): in charge of organizing the centre's operations and the work of the staff
- ▶ In centres where home-care service is offered, up to **8 home care operators** and **a nurse** can reach approximately 200 patients per year.

SERVICES

Patients served

DREAM realized early on that it was not feasible to offer treatment indiscriminately to all people with HIV. In order to use limited resources most efficiently, the project gives preference to carefully selected groups of patients:

- ▶ **Pregnant women**, to prevent mother-to-child-transmission and ensure the mothers' survival.
- ▶ **Skilled workers**, especially in the health sector, such as doctors, nurses, laboratory technicians and other personnel. Today more than 170 employees in the health sector are receiving treatment.
- ▶ **Employees of certain businesses**, as DREAM favours collaboration with business entities that offer antiretroviral treatment to their employees and their families in order to avoid the loss of skilled personnel. This decision aims to preserve the economic and

productive fabric of the country. Collaboration generally consists of financial co-sponsoring of treatment of employees of respective companies. In some cases, doctors employed by the firms are trained in providing HIV treatment. This enables these doctors to manage free-of-charge clinics—in space made available by the same companies—where antiretroviral treatment is provided. The doctors are further supported in this initiative by, for example, free access to laboratory testing.

However, patients who do not fulfil these criteria but live within the catchment area of the centres are eligible to access all services offered.

Community Care and Home Care services (CCHC)

All patients served by DREAM have access to CCHC. Home care is intended for patients whose clinical conditions do not allow them to access outpatient and day hospital services. It is a service for patients who are the weakest in both clinical and social terms (for example, those who do not have parents or other relatives to support them), and represents a guarantee of care to all.

In developing countries, reaching health-care centres is often difficult, and it becomes even more challenging for patients who do not have the resources or energy to seek care. CCHC attempts to redress these challenges by providing a way to bring care to places that otherwise would never be reached, ensuring that all patients can enjoy their right to health services. Such an approach helps to overcome the isolation and stigma that so many patients face and enables them to build a support network, involving families in the care and recovery process.

In addition to providing antiretroviral drugs, a wide range of interventions is needed that takes into account the patient's overall needs. The full package of services is delivered through ambulatory and home-care activities (Table 2). This direct contact with the patients permits regular monitoring of treatment, showing that a lack of specialist HIV/AIDS facilities need not be an obstacle to comprehensive care.

The home care service attends to 400 patients per year for an average of 60 days each, mostly in the area of Machava. Patients benefiting from this service receive visits at least once a week. Services may be provided on a daily basis if the patients' clinical state is critical or they are no longer able to care for themselves, or if nursing services are required frequently (for example, for the treatment of pressure sores).

As of May 2004, CCHC services as well as Mother and Child Prevention and Care (MCPC, see below) services have been operational in nine health centres and five provinces.



Mother and Child Prevention and Care (MCPC)

DREAM's preferential treatment of pregnant women and the mother-and-child-pair is a choice for Africa's future.

Pregnant women are encouraged to undergo HIV-testing, with the assurance that they will receive care for their own condition and in the hope that they will bear a healthy child. These women are treated with HAART during pregnancy. After delivery, HAART continues if they meet clinical, virological or immunological criteria as assessed during pre-treatment antenatal care. Treatment regimens are safe and easily followed and they continue until one month after delivery (see Figures 1 and 2). Nutritional support is provided to women based on an established protocol in order to improve their pregnancy, and often helps to sustain other children in the family. Table 2 summarizes the services delivered to women attending MCPC.

Table 2. A wide range of services is offered at CCHC and MCPC

Services		CCHC	MCPC
Counselling	VCT	✓	✓
Laboratory Services	CD4-cell monitoring	✓	✓
	Viral load monitoring	✓	✓
	Biochemistry	✓	✓
	Haemogram	✓	✓
Treatment and care	Antiretrovirals	✓	✓
	Opportunistic infections	✓	✓
	Nutritional supplements	✓	✓
	Sexually transmitted infections	✓	✓
Other	Formula feeding kit	no	✓
	Mosquito nets	no	✓
	Health education	✓	✓

There are four DREAM centres in Mozambique, where pregnant women and mothers with neonates can seek advice, support, encouragement and friendship (Matola and Polana Caniço in the South, Beira in the Centre and Quelimane in the North). With the help of staff at the centre and through meeting other women in a similar situation, women living with HIV find that their fears and confusion can be overcome. For example, by watching other mothers feeding their children with formula milk, they may be reassured not to breastfeed in order to avoid the risk of HIV transmission to their newborn infant. This support is often crucial for women who are facing the difficult consequences of HIV, especially if they lack the support of a partner or other family members.

