PERSPECTIVES AND PRACTICE IN ANTIRETROVIRAL TREATMENT

Antiretroviral therapy in primary health care: experience of the Chiradzulu programme in Malawi

CASE STUDY

World Health Organization

MEDECINS SANS FRONTIERES

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and the Ministry of Health and Population, Chiradzulu District, Malawi

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INTRODUCTION

The programme of Médecins Sans Frontières (MSF) in Chiradzulu District, Malawi, has demonstrated the value and feasibility of antiretroviral therapy (ART) in a poor rural context. Some 2194 patients were receiving ART in March 2004 and the clinical results were comparable to those found in developed countries.

Although the Chiradzulu programme is still evolving and the treatment systems and point of care are still being modified, the project already shows that, when treatment is adapted to local conditions and adequately supported by human and financial resources, comprehensive HIV/AIDS care, can be effectively provided in a rural setting.

The Chiradzulu programme is one of MSF's largest. MSF currently provides ARV drugs to more than 13 000 patients in 56 projects and 25 countries. These projects provide a continuum of care, including prevention efforts (health education and the prevention of mother-to-child transmission of HIV), voluntary counselling and testing, the treatment and prevention of opportunistic infections, ART and psychosocial support.

The present case study outlines the ways in which MSF and the Ministry of Health and Population (MOHP) have sought to simplify treatment and diagnosis and to modify the delivery of care in order to increase the number of patients benefiting from ARV treatment. This pilot experience demonstrates how ART can prolong the lives of patients in resource-poor settings.

CONTEXT OF THE PROGRAMME

Malawi, a landlocked country in southern Africa, is contiguous with Mozambique and Tanzania to the north and with Zambia to the west. It is severely affected by the HIV/AIDS epidemic. In 2003 the prevalence of HIV/AIDS among women attending antenatal clinics was estimated to be 19.8%, one of the highest rates in the world (1). Moreover, it has been estimated that 1 100 000 adults and children are HIV-positive (2). HIV/AIDS is now the leading cause of death in the normally productive age group of 20-49 years and is estimated to kill 86 000 adults and children every year. It has reduced life expectancy at birth to 38.5 years (3).

The health sector infrastructure in Malawi is weak and has been unable to cope with this burden of chronic illness. Comprehensive HIV care and support, including highly active antiretroviral therapy (HAART), is urgently needed both to reduce individual suffering and to dispel the fear, despair and hopelessness associated with HIV/AIDS. HAART would also help to diminish the massive losses in productivity caused by AIDS.

MOHP is in the process of implementing a national HIV programme including HAART in 54 hospitals throughout the country, including all 23 MOHP district hospitals. The first patients have started receiving antiretroviral treatment as of July 2004 in three hospitals, with the other facilities scheduled to begin treatment from October 1. The target is to have 43,000 patients under treatment within a year, out of an estimated 85,000 -125,000 people who currently need treatment. The programme involves using generic fixed-dose combinations as first-line, but does not currently include alternative first-line regimens or second-line regimens. Children will be enrolled on treatment within a year of the programme's start. Treatment will be free of charge in all facilities, including private clinics.

Beginning of AIDS care in Chiradzulu District

Chiradzulu district in southern Malawi had a population of 252 000 in 2002, 90% of whom earned their living by farming. It is estimated that 25% of the adult population is HIV-positive and that over 2500 people are in stage 4 of the disease and therefore in urgent need of HAART, while 5000 are symptomatic and would also benefit from immediate access to treatment.

MSF has been working in Chiradzulu district since 1997 in collaboration with MOHP. The programme began by focusing on reducing the transmission of HIV within existing facilities of MOHP and rural missions. Initial prevention activities included the implementation of universal precautions, the provision of safe blood products and the management of sexually transmitted infections. The programme, which was primarily focused on youth, commercial sex workers and the police force, also provided information, education and communication on safer sex and testing and counselling.

