Antiretroviral Therapy in Primary Health Care:

Experience of the Chiradzulu programme in Malawi

Case Study

Médecins Sans Frontières (MSF) Malawi

July 2004

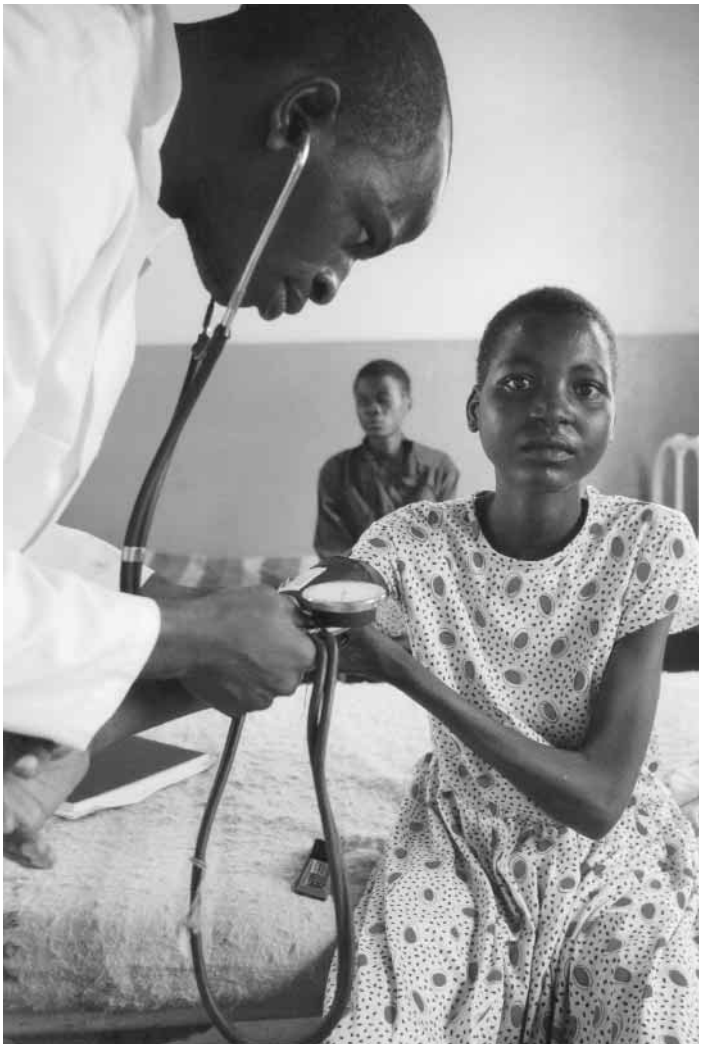
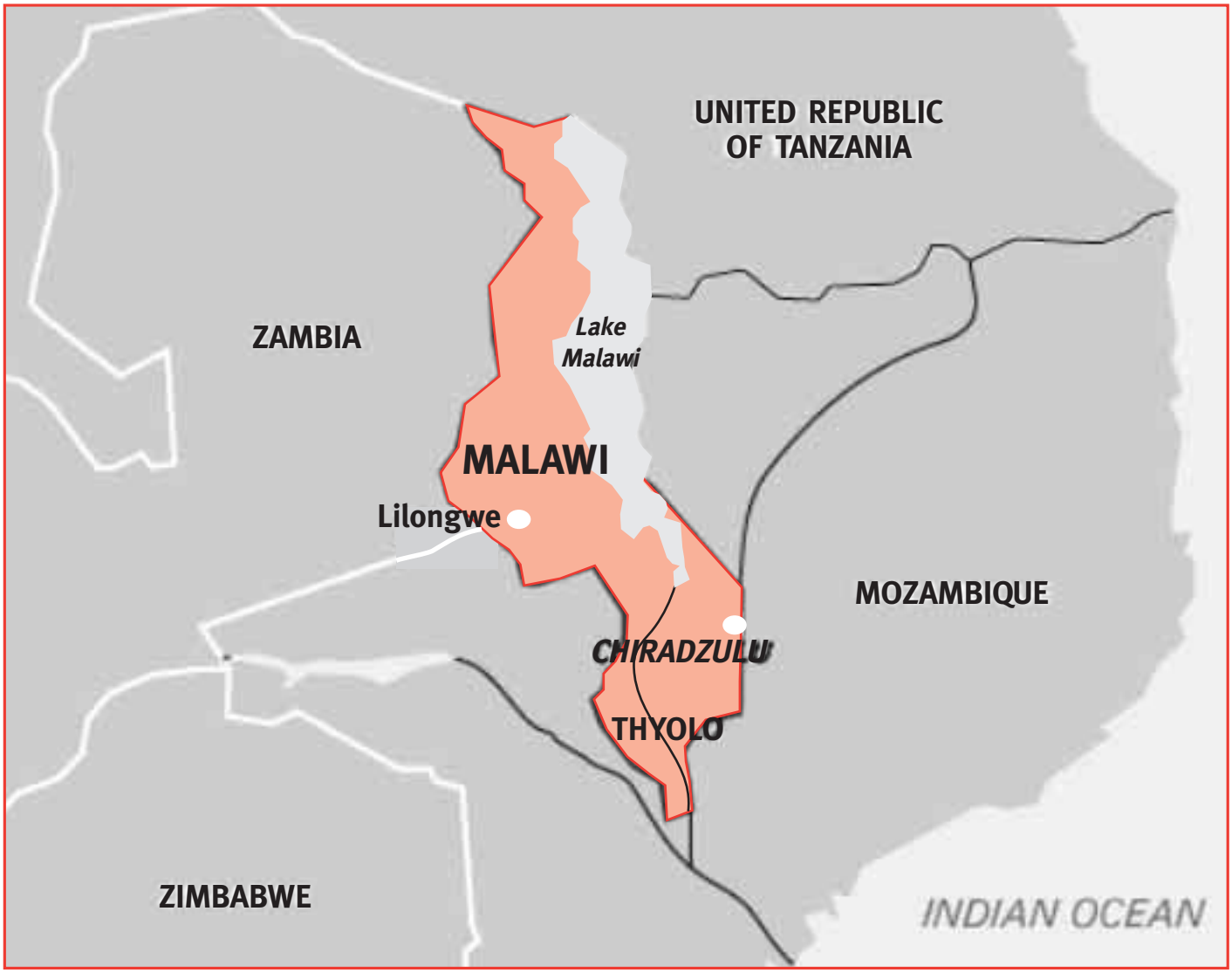