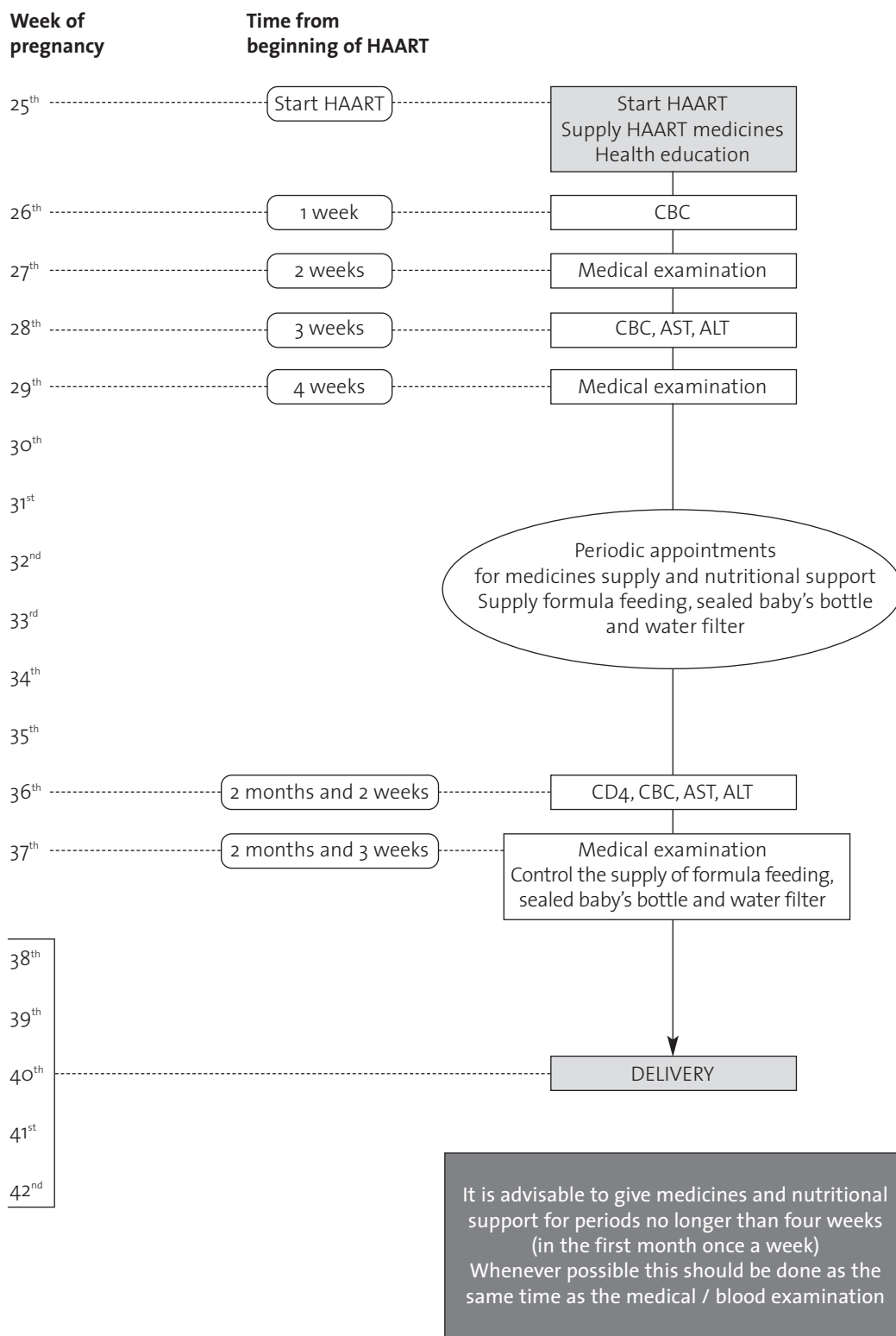
When childbirth is near, each woman receives a basic kit for formula feeding. It contains a water filter, a bottle, and formula milk, along with an information sheet with drawings and simple graphics, which depict formula feeding. These kits are intended for women who may be unable to reach the centre to give birth so they can put into practice what they have learned to keep their healthy baby HIV-free. However, the women are educated about the importance of reaching the centre within three days of delivery to permit the provision of care their infant may need.



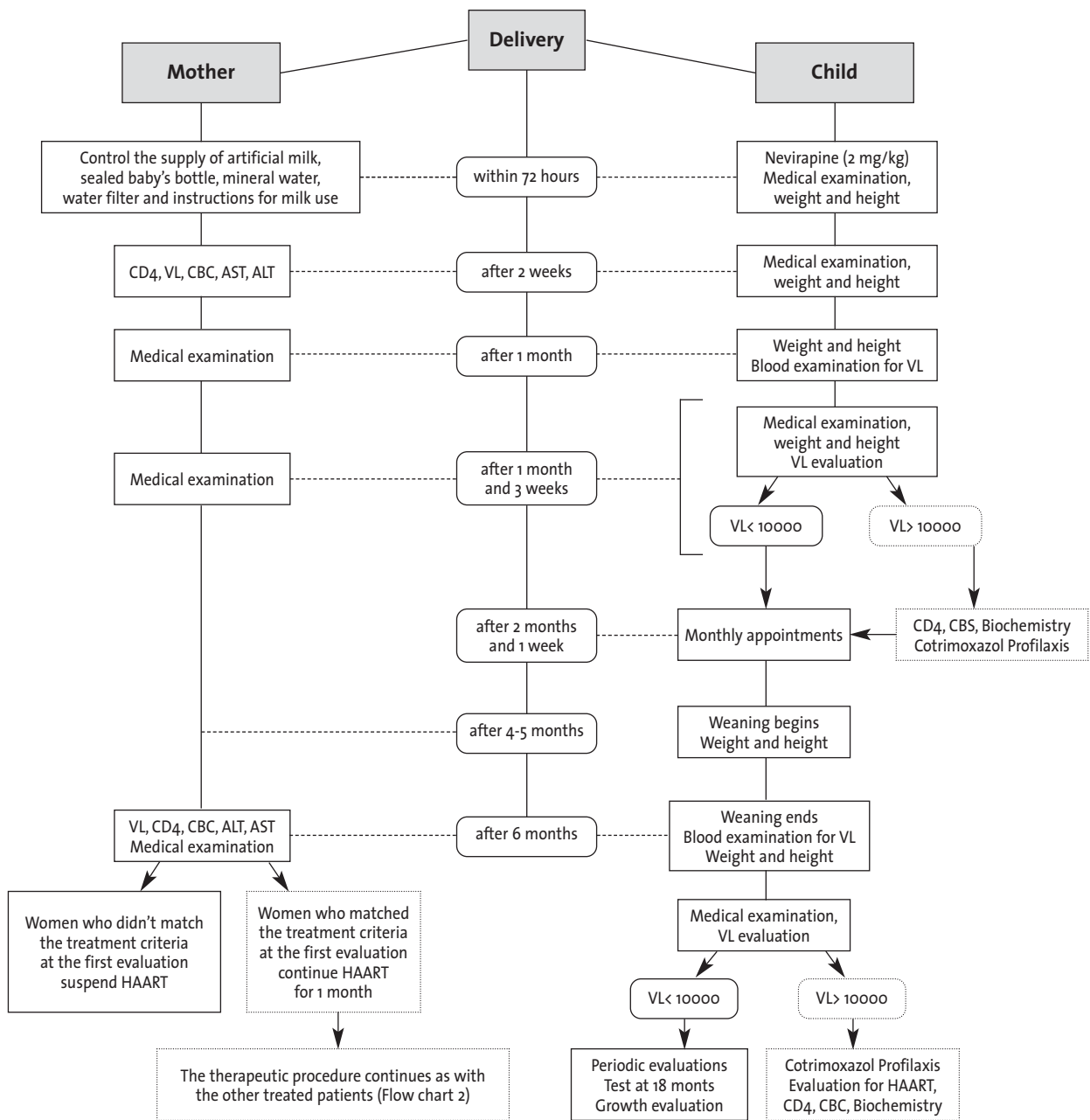
The first time a mother comes to the DREAM centre holding her newborn baby in her arms, the happy event is heralded as a victory over the virus. It is celebrated with a party, gifts and other tokens, which all serve to strengthen ties between the mother and the centre. This bond helps to ensure successful treatment.