In 1999 the project added a component of care for HIV-infected inpatients. The management of opportunistic infections in all health facilities and the prevention of mother-to-child transmission (PMTCT) in the Chiradzulu District Hospital were added in 2001. HAART was introduced at the District Hospital in the same year, the most severely affected patients receiving treatment first, and a monitoring component was included. The programme was also designed to demonstrate that HAART would lengthen life and allow people to regain their autonomy.

HAART was then extended from the Chiradzulu District Hospital to all 11 peripheral health facilities in the district. The programme evolved from initiating treatment in only a handful of patients per month when it began, to doing so in more than 210 in March 2004, by which date there were 3122 patients under care in 12 facilities. Of these patients, 2194 were receiving HAART.

This dramatic increase in the case-load has been attributable to modifications in the criteria for initiating treatment and to simplification of the programme. The modifications have included the elimination of mandatory CD4 counts and other laboratory tests as criteria for initiating HAART, the training of nurses and clinical officers to be more involved in initiating and monitoring HAART, and the provision of care closer to the communities in need.

OVERVIEW OF THE PROGRAMME

Initial design

When the treatment programme began at the District Hospital in July 2001, patients presenting with clinically advanced HIV were selected for treatment on the basis of CD4 counts or WHO clinical staging criteria. The assessments were carried out by a selection committee consisting of representatives from the District Administration and MSF, which met once or twice monthly. Adults were eligible for treatment if they had CD4 counts of <200/ml or were at WHO stage 4; children qualified if they were at less than 15% of the normal CD4 ratio.

The selected patients completed two sessions of treatment counselling and then began receiving HAART. The initial design of the programme required all patients to begin therapy at hospital-based HIV clinics. However, some patients were referred to health facilities closer to their homes for follow-up.

Steps to increase patient numbers

In August 2002, several steps were taken in August 2002 to increase the numbers of people beginning treatment:

- the number of opening days per week of the HIV clinic in the District Hospital was increased from three to five;
- to speed treatment initiation the selection committee, which had never refused treatment to a patient, was disbanded, and patients meeting the criteria were immediately referred to counsellors;
- the number of patients in initial HAART counselling sessions was increased from one to five or six;
- the clinic began offering a full set of services every day;
- consultations were made available at health facility level, closer to patients.

The stipulation that therapy could only begin after CD4 counts had been obtained was changed at the beginning of 2003 to allow patients in late WHO stage 3 and in stage 4 to be added on the basis of clinical criteria alone.