Photo: Gael Turine



CASE STUDY

~~The Médecins~~ Sans Frontières (MSF) programme which provides highly active antiretroviral treatment (HAART) to patients living with HIV/AIDS in Chiradzulu, Malawi, has demonstrated the value and feasibility of ARV treatment in a poor rural context. Around 3,000 patients are now on HAART in this programme and clinical results are comparable to those found in developed countries.

Although the Chiradzulu project is still evolving, and treatment systems and point of care continue to be modified, the project has already shown that when treatment is adapted to local conditions and is supported by human and financial resources, rural health systems can effectively provide comprehensive HIV/AIDS care.

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

In addition to Chiradzulu, MSF runs an antiretroviral treatment programme in Malawi's Thyolo district. In March 2004, 385 people were being treated in this project. This case study focuses exclusively on the Chiradzulu programme, however. It outlines the ways in which MSF and the Ministry of Health and Population (MoHP) sought to expand the number of patients benefiting from antiretroviral treatment by simplifying treatment and diagnosis protocols and modifying care delivery.

PROGRAMME CONTEXT

Malawi

Malawi is a landlocked country classified as least developed by the United Nations, which lies in southern Africa, flanked by Tanzania and Mozambique to the north and south, and Zambia to the west. Malawi is severely affected by the HIV/AIDS epidemic: in 2003, national HIV/AIDS prevalence was one of the highest in the world, estimated at 19.8% of those attending antenatal clinics[1], and the National AIDS Commission estimates 1,100,000 adults and children were living with HIV/AIDS[2]. HIV/AIDS is now the leading cause of death in what should be the most productive age group (20-49 years). In total, HIV/AIDS kills an estimated 86,000 adults and children every year in Malawi and has reduced life expectancy to 38.5 years[3].

Malawi's health infrastructure is weak and has so far been unable to cope with this burden of chronic illness. Comprehensive HIV care and support, including HAART, is urgently needed, both to reduce individual suffering and to dispel the fear, despair and hopelessness that currently surround HIV/AIDS. Additional accessibility to HAART would also help address the massive loss of productivity due to AIDS.

The Malawi 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 started receiving antiretroviral treatment on July 1st in three hospitals, with the other facilities scheduled to begin treatment from October 1st. The target is to have 43,000 patients under treatment within a year, of an estimated 85-125,000 people who currently need treatment. The programme involves using generic fixed-dose combinations as first-line, but does not at present include alternative first-line regimens or second-line regimens. The first children will be enrolled on treatment within a year of the programme starting. Treatment will be free of charge in all facilities, including private clinics.

Beginning of AIDS care in Chiradzulu District

Chiradzulu district, which sits north-east of the commercial capital Blantyre in the southern tip of Malawi, has a population of over 250,000, 90% of whom earn their living by farming. Twenty-five per cent of the adult population is estimated to be HIV positive. Over 2,500 people are estimated to be in stage IV of the disease and therefore in urgent need of HAART, while another 5,000 people are already symptomatic and would also benefit from immediate access to treatment.

MSF has been working in Chiradzulu District since 1997 in collaboration with the Ministry of Health and Population of Malawi. The programme focused first on reducing transmission of HIV within existing Ministry of Health and rural mission health facilities. Prevention activities included implementation of universal precautions, provision of safe blood products and 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 voluntary counselling and testing (VCT).

In 1999, the project added a component of care for HIV-infected inpatients. Then starting in 2001, management of opportunistic infections was offered in all health facilities in the district and prevention of mother-to-child transmission (PMTCT) was offered at the district hospital. In the same year, MSF started providing some HAART treatment and follow-up at the district hospital, giving priority treatment to the sickest patients. In addition to treating patients in need, the programme was designed to demonstrate that HAART would prolong life and allow people to regain their autonomy.

HAART was extended from the district hospital to all 11 peripheral health facilities in the district within a year. The programme evolved from starting only a handful of patients on treatment every month to over 100 patients a month in May 2003, and more than 210 patients in March 2004. By March 2004, the programme was caring for 3,122 patients in 12 facilities, and providing HAART to 2,194 patients.

This dramatic increase in caseload was made possible by modifying criteria for initiating treatment and simplifying the programme. The changes made included: eliminating mandatory CD4 counts and other laboratory tests before initiating HAART, training nurses and clinical officers to be more involved in initiating and monitoring HAART, and offering care closer to the communities in need.

PROGRAMME OVERVIEW: ADAPTING CARE TO INCREASE CAPACITY

Expanding capacity

The number of patients in the Chiradzulu programme has increased rapidly. In March 2004, 3,122 patients were attending consultations; this is over three times more than the previous year. Of those, 2,194 were receiving ARV treatment in March 2004, over four times more than the previous year. In total, since the start of the programme, 2,692 patients have started ARVs. The difference between those initiated on treatment and the number of people on treatment today is due to death, loss to follow-up or treatment discontinuation.

Initial design of the programme

When the treatment programme started at the district hospital in July 2001, patients presenting with clinically advanced HIV were selected for treatment according to CD4 count or WHO clinical staging criteria. The assessment was carried out by a selection committee consisting of representatives from the district administration and from MSF. The committee met once or twice monthly. Adults were eligible for treatment if they had CD4 counts of less than 200 cells/ml or were at WHO stage IV; children qualified if they were at less than 15% of the normal CD4 level.