COMMUNITY OF SANT’EGIDIO – DREAM PROGRAMME

Figure 1. Flow chart 1 Treatment of HIV+ women during pregnancy



COMMUNITY OF SANT'EGIDIO – DREAM PROGRAMME
Figure 2. Flow chart 2 Mother-child protocol after delivery



It is advisable to give medicines and nutritional support for periods no longer than four weeks (in the first month once a week) Whenever possible this should be done as the same time as the medical / blood examination

TREATMENT

HAART was introduced in March 2002. According to WHO guidelines for treatment in resource-limited settings, the first-line treatment used in the programme consists of nucleoside reverse transcriptase inhibitors (NRTI) and non-nucleoside reverse transcriptase inhibitors (NNRTI). Protease inhibitors (PI) are not considered as part of the first-line regimen, though they may be used in the event of treatment failure or intolerance of first-line combinations. There are two basic fixed-dose combination regimens available:

- ▶ zidovudine (AZT) – lamivudine (3TC) – nevirapine (NVP)
- ▶ stavudine (d4T) – lamivudine (3TC) – nevirapine (NVP).

The zidovudine-containing regimen is preferred both because of its higher genetic barrier to mutations inducing viral resistance and—particularly in MCPC—because there is more experience with the use of this drug. In the event of anaemia (hemoglobin below 8 gm/100 ml), preference is given to the stavudine-containing regimen.

The second-line treatment includes the following drugs:

- ▶ indinavir (IDV) / ritonavir (RTV)
- ▶ nelfinavir (NFV)
- ▶ didanosine (DDI)
- ▶ abacavir (ABC).

Criteria for providing HAART

HAART is offered to all patients who fulfil the following criteria:

- ▶ WHO clinical stage III-IV, or
- ▶ CD4 cell count below 200/ μ L, or
- ▶ CD4 cell below 350/ μ L and viral load above 55 000 copies/ml.