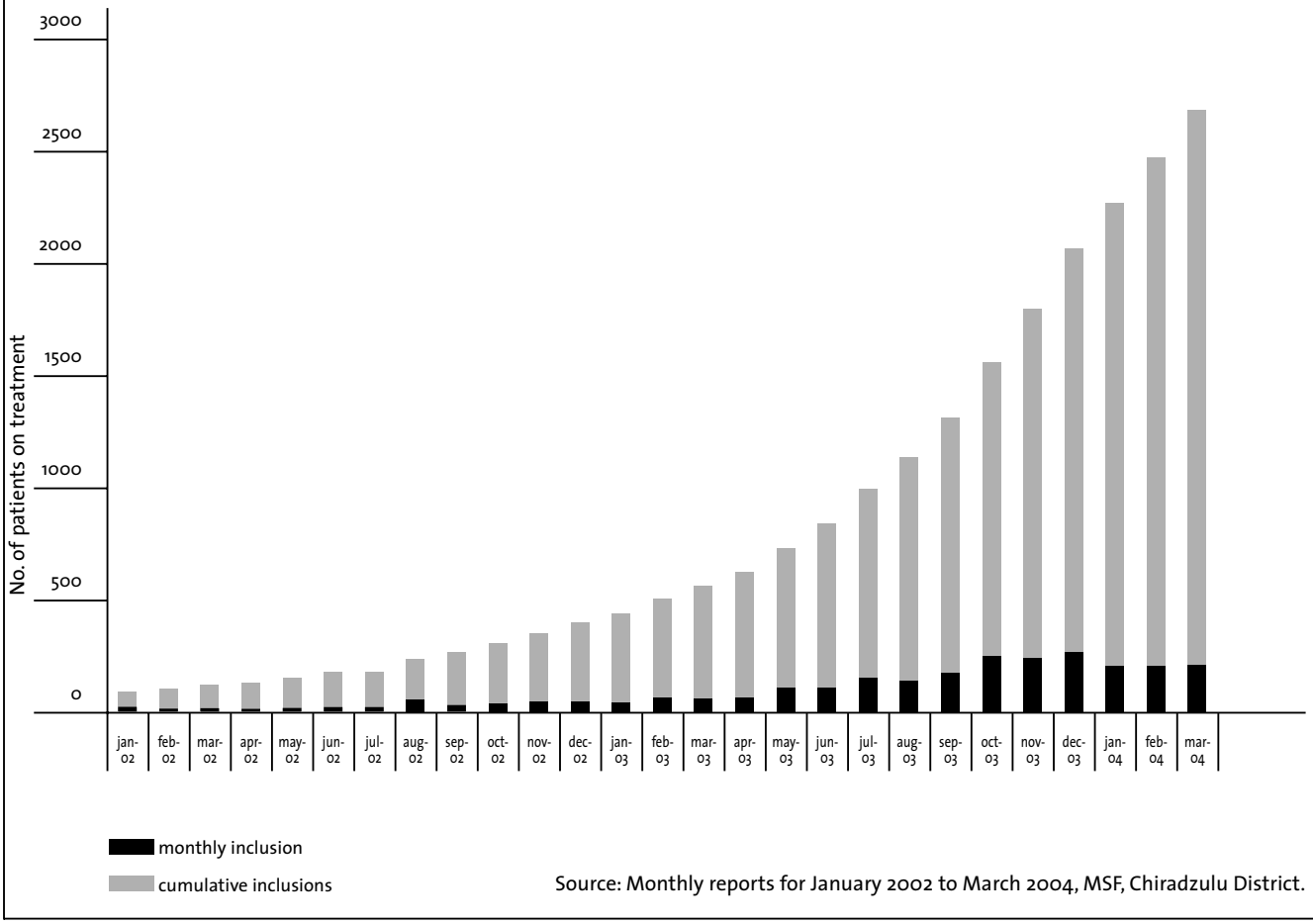
Table 1: Total consultations categorized by WHO staging

WHO stage	Patients (%)
1 (asymptomatic)	738 (11.7)
2	986 (15.6)
3	2725 (43.3)
4	792 (12.6)
Unspecified[a]	1055 (16.7)
Total patients HIV+	6296

[a] Refers to a lack of data when clinicians cannot access the diagnostic method needed to code for WHO staging.
Source: MSF.

In March 2004, 3122 patients were attending for consultations, of whom 2194 were receiving ARV treatment, a fourfold increase over the previous year. Since the inception of the programme, 2692 patients have started ART, the difference of 498 being attributable to death, loss to follow-up, or discontinuation of treatment.

Fig. 1: HAART monthly and cumulative inclusions, Chiradzulu, January 2002 to March 2004



Source: Monthly reports for January 2002 to March 2004, MSF, Chiradzulu District.

Decentralization

HIV clinics have been run at health facilities, instead of exclusively at the District Hospital, since December 2002. They now account for 40% of consultations. It is intended to transform the District Hospital into a referral centre that can provide specialized services and care.

Beginning in early 2003, twice-monthly HIV clinics run by two clinicians were initiated at 11 health facilities in the District. These facilities introduced voluntary counselling and rapid testing. Patients were thus enabled to begin ART without having to go to the District Hospital. This was an important step since patients often took more than three hours to walk to the hospital.