Patients who had been selected had to complete two sessions of treatment counselling before starting HAART. The initial programme design required all patients to begin treatment at hospital-based HIV clinics, although some were referred to health facilities closer to home for treatment follow-up.

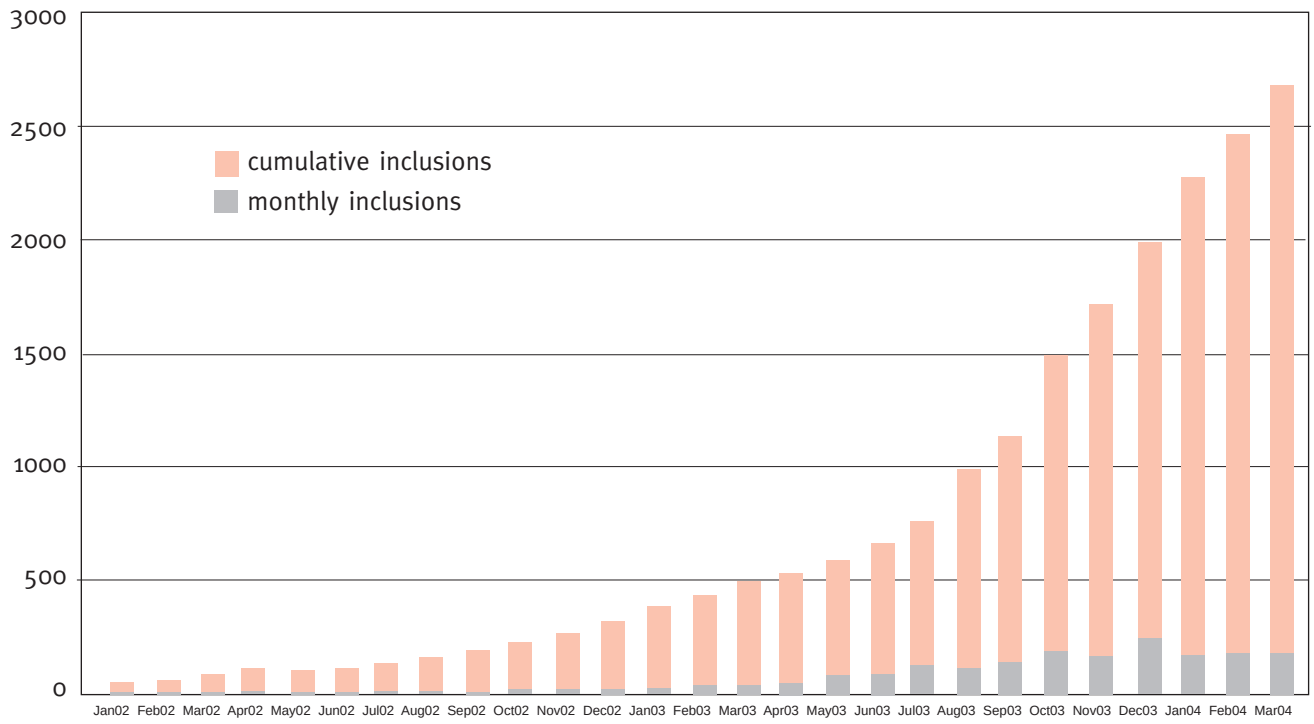
Steps to increase patient numbers

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

- the HIV clinic in the district hospital increased its opening times from three to five days a week;
- the selection committee was disbanded (instead, patients meeting criteria were immediately referred to counsellors)[4];
- initial HAART counselling sessions that were previously conducted one-on-one, were conducted in groups of five to six patients; and
- the clinic began offering a full set of services every day rather than different services on different days.

In early 2003, the stipulation that no patient was to start treatment without CD4 count measurements was changed to allow late stage III and stage IV patients to be treated based on clinical criteria.

Graph 1 : HAART monthly and cumulative inclusions Chiradzulu. January 2002 - March 2004



Source: MSF-France, Chiradzulu.