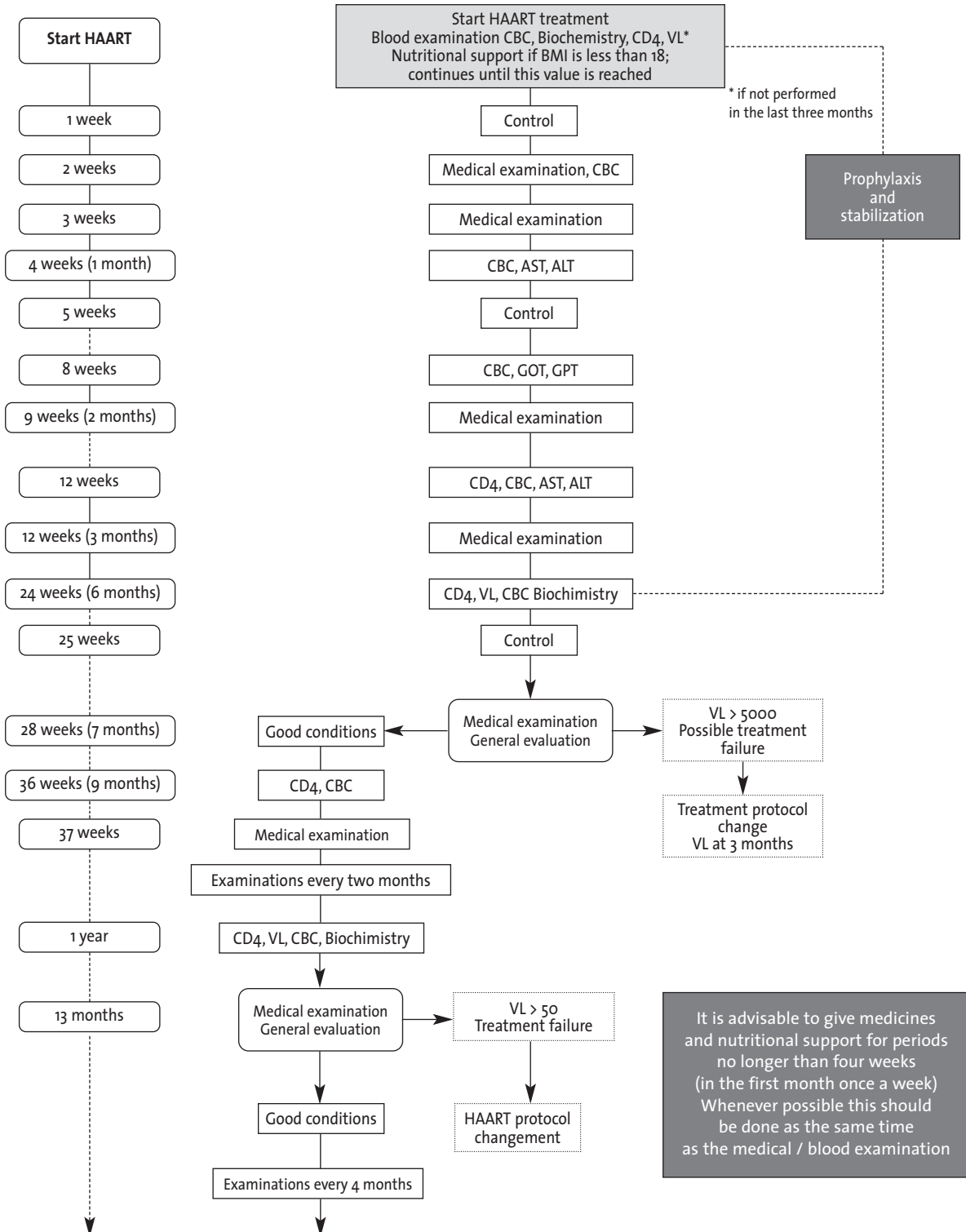
To prevent mother-to-child-transmission, HAART is also offered to all HIV-positive pregnant women starting from their 32nd week of pregnancy, irrespective of their clinical, virological or immunological status. Women who do not meet the general criteria to start HAART stop the treatment within six months of delivery.

In addition to HAART, cotrimoxazole prophylaxis is provided to all patients with CD4 cells count below 200/ μ L (Figure 3).

COMMUNITY OF SANT'EGIDIO – DREAM PROGRAMME

Figure 3. Flow chart 3 Treatment of adult patients

Time from the beginning of HAART



ADHERENCE SUPPORT

The DREAM programme is patient-centred. Staff training focuses on the quality of the relationship with patients and stresses that patients must be welcomed at all times, politely, openly and with respect. The patient–staff relationship develops through direct, regular contact and support for patients and their families.

HIV-positive patients—irrespective of whether they are included in the HAART protocol—have at least four clinic appointments during the first year and two visits in the following year. Patients on HAART are scheduled as follows:

- ▶ First month of treatment: fortnight visits
- ▶ Second and third month of treatment: fortnight visits
- ▶ Following six months: visits every three months
- ▶ After 12th month: visits twice yearly.

Patients who have failed to come to a scheduled appointment without an explanation will be traced the following day.

Based on a ‘Promoting Health Approach’, DREAM has established a number of elements to improve adherence (Table 3). Factors facilitating this process include:

- ▶ Predisposing factors—those that pave the way for understanding and acceptance of treatment
- ▶ Enabling factors—those that make treatment possible
- ▶ Reinforcing factors—those that support patient adherence.

Table 3. DREAM project elements to ensure adherence

<i>Predisposing factors</i>	<ul style="list-style-type: none"> ▶ Group health education lesson ▶ Health education leaflets ▶ Pre-test counselling ▶ Post-test counselling ▶ Doctor/ patient interview ▶ Ongoing training of personnel
<i>Enabling factors</i>	<ul style="list-style-type: none"> ▶ Computerization ▶ Integration within the National Health System ▶ Local personnel: <ul style="list-style-type: none"> > Programme management > Communication with the patients in their dialect > Strengthening patients' trust ▶ Coordinator of the team: <ul style="list-style-type: none"> > Organizational tasks ▶ Different colour cards to remember different appointments (collection of blood, medical visit, intake of drugs, nutritional supplements) ▶ Free diagnosis and HAART treatment ▶ Fixed-dose combination treatment regimen ▶ Illustrations to show how to take the drugs ▶ Nutritional support ▶ Results-based incentive programme: <ul style="list-style-type: none"> > Regular meetings with patients outlining programme results ▶ Integration between the day hospital and laboratory ▶ Services open eight hours per day, five days a week
<i>Reinforcing factors</i>	<ul style="list-style-type: none"> ▶ Home-care service for vulnerable patients ▶ Local staff ▶ Involvement of the family in patients' treatment programme ▶ Telephone calls to remind patients of their appointment ▶ Patient-care provider relationship marked by courtesy

“Mulheres para o DREAM” (Women for DREAM)—an innovative approach to support adherence

Patients on treatment have become one of DREAM’s best resources. Often, they form self-help groups to support one another. In the case of ‘Mulheres para o DREAM’, women have set up an association to support patients receiving treatment to adhere to treatment protocols. The association aims to achieve this by sharing the members’ positive experiences in treatment with ARVs. This has a profoundly encouraging impact for those on treatment. Peer education and emotional support are therefore crucial elements of support to new patients, including supporting adherence, particularly in the first period of treatment.