Table 2: ART enrolments by hospital or health facility

Patients starting ART	Adults	Children	Total
Number of patients between 1 July 2001 and 30 April 2003*			
At the District Hospital	512	44	556
At a health facility	45	5	50
Number of patients between 1 May 2003 and 31 March 2004*			
At the District Hospital	955	89	1044
At a health facility	591	74	665
Total	**2103**	**212**	**2315**

*Some patients without complete data are excluded. Source: MSF, Chiradzulu.

2: ART initiations by hospital and health facility

Treatment regimens

Each regimen used in the programme included two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI) or protease inhibitor.

At the outset of the programme the vast majority of patients were started on zidovudine/lamivudine + nevirapine (ZDV/3TC + NVP). This was changed in October 2002 to the triple fixed-dose combination (FDC) stavudine/lamivudine/ nevirapine (D4T/3TC/NVP). Fixed-dose combinations makes it easier for patients to adhere to treatment.

Other drugs used in the programme are didanosine (ddI), an NRTI and efavirenz (EFV), an NNRTI. Currently the only protease inhibitor in use is nelfinavir (NFV).

The initiation of therapy involves patients taking fixed-dose D4T/3TC plus NVP separately to allow the latter to be titrated up in accordance with the recommended regimen. For patients on concomitant rifampicin-containing tuberculosis treatment, D4T/3TC + EFV is used as the first-line therapy in accordance with WHO guidelines.

Syrups are used for very young children weighing under 10 kg. For older children a dosing chart is used so that doses can be given in relation to weight. Because of the lack of paediatric formulations, fixed-dose tablets are cut and additional NVP is given when necessary. Paediatric FDCs are urgently needed so that this practice can be abandoned.

Table 3: Preferred ARV regimens

	First-line regimens	Second-line regimens
Adults	D4T/3TC/NVP (FDC)	ZDV + ddI + NFV
Children	3TC + ZDV + NVP	D4T + ddI + NFV
	3TC + D4T + NVP	ZDV + ddI + NFV

Adherence support / patient follow-up

Before HAART is initiated, patients attend a group session with a counsellor, who explains not only the nature of the treatment but also other issues, e.g. transmission. Individual counselling takes place a week later, when the patients are asked what they remember from the group session. Each patient who demonstrates a satisfactory understanding of the matters covered receives enough drugs for two weeks. At follow-up visits the remaining pill stocks are counted and the patients are asked if they have any problems in taking their medicines.

This is a departure from the first year of the programme, when, in order to assure adherence to treatment, the care team systematically made home visits during the first weeks of each person's HAART. This practice was abandoned in 2002 because of the increase in the patient load.

When home visits stopped the work done by dispensing nurses was supplemented by non-medical personnel who had been trained to perform adherence counselling.

By the end of 2002, 2% of patients had been lost to follow-up. By March 2004 the corresponding proportion was 12% (7.5% of adults and 4.7% of children). In order to combat this trend, greater access is being given to adherence counselling at health facilities. Sometimes this counselling takes place in groups so that more patients can be reached with the same human resources.

In addition to the formal adherence support provided by MSF and MOHP, a group of people living with HIV/AIDS has created a support group who are assisted by adherence counsellors.

Pill counts at the time of consultation indicate that more than 90% of patients adhere to treatment. A mean increase of 178 CD4 cells/mm^3 at 12 months confirmed that treatment was successful.

The frequency of follow-up visits depends on the clinical condition of the patients. During the first trimester following HAART initiation, all patients receive medical consultations as well as counselling sessions.

After the first trimester a nurse assesses the need for and frequency of medical consultations. In general, patients who have stabilized and are doing well on treatment are seen every two months by a nurse or a clinician when they come to renew their prescriptions. At the same time they receive adherence counselling from the treatment counsellor if adherence problems are identified.