Table 1: Total consultations categorized by WHO staging

	WHO Staging	Patients
Stage WHO I (asymptomatic)	738	11.7%
Stage WHO II	986	15.6%
Stage WHO III	2725	43.3%
Stage WHO IV	792	12.6%
Unspecified*	1055	16.7%
Total patients HIV+	6,296	100.0%

(* "Unspecified" refers to patients for whom data were not available.)

Source: MSF-France, Chiradzulu

Decentralization

In Chiradzulu, HIV clinics have been run at health facilities instead of exclusively at the district hospital since December 2002, and non-hospital consultations now account for 40% of overall visits. The plan is to transform the district hospital into a referral centre that can provide specialized services and care.

Beginning in early 2003, bi-monthly HIV clinics run by two clinicians were initiated at 11 health facilities in the district. These health facilities introduced voluntary counselling and rapid tests, allowing patients to begin HAART without having to go to the district hospital. This was an important step, since patients often live more than three hours' walking distance from the hospital.

Treatment regimens

All regimens used in the programme include two nucleoside reverse transcriptase inhibitors (NRTI) plus one non-nucleoside reverse transcriptase inhibitor (NNRTI) or protease inhibitor.

Initially the vast majority of patients were started on zidovudine/lamivudine+nevirapine (AZT/3TC+NVP). However, in October 2002, this was changed to the triple fixed-dose combination (FDC) stavudine/lamivudine/nevirapine (D4T/3TC/NVP). This simple regimen of one pill twice a day makes it easier to initiate more patients on treatment.

The NRTI didanosine (ddI) and the NNRTI efavirenz (EFV) are also used in the programme. The only protease inhibitor currently used in the programme is nelfinavir (NFV).

At the start of treatment, patients take fixed-dose D4T/3TC with a separate dose of nevirapine to allow the nevirapine to be titrated up as is required by the drug's indication. For patients who are taking concomitant rifampicin-containing TB treatment, D4T/3TC + EFV is used as first-line treatment, in accordance with WHO guidelines.

Syrups are used for very young children (under 10kg). For older children, a dosing chart is used to calculate dose by weight. Because of the lack of paediatric dosages, fixed-dose tablets are cut, and additional nevirapine added when necessary. Paediatric FDCs are urgently needed to put an end to this stop-gap solution.

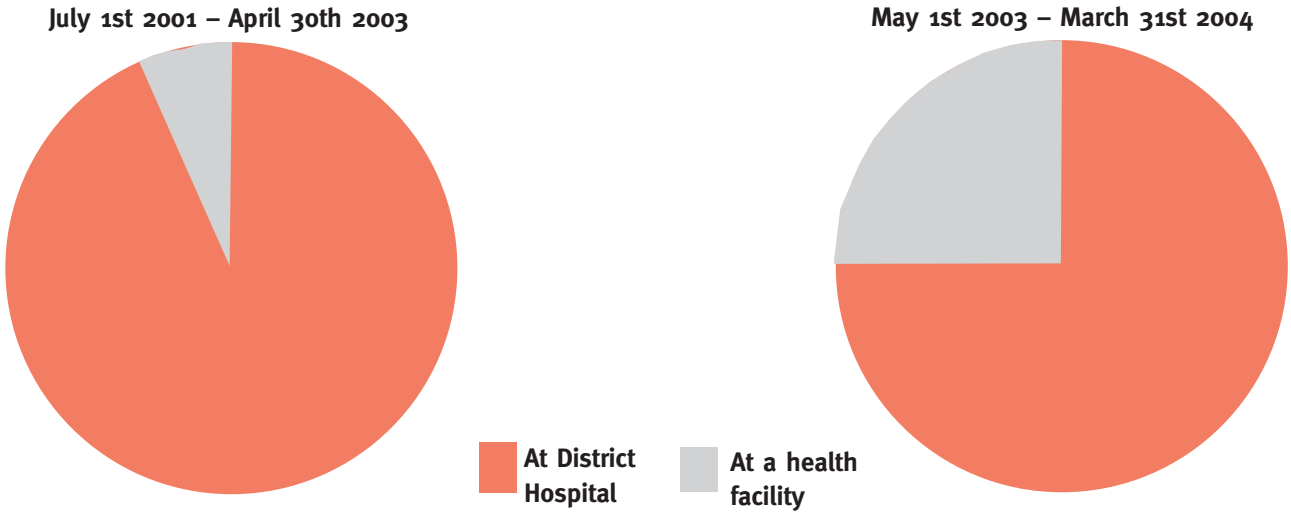
Table 2: ARV enrolments, by hospital or health facility