Special attention is devoted to support the treatment of mothers with children and to help them administer drugs, monitor their children’s health conditions and provide nutritional supplements. The women in the association also provide health education to patients while they are waiting to be attended at centres.



Box 3. Communication for improving adherence to treatment

Measures to support adherence to treatment are among the most important elements of any antiretroviral treatment programme. DREAM has recorded high adherence rates among patients, which are rooted in the careful communication of positive messages, such as:

HIV is not a death sentence.

During testing and counselling, patients are assured that, in the case of a positive test result, they will have access to a programme providing free ARV treatment. Drugs that have become available have resulted in rapid improvement of the patients’ clinical condition, a renewed wish to live, and the possibility for many to return to a normal social and working life. Informing patients that their chances of survival with HIV can be greatly enhanced through effective treatment leads to an acceptance rate of more than 95%. While this knowledge is crucial for the patient, it also plays an important role in the prevention of further transmission.

DREAM guarantees therapy to all, free of charge.

The experience of many African countries shows that lack of financial resources is one of the main reasons for patient discontinuation of treatment. The provision of treatment free of charge removes this obstacle.

No patient is left alone.

All patients are accompanied throughout treatment; they are educated about what to expect from the course of treatment and provided with support to ensure adherence. Patients are always urged to contact the centre for any problem that may arise, either by phone or in person.

Confidentiality, respect, courtesy, availability of staff, and a pleasant, welcoming environment.

These are all factors that contribute to patients’ decision to return for follow-up. For example, treatment facilities must consistently be maintained and kept clean, in line with stringent health and sanitary standards. In addition to improving adherence, the good condition of the facility is vital to ensuring human dignity.

THE LABORATORY

In order to perform CD4 cell count and viral load measurement free of charge, DREAM has included the development of specialized molecular biology laboratories. In addition, basic biochemistry and haematological profiles are carried out on a regular basis. Currently, there is a laboratory in the main hospital in Maputo (Southern Mozambique) and Beira (Central Mozambique), and another laboratory is planned to open before March 2005 in Nampula (Northern Mozambique)¹.



It is also planned to set up one regional molecular biology reference laboratory to provide access to advanced HIV diagnostic and monitoring procedures in different provinces. This will enable centralized, specialized centres to support the decentralization of high-quality HAART. Moreover, laboratories can become state-of-the-art training centres for staff from provinces or even from other countries, as is already the case in the Maputo and Beira laboratories. This approach is an investment for the future, both in training staff in highly specialized work and in the procurement of equipment.

Laboratory tests performed include:

- ▶ regular monitoring to enable a change in ARV treatment regimen if resistant virus emerges; and
- ▶ identification of potential toxicities as a result of treatment.

These tests require a variety of analytical techniques with differing levels of complexity and staff specialization. The first level involves basic laboratory tests such as the haematological profile and biochemistry. These tests are crucial to

monitor kidney and liver abnormalities, which may result as side effects of drugs used in the treatment regimen. The second level comprises lymphocyte sub-populations counts, specifically CD4+ and CD8+ (a drop in the CD4+/CD8 rate is one of the signs of HIV-induced immunodeficiency progression), to monitor antiretroviral therapy and the patient's state of health.²

Regular maintenance of the sophisticated equipment in a molecular biology laboratory is essential to maintaining quality standards. Laboratories must therefore be run by skilled personnel. Maintenance technicians need to be trained to ensure appropriate technical intervention as necessary. Laboratory staff requires a minimum ability to perform basic maintenance of instruments. This allows the laboratory to be self-sufficient in cases where maintenance technicians cannot intervene immediately.

TRAINING AND HUMAN RESOURCES

Training is a key component of the DREAM strategy. The project operates through teams of national personnel, including doctors, medical technicians, nurses, biologists, laboratory technicians and social workers. The multi-disciplinary approach is essential for the long-term sustainability of the project. However, the use of national personnel requires a strong investment in human resources and a commitment to



¹ Viral load testing is not currently considered essential under World Health Organization (WHO) antiretroviral treatment guidelines for resource-poor settings as a means of guiding decision-making on initiating treatment or the regular monitoring of ART response. WHO recommends that the use of viral load testing be confined primarily to the definitive diagnosis of HIV infection in children < 18 months of age vertically exposed to HIV during pregnancy, or in special circumstances such as the evaluation of more complex cases. Furthermore, WHO regards the monitoring of resistance using viral load testing in resource-poor settings as appropriate only when undertaken for the purposes of surveillance of HIV resistance on a population basis. These tests are undertaken for patients by the DREAM project on an exceptional basis through the availability of specially dedicated laboratory resources.

² Liotta G et al. Is total lymphocyte count a reliable predictor of the CD4 lymphocyte cell count in resource-limited settings? *AIDS*, 2004, 18: 1082-1083.

both academic and hands-on training, both on-site and abroad. Therefore, an ongoing training programme has been provided since the start of the project. DREAM has performed training courses in HIV/AIDS treatment and care for home-care assistants, nurses, biologists, laboratory technicians, service coordinators and physicians.

DREAM has developed a unique model for partnership between national and international staff. International volunteers are always present at the facilities, guaranteeing necessary technical and training support for national personnel, without ever replacing them.

INTRODUCTION OF MODERN TECHNOLOGY

A software entitled DREAMS (DREAM – Software) has been produced for use in the project to respond to the following needs:

- ▶ communication between all the centres
- ▶ management of case-load
- ▶ training
- ▶ monitoring activities such as diagnoses, visits, pharmacy service, delivery of food and other supplies, community and home-care services
- ▶ support for programmes that facilitate patient adherence (e.g. by checking missed appointments at the end of each day of service)
- ▶ granting national health workers the opportunity to access European and North American colleagues for consultation purposes, and to get a second opinion, if needed.