An annual CD4 count is performed on all patients. Until now the diagnosis of treatment failure has been based on changes in CD4 counts, when available, and on clinical symptoms. There has been no access to testing for viral load.

A nurse provides individual counselling

LABORATORY MONITORING

Testing and counseling with use of rapid HIV tests are conducted at the health facilities where comprehensive care is provided.

An MSF laboratory supervisor runs the District Hospital laboratory where CD4 monitoring is conducted, supported by an MOHP technician and an MSF technician.

The monitoring guidelines were revised when increases occurred in the numbers of patients seen in the outpatient ward. At the outset of the programme, CD4 measurements were made for all patients by means of Dynabeads™, a manual technique allowing a technician to assess only 12-18 samples a day, with quality control involving routine verification of a subset of samples at the Wellcome Trust Centre in Blantyre. This procedure eventually placed a considerable burden on the laboratory facility and delayed the inclusion of patients. The criteria for initiating treatment were therefore modified at the beginning of 2003 so that patients in late stage 3 and all those in stage 4 could enter the programme without CD4 counts having been obtained.

In patients who show no clinical signs of disease, treatment protocols now require annual CD4 testing for monitoring purposes. In order to increase monitoring capacity, MSF has begun testing a cyberflow machine (Partec™) that can perform 50 CD4 tests per day.

HUMAN RESOURCES AND TRAINING

There is a critical shortage of health workers in Malawi because of a lack of sufficient numbers of newly trained personnel, difficult working conditions, migration to countries where salaries are higher, HIV-related mortality, and other factors. Table 4 shows the extent of such shortages in Chiradzulu District.

The MSF HAART programme has had to draw on both local and expatriate staff in order to obtain direct medical services, technical assistance and training. The local personnel include a doctor, three nurses, six clinical officers, six counsellors and a laboratory technician, a logistician/administrator, a logistics officer, two data-entry clerks, two midwives, an information, education and communication officer, and supporting staff. The MOHP clinicians were trained by MSF in HIV care and the delivery of HAART.

As there were insufficient numbers of nurses available to do counseling, in 2001, the MSF programme began training non-medical people with Malawi School Certificates (the equivalent of high school graduate) to fill this role. Currently, six counsellors have completed a six-week National AIDS Commission curriculum course and are supervised by an expatriate nurse. They work both as testing, and adherence counsellors. MOHP officials supported this solution. The experience of training non-medical personnel to act as counsellors has shown that responsibility can be devolved in order to reach more patients.

However, the consequences of these changes on the continuum of care have to be considered. For example, the increased patient load resulted in a need for more counsellors. When more counsellors were provided, more patients qualified for treatment. This led to clinicians being overwhelmed by the need to initiate and follow up patients.

The Chiradzulu HIV programme has responded by offering additional training on the diagnosis and treatment of opportunistic infections and on ARV follow-up for nurses so that more patients could be handled by each health worker.

Local and expatriate staff plan training

Table 4: Medical staff, Ministry of Health and Population, Chiradzulu District, Malawi

	Posts	Vacancies	Unfilled posts %
Health facilites			
Doctors	0	0	0
Nurses	20	2	10
Medical assistants	6	3	50
Hospital			
Doctors	1	0	0
Clinical officers	10	4	40
Medical assistants	9	7	78
Nurses	75	52	69
Community			
Nurses	19	14	74

Source: MSF, Chiradzulu.

Table 5: Supplemental local and expatriate medical staff, ARV programmes, Médecins Sans Frontières, Chiradzulu District, Malawi

	Local	Expatriate
Doctors	1	3
Nurses	3 (including 1 for hygiene and quality of care)	1 (counsellors' coordinator)
Medical assistants:		
◗ Clinical officers	6	
◗ Counsellors	6	
◗ Laboratory technicians	1	1

Source: MSF, Chiradzulu.