	PATIENTS STARTED ON ARV THERAPY		
	Adults	Children	Total
Nº of patients 1 July 01 - 30 April 03			
At the district hospital	512	44	556
At a health facility	45	5	50
Nº of patients 1 May 03 – 31 March 04			
At the district hospital	955	89	1044
At a health facility	591	74	665
TOTAL	**2103**	**212**	**2315***

(* Total number started on ARVs was 2,692. Patients for whom data were not available are not included.)

Source: MSF-France, Chiradzulu.

Graph 2: ARV initiations, by hospital or health facility



* Some patients without complete data are not included.

Source: MSF-France, Chiradzulu.

Treatment regimes

	First-line	Second-line
Preferred ARV regimens	D4T/3TC/NVP (FDC)	AZT+ddI+NFV
Adult	3TC + AZT + NVP	D4T+ddI+NFV
Children	3TC + D4T + NVP	AZT+ddI+NFV

Adherence support/patient follow-up

Before initiation of HAART, patients attend a group session led by a specialised nurse and a counsellor, who explain the nature of treatment and other HIV issues, such as transmission. One week later, a second, individual counselling session takes place. The patient is asked what they remember from the first session and, if considered to have gained enough understanding, they receive two weeks' supply of drug therapy. At follow-up visits, the patient's remaining pill stocks are counted, and health staff ask the patient about any problems they are having taking their medicines.

This is a departure from the system used in the first year of the programme when the care team conducted systematic home visits during the first weeks of a person's HAART to ensure adherence to treatment. This practice was dropped in 2002, because it became unsustainable as patient loads increased.

Once home visits were stopped, the work of dispensing nurses was supplemented by non-medical staff that had been hired and trained to perform adherence counselling (cf "Human resources and training" on page 7).

At the end of 2002, 2% of patients had been lost to follow-up. By March 2004, this number had risen to 7% (7.5% in adults and 4.7% in children). This rise is being addressed in the programme by increasing access to adherence counselling at health facilities. Adherence counselling sometimes now takes place in groups, in order to reach more patients with the same human resources.

In addition to formal adherence support provided by MSF and the MoHP, people living with HIV/AIDS have created a support group trained by adherence counsellors.

From pill count at the time of consultation, it is estimated that more than 90% of patients are adherent to treatment. Treatment success is confirmed by patients' mean CD4 change – the patients have an average increase of 178 cells/mm3 at 12 months.

In terms of clinical follow-up, the frequency of visits is adapted to the patient's clinical condition. During the first trimester following the start of treatment, all patients receive medical consultations as well as counselling sessions. After the first trimester, a nurse assesses the need and frequency of medical consultations. In general, patients who have stabilized and are doing well on treatment are seen every two months by a clinician when they come to collect their prescription refills. At the same time they receive adherence counselling from the dispensing nurse and the treatment counsellor if adherence problems are identified.

At present, all patients undergo an annual CD4 count. Until now, diagnosing treatment failure has relied on detecting change in CD4 count (when available) and on clinical symptoms. There has been no access to viral load testing.

Laboratory monitoring

Voluntary counselling and testing, using rapid diagnostic tests, is conducted at the same health facilities where comprehensive care is provided.

An MSF laboratory supervisor runs the district hospital laboratory where CD4 monitoring is done and works with one MoHP technician and one MSF technician.