All DREAM activities are monitored using DREAMS. A computer network links all centres to the laboratories and to a coordination centre. This system ensures efficient monitoring of patients receiving treatment. The data collected can subsequently be used to improve the quality of interventions through applied research.

Security of information and confidentiality are guaranteed through separation of all personal details. Each patient is automatically assigned an identification number (ID), which is then used to identify him/her in subsequent contacts with programme services; this ID becomes the patient's reference and file number. At each medical consultation, all clinical notes are entered directly into the computer system. For every new contact, a log is created indicating the patient's symptoms, diagnosis and treatment prescribed. A space for additional notes by the physician on the patient's symptoms and

diagnosis is provided. At the end of the consultation, a new log is printed and inserted into the patient's clinical file.

Laboratory exam reports reach the care centres in hard copy or by e-mail, on computer diskette or digital pens. DREAMS stores the results of haemato-chemical tests of patients, permitting efficient monitoring of changes over time. With each incoming report, an update summarizing all laboratory levels is printed and added to the patient's file.

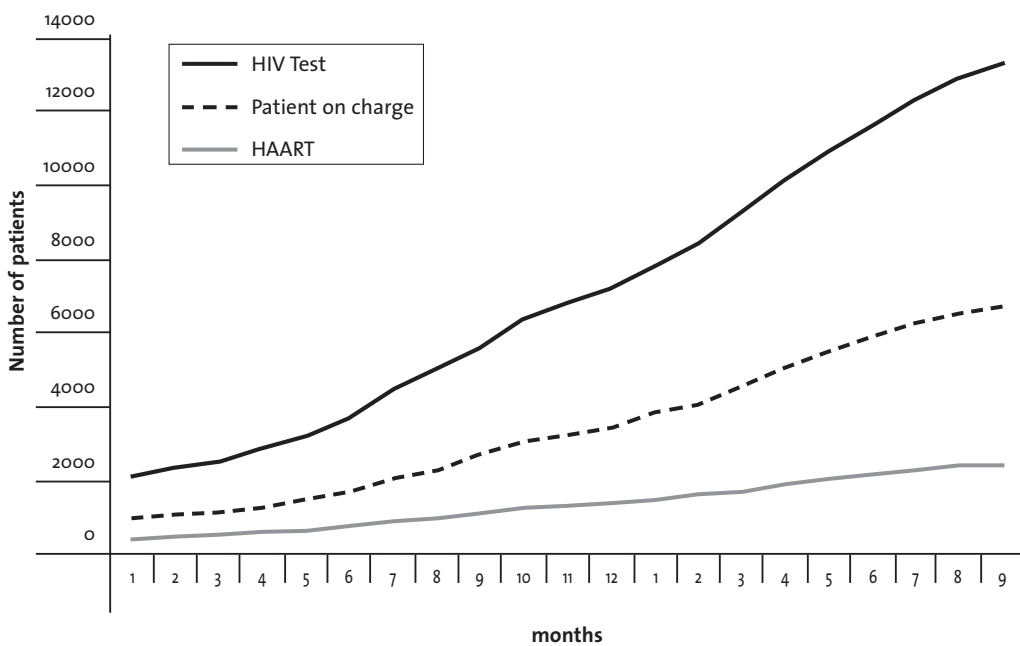
A satellite network for broadband communication over long distances has been established. It is expected that this network will be used more frequently with tele-medicine and tele-diagnostic methods, and should include the transfer of images. A complementary wireless network is used for internal communications.

RESULTS

Process and output indicators

At the end of September 2004, a total of 13 284 people underwent HIV screening and confirmatory rapid tests both in the CCMC and MCPC services operational in the Mozambican DREAM Centres. As a result, more than 6700 HIV-infected patients have been identified and are currently beneficiaries of the programme. Nevertheless, it is estimated that there are more than 60 000 direct and indirect beneficiaries of the programme. During the period September 2003 to September 2004 the number of new patients increased significantly; each month approximately 700 HIV tests were performed and about 300 new patients attended. An annual twofold increase in the number of beneficiaries has been predicted. Cumulative data from January 2003 to September 2004 (Figure 4) indicate that by the end of that period, 2373 patients started HAART, of whom 1837 currently still receive it. Of those who discontinued therapy, 279 (11.7%) started ART during pregnancy for the purpose of preventing vertical transmission of HIV to their infant (thus treatment was stopped after delivery); 145 patients (6.1%) died and 112 (4.7%) abandoned the programme. In addition, about 800 children born to HIV-infected mothers have received care and their health status has been monitored.