DRUG AND RESOURCE MANAGEMENT

As from the beginning of the programme, MSF sought to purchase drugs locally. Before procurement began, an MSF pharmacist visited the country to assess potential local distributors of generic and branded products. On the basis of this assessment, manufacturers of unregistered products were asked by MSF to submit registration dossiers. Pending availabilty in Malawi, purchases were made from originator companies in Europe. By November 2001, MSF had succeeded in obtaining all the necessary ARV drugs through local distributors. At present, two medicines are not available locally (EFV 600 mg and NFV powder) because the manufacturer has not registered them.

The programme now relies primarily on the WHO prequalification system to validate the quality of ARV drugs. If there are no prequalified sources of necessary drugs, MSF either assesses additional sources through its internal validation process or purchases originator products locally or from Europe. A small supply of drugs is kept in the pharmacy of the District Hospital. Bulk supplies are maintained at an MSF storage facility. The setting up of drug dispensing at mobile clinics is time-consuming and a better system should therefore be developed.

Rapid increases in patient numbers presented a major challenge, especially when case-loads and drug requirements were difficult to predict. The buffer stock covered immediate requirements but extra orders had to be placed in order to meet a dramatically increased demand and ensure continuous treatment.

Exact drug demand being difficult to forecast, it was necessary to build local buffer stocks and strong links with the suppliers. A particular problem was the suppliers' need for three months' notice to deliver orders. On the other hand, the use of FDCs reduced the number of products to be managed and has made supply easier.

The maintenance of diagnostic supplies also presented a challenge: supplemental orders were necessary when stocks of rapid tests were more quickly depleted than had been anticipated.

COMMUNITY INVOLVEMENT

The need for strong community linkages in Chiradzulu was recognized at the outset of the project. Between May and August 2002, 85 community chiefs received HIV education. They were informed about disease progression, prevention and care, and were encouraged to disseminate information on the availability of treatment in their communities. The chiefs also promote prevention strategies, e.g. by supporting the distribution of condoms.

Some people living with HIV/AIDS who receive HAART have formed a peer support group involved in adherence counselling, community education and other roles.

MONITORING THE PROGRAMME

Medical information collected on a standardized form at every consultation is fed into an MSF/Epicentre-designed data management system (FUCHIA) that produces standardized reports, including key epidemiological indicators of, e.g. activity, morbidity and mortality. The patients keep a copy of the form as part of their personal medical files.

PATIENT OUTCOMES

It is important to note that 74% of patients, including the first group admitted late in 2001, are still alive and taking treatment. Fifteen per cent of patients have been on ART for more than a year.

Of the 2317 patients who commenced ART at the beginning of the programme, and for whom complete data exist, 230 died and 169 were lost to follow-up. In addition, 99 experienced side-effects attributable to ART which were severe enough to necessitate that at least one drug be changed.

A majority of patients for whom there were baseline CD4 measurements were severely immunocompromised when treatment began: 12.6% of patients had CD4 counts under 50, while 38% had CD4 counts of 50-200. The mean CD4 gain was strong: 85 after six months for 188 patients, 178 after 12 months for 192 patients, and 180 after 18 months for 29 patients (Table 6). The vast majority of patients who did not have baseline CD4 tests were at WHO stage 3 or 4 at the time when treatment was initiated.

There is no access to routine viral load testing in Chiradzulu. To assess the programme, a measure was taken of viral loads in 477 patients who had been on treatment for at least six months. 407 patients were found to have undetectable levels of virus (less than 400 copies), demonstrating that HAART is able to reduce viral replication in patients at Chiradzulu.

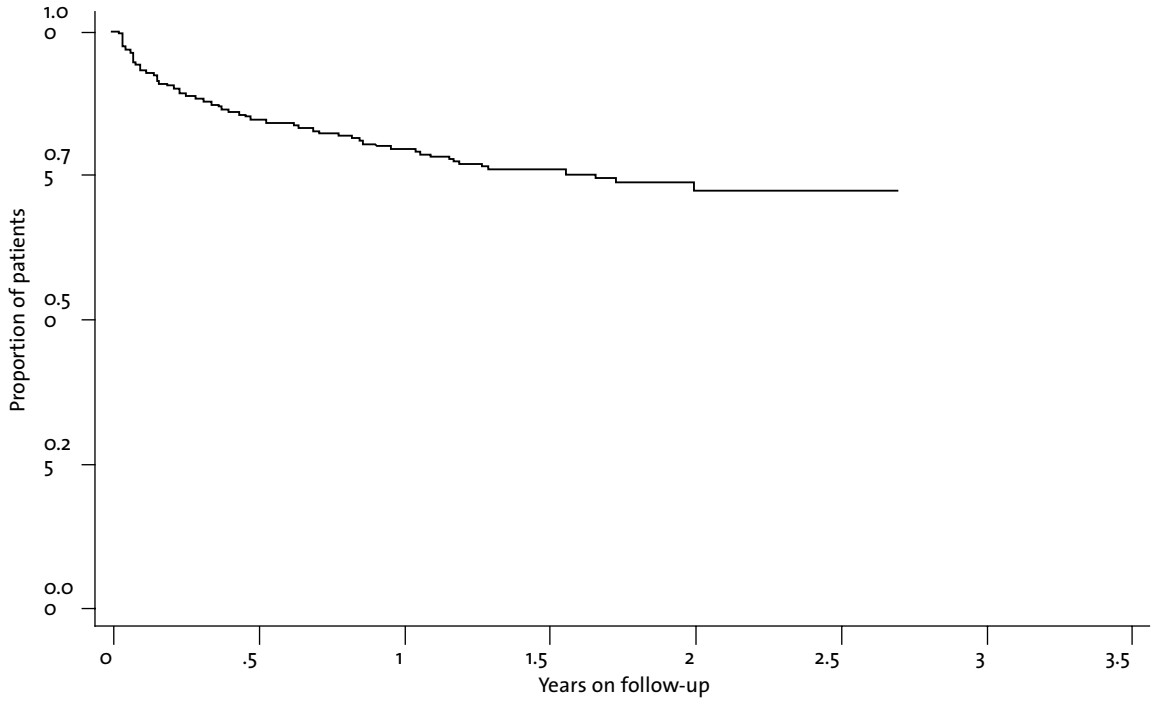
Table 6: Patient outcomes*

	Adults	Children <13	Total
Patients who began ART since outset of programme	2105	212	2317
Patients alive, followed up and still on treatment	1680	174	1854
Recorded patient deaths since the biginning of programme	209	21	230
Patients lost to follow-up	159	10	169
Patients who stopped treatment	57	7	64
Patients who stopped at least one drug because of side-effects	94	5	99
Baseline CD4 at start of ART			
<50:	264 (12.6%)		
50-200 (<15% children):	800 (38%)	74 (86%)	
200-500 (15-24% children):	253 (12%)	7 (8.1%)	
>500 (>25% children):	13 (0.6%)	5 (5.8%)	
Not available:	775 (36.8%)		
Mean CD4 change at:			
6 months	85 (n = 188)		
12 months	178 (n = 192)		
18 months	180 (n = 29)	Not available	
Weight gain in kilograms:			
6 months	3.5 (95% CI: 3.1 –3.8)		
12 months	4.5 (95% CI: 4.0 –5.1)		
18 months	3.8 (95% CI: 2.9 –4.7)		

*Some patients for whom the data are incomplete have been excluded. Source: MSF, March 2004.

Fig. 3: Probability of patients' clinic attendance while on ARVs

Probability of patients attending for clinic appointments while on ART, excluding patients who died and those lost to follow-up



Source: MSF, Chiradzulu.