Figure 4. Cumulative number of patients attended to in the Mozambican DREAM Centres, January 2003 through October 2004

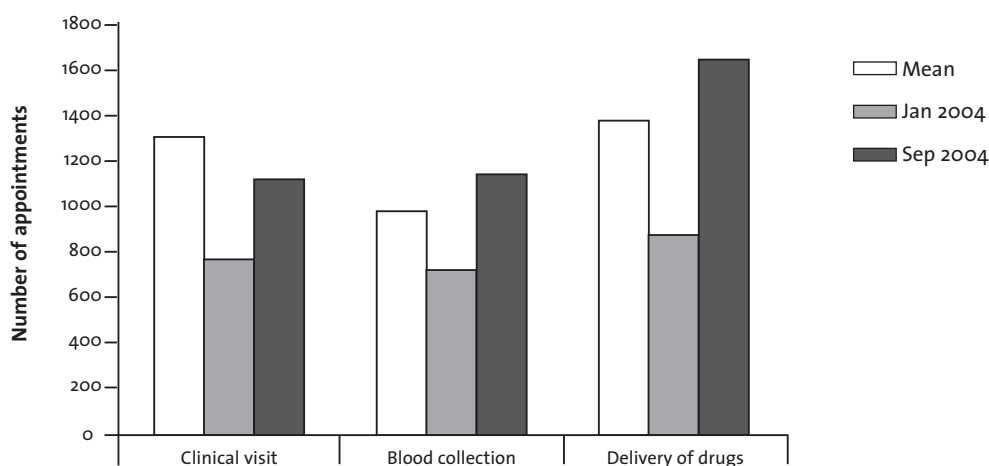


*Note: Patients "on charge" – patients that are being monitored (i.e. frequent clinical, immunological and biological check-up) following a positive HIV test result; patients on ART are included in this subgroup

In light of the rising number of patients, the laboratory services have grown accordingly. Approximately 600 viral load tests and 1000 CD4 cell counts were performed each month during the last year.

By September 2004, the overall dropout rate of the programme was 6% (394 of 6714 patients). This is equivalent to 0.2% per month, calculated over 27 months of activity. Between January and September 2004, more than 950 appointments for medical visits, delivery of drugs and blood collection were made per month (Figure 5).

Figure 5. Considerable increase in number of appointments at DREAM between January and September 2004



Preliminary outcomes

The preliminary outcomes are based on a retrospective analysis of the clinical cards of the beneficiaries of the Community Care and MCPC services^{3,4,5,6}. For the Community Care service, the data from a cohort of 1348 adult patients (mean age of 34 years; 62% females) was analysed. For all of these patients a complete clinical and laboratory baseline is available (Table 4). The initial clinical conditions of patients were generally quite poor. In approximately 42% (562) of these patients, the first CD4 cell count was below 200/ μ L. During the first clinical examination, almost 60% (784) of the patients were classified as WHO clinical stage III-IV. In November 2003, some of those in stages III-IV did not start

HAART either because they had already died, they were too ill to start treatment (i.e. with vomiting, or diarrhoea needing attention) or because their laboratory results were pending. However, 643 patients started HAART. Their baseline was generally the worst in terms of viral load, CD4 count, body mass index and haemoglobin if compared with the sub-sample of patients that did not receive HAART (Table 5). The death rate was 7.2% (46/643) and 11.9% (84/705) for the HAART and non-HAART groups respectively. The overall monthly mortality rate of 0.4% remained stable between September 2003 and February 2004.

³ Marazzi MC et al. Primi risultati del Programmema DREAM (Drug Resources Enhancement against AIDS in Mozambique) in Mozambico. *Ig Sanità Pubblica* 2002 Nov-Dic; 58 (6): 431-440.

⁴ Emberti Gialloreti L et al. Increase in survival in HIV-1 infected subjects in Matola-Mozambique, after the introduction of combination therapy with generic manufactured antiretrovirals: preliminary results from the DREAM cohort. Abstract of 10th Conference on Retroviruses and Opportunistic Infections, Feb 10-14, 2003 Boston, p. 122.

⁵ Liotta G et al.* Mother and Child Prevention and Care: Results from the DREAM Programme in Mozambique. Univ. of Tor Vergata, Rome, Italy; ²Community of Sant'Egidio, Rome Italy; ³Natl. Inst. of Hlth., Rome, Italy; ⁴Natl. Inst. of Infectious Diseases "L.Spallanzani", Rome, Italy; ⁵Ministry of Hlth., Maputo, Mozambique; and ⁶LUMSA, Rome, Italy

⁶ Palombi L et al. One Year of HAART in Mozambique: Survival, Virological, and Immunological Results of DREAM Project in Adults and Children. *Univ. of Tor Vergata, Rome, Italy; Natl. Inst. of Infectious Disease "L.Spallanzani", Rome, Italy; Community of Sant'Egidio, Rome Italy; Natl. Inst. of Hlth., Rome, Italy; Ministry of Hlth., Maputo, Mozambique; LUMSA, Rome, Italy; and Inst. Superiore di Sanita, Rome, Italy*

Table 4. Base-line characteristics of 1348 patients in Community Care service

Patient characteristics	Patients receiving HAART (n=643)	Patients not receiving HAART (n=705)
Age (in years)	34.3	32.8
Body Mass index	20.5	21.9
Haemoglobin (g/dl)	10.1	10.7
CD4 cells count (per μ L)	192	434
Viral Load (Log)	5.1	4.9

The effect of HAART on immunological and virological parameters has been assessed in a subgroup of 348 patients receiving HAART for more than six months (mean time of 222 days). In these patients all parameters improved; CD4 cells increased more than twofold and 70% of those observed achieved an undetectable viral load (Table 5).

Table 5. Comparison of parameters in patients receiving HAART

Patient characteristics	Patient evaluation pre-HAART*	Patient evaluation after six months of HAART*	% difference
Body weight (kg)	54.2 (\pm 9.7)	58.7 (\pm 7.7)	8.4
Haemoglobin (g/dl)	10.1 (\pm 6.5)	11.2 (4.3)	12.0
CD4 cell count (per μ L)	155 (\pm 54)	348 (\pm 72)	124.5
Viral Load (Log)	15.600 (\pm 13.800)	350 (\pm 4.900)	97.9

* Average (numbers in brackets indicate standard deviation)

A model to assess survival differences (Cox Proportional Hazard Model) showed that the group of patients receiving HAART had 15% more survivors after one year of treatment compared to the group not receiving HAART. In other words, about 95% of patients in the HAART group and 80% of patients in the non-HAART group survived during the study period.

The rate of HIV infection among infants born to HIV-infected mothers remained below 4% at one month and six months after birth. Considering that in the absence of interventions about a third of infants born to HIV-infected women will become infected with the virus, the DREAM project has been effective in preventing vertical transmission of HIV.

Some data are available on a group of 570 pregnant women accepted into the service prior to November 2003. About 105 (19%) of those women were lost to follow-up and 280 women were assisted through delivery. The mean age of these 280 mothers was 23.7 years; about 10% of the pregnant women had a CD4 count < 200/μL. At first visit, about 22% had a viral load above 55 000 copies/ml. The mean time on HAART before delivery was 62 days. Less than 10% of mothers gave mixed feeding to their baby. Qualitative viral load tests were performed on 146 children born to mothers participating in the MCPC programme. At 1 month of age, 6 infants (4.1%) were reported to be HIV-infected. Of the 55 infants who were tested at 6 months of age, 2 (3.7%) were HIV-infected. The infant mortality rate and maternal mortality rate were 84.7‰ and 0.62% respectively; both values are lower than those reported among the Mozambican general population (114‰ infant mortality and 1% maternal mortality).⁷

COSTS

Based on the total expenses incurred and the number of people assisted, *the gross cost per patient year* was US\$ 480 at baseline in 2003. However, this estimate has not taken into account the following factors:

- ▶ Patient profile: level of assistance required, treatment status (i.e. whether patient receives HAART or not), stage of disease, pregnancy
- ▶ Number and type of opportunistic infections
- ▶ Time of entry into the DREAM project.

The average cost per HAART patient per year was some US\$ 800 in 2003, including all direct (drugs and laboratory exams) and indirect costs (personnel, running cost of the clinical centres, administration unit).

The use of generic fixed-dose combination drugs has lowered the drug price to about 5% of the price of patented pharmaceutical products (i.e. treatment with generic drugs costs approximately US\$ 270 per patient per year compared with at least US\$ 5000 per patient year with a treatment with brand-name drugs). The total patient care cost is likely to drop further through potential price reduction of, for example, kits for laboratory analysis.

LESSONS LEARNED

A public health programme can offer treatment to people with HIV/AIDS at very contained prices while maintaining high standards.

The high prevalence of HIV in sub-Saharan Africa has resulted in the urgent need to provide antiretroviral drugs. However, the current availability of ARVs is disproportionate to the number of people living with HIV/AIDS in need of treatment. The first step is to apply findings of clinical trials to public health. Secondly, the intervention model must take into account the reality of African patients. Basic health services are limited, travelling long distances may prevent them from seeking care, and people living with HIV/AIDS still face stigma and discrimination. To overcome the challenges involved in providing effective HIV treatment and care, and to address the need for preventing further transmission, a

⁷See Osman NB et al. Perinatal outcome in an obstetric cohort of Mozambican women. *Journal of Tropical Pediatrics*, 2001. 47(1):30-8 and UNDP. Rapporto 2003 su Lo Sviluppo Umano - 14: Le Azioni contro la Povertà. Trento - Italy. Rosenberg & Sellier; 2003

comprehensive and sustainable approach is required. DREAM represents such a model, bringing on board the extraordinary example of people living with HIV/AIDS themselves.

Investment in training is a key strategy in the battle against HIV in these countries.

Training of people involved in providing services for people living with HIV/AIDS has become a key component of programmes to fight HIV/AIDS and is crucial to ensuring long-term sustainability and scale-up of HIV/AIDS programmes. This outcome is attainable in the short term, provided that national and international institutions assist in the transfer of knowledge and expertise to those on the ground. This “new class” of professionals will be capable of pushing ahead health development in their own countries.

Adherence is strongly increased when drugs are free of charge

Adherence to treatment is one of the most critical aspects of a public health approach to HIV control in Africa. In the experience of DREAM, a high level of adherence arises from two factors:

1. Assurance of access to treatment, which would allow patients to lead a practically normal life for a long time in the majority of cases. This assurance is provided to patients from the first time they access the service, and is a very strong motivation for adherence.
2. Treatment is free of charge. This information is given to patients at the first meeting. The decision to provide free treatment was based on the following considerations: if HIV is a public health problem, the system has a clear interest in ensuring access to treatment because the benefits extend to the entire population. Free treatment overcomes many of the challenges that are related to fees for services, in particular limited adherence to treatment and potentially resulting drug resistance.

The availability of treatment helps to reduce stigma related to HIV. Associations of HIV-positive patients become particularly powerful in the fight to eradicate fear.

DREAM has proven that that the chain binding AIDS and death together can be broken. As a result, fear and stigma, which haunt so many people with AIDS, may be overcome. Those who access treatment find their lives transformed, and this change often leads to a new awareness of their place in society. Their fear is diminished, often leading to a desire to speak from experience for the benefit of others. Many associations of people living with HIV/AIDS have been created within the framework of the DREAM programme, setting in motion a dynamic process of awareness-raising within Mozambican society.

CONCLUSION

DREAM is expanding through the use of successful approaches. The DREAM project has begun activities in Malawi, will be replicated in Guinea Bissau, Guinea Conakry and the United Republic of Tanzania. It is likely that the projects will have a positive impact that may even include a change in behaviour patterns. This leads to greater nationwide awareness of the prevalence and risk of HIV infection and a stronger national response to the HIV/AIDS epidemic.

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