LESSONS LEARNT: TREATING MORE PATIENTS WITHIN LIMITED HEALTH CARE STRUCTURES

The Chiradzulu programme is still evolving. By learning through experience the Chiradzulu team has successfully employed various strategies to increase the numbers of patients under care in poor rural settings with limited health care infrastructures.

- *Simplification.* Increases in patient enrolment rates rose rapidly because of:
  - the use of FDCs, which simplified the treatment regimens, made prescribing easier for clinicians and generally facilitated compliance with treatment;
  - the decentralization of the point of care from the District Hospital to community health facilities, increasing the reach of the programme;
  - the reallocation of tasks among health staff professionals in order to enable existing and supplemental staff to handle larger case-loads, e.g. through the training of nurses and clinical officers to assume some tasks formerly performed by doctors;
  - the reduction of dependence on laboratory monitoring for the initiation of treatment. (An absence of access to monitoring was not allowed to act as a barrier to treatment: the requirement to have CD4 counts before initiating treatment was dropped for patients in WHO stages 3 and 4. Table 7 indicates steps for simplifying treatment protocols.)
- *Aggressive drug procurement.* Initial labour-intensive efforts to register both generic and brand suppliers, keeping the overall drug cost to a minimum,

will make the programme more sustainable over the long term. The introduction of the WHO prequalification process has made it much easier than before to choose drug suppliers.

Major challenges

- *Clinical monitoring*. At the health centre level there is an urgent need to develop clinical algorithms so that nurses working in isolated locations can follow up patients within existing structures and with existing resources. HAART should be integrated into the work of standard outpatient departments.

- *Laboratory monitoring*. There is a need for CD4 and viral load monitoring tests that are more affordable and easier to use. The most urgent requirement is for a means of measuring viral load so that patients can be switched to second-line combinations when their viral load is rising but before they fail clinically.

- *Paediatric formulations*. Current treatment regimens are complex, cumbersome, difficult to administer and expensive. There is an urgent need for the development of new formulations including paediatric FDCs.

- *Second-line therapy*. During the next two years the programme will face the challenge of growing numbers of patients who fail first-line treatment. There is consequently an urgent need to advocate for lower prices of second-line drugs and the development of new FDCs.

Table 7: Changes in MSF protocols allowing increased numbers of patients to be treated, Chiradzulu District, Malawi

Before simplification	After simplification
Testing only at District Hospital.	On-site rapid testing extended to health facilities.
HAART inclusion/follow-up only at District Hospital.	Inclusion/follow-up extended to 11 local health facilities, visited twice monthly by clinicians.
Inclusion on basis of: CD4 count <200 (<15% for children).	Inclusion on basis of: HIV stage advanced-3 or stage 4; **or** HIV stages 1, 2 or 3 plus CD4 count <200; **or** pregnant women in PMTCT programme plus CD4 count <350; **or** HIV stage 1, 2 or 3 plus CD4 count <15% (for children).
Applicants' eligibility reviewed by selection committee.	Clinicians and counsellors make assessment for inclusion.
Retained patients attend two ARV counselling sessions before treatment.	First counselling session in groups of five or six; second session is one-on-one and is a week later at hospital or two weeks later at health facility.
HIV clinic in District Hospital open three days a week.	HIV clinic in District Hospital open five days a week.
First-line protocol: ZDV/3TC/NVP.	First-line protocol: fixed dose d4T/3TC/NVP. (This change was made to assist adherence through use of FDC.)
First-line protocol available in four pills.	First-line protocol available in triple FDC, two pills a day.
Only clinicians perform diagnosis and treatment of opportunistic infections and follow up stable HAART patients.	Nurses trained in diagnosis and treatment of opportunistic infections and in follow-up of stable HAART patients in order to relieve strain on clinicians.
Systematic home visits in first weeks of HAART.	Counselling/adherence support sessions at hospital/health facility ongoing but especially in first months of HAART.
CD4 counts performed at least every six months to monitor progress.	CD4 counts performed only annually once HAART initiated (or when clinical signs appear).

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