As the number of patients seen in the outpatient ward has increased, monitoring guidelines have been revised. At the outset of the programme, all patients underwent CD4 measurements. The CD4 counts were carried out using a manual technique called Dynabeads, in which one technician assessed a maximum of 12-18 samples a day (quality was controlled by routinely verifying a subset of samples at the Wellcome Trust centre in Blantyre).

Over time, however, this placed a considerable burden on the laboratory facility and was slowing down patient inclusion. The criteria for initiating treatment were therefore modified at the beginning of 2003 so that all stage IV and late stage III patients were allowed to enter the programme without CD4 testing.

To increase monitoring capacity, MSF has begun testing a cyberflow machine (Partec) which can conduct 50 CD4 tests per day. Use of the Partec machine currently allows for CD4 tests to be carried out on all pregnant women and some asymptomatic patients, a number of whom have low CD4 counts and should be enrolled on ARVs.

In patients who show no clinical signs of disease, CD4 testing is carried out once a year for monitoring purposes.

Human resources and training

Malawi has a critical shortage of medical professionals due to, among others: HIV-related deaths; lack of sufficient training of new professionals; "brain drain" to countries with higher salaries; and difficult working conditions. As the table below illustrates, Chiradzulu is no exception: the district is chronically short-staffed in all health worker categories.

The MSF HAART programme has therefore had to draw on a mix of local and expatriate staff to provide direct medical services, technical assistance and training. Local

Table 3: Medical staffing at facilities, Ministry of Health and Population, Chiradzulu District

	Post	Vacancy	% post not filled
Health Facility			
Doctors	0	0	0
Nurses	20	2	10
Medical assistant	6	3	50
Hospital			
Doctors	1	0	0
Clinical officer	10	4	40
Medical assistant	9	7	77.8
Nurses	75	52	69.3
Working in Communities			
Nurses	19	14	73.7

Source: MSF-France, Chiradzulu

Table 4: Supplemental local and expatriate medical staff working for MSF ARV programs

	Local	Expatriate
Doctors		3
Nurses	3 (includes 1 for hygiene and quality of care)	1 (counsellors' coordinator)
Medical assistants:		
Clinical officers	5	
Counsellors	6	
Laboratory technician	1	1

Source: MSF-France, Chiradzulu

staff include: one logistician/administrator, one logistics officer, two data-entry clerks, two midwives, an information, education and communications officer, as well as support staff. In addition, Ministry of Health clinicians were trained by MSF in HIV care and HAART delivery.

In 2001, in response to staff shortages and the heavy workload of existing staff, the MSF programme began to offer counselling training to non-medical people with Malawi School Certificates (the equivalent of O-levels), since there were not enough nurses available to play this role. Currently, six counsellors have completed a six-week National AIDS Commission curriculum course. They work both as VCT and adherence counsellors and are supervised by an expatriate nurse.

Health officials at the MoHP were open and supportive of the idea, and the positive experience of training non-medical staff to act as counsellors has shown that it is possible to successfully devolve responsibility in order to reach more patients.

However, the consequences of these changes on the continuum of care need to be considered. For example, increased patient load resulted in a need for more counsellors. But when counsellors were added, more patients qualified for treatment. Clinicians became overwhelmed by the need to initiate and follow patients.

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

Drug and resource management

From the beginning of the programme, MSF sought to purchase drugs locally. Before procurement began, an MSF pharmacist visited the country to assess the potential local distributors of generic and branded products. Based on this assessment, manufacturers of unregistered products were asked by MSF to file registration dossiers. While waiting for products to become available in-country, purchases were made from originator companies in Europe. By November 2001, MSF had managed to obtain all needed ARVs through local distributors. At present, only two medicines are not available locally (EFV 600mg and NFV powder), as the manufacturers, Merck and Roche, have not registered the two drugs in Malawi.

The programme now relies primarily on the WHO prequalification system to validate quality of ARVs. When there are no prequalified sources of needed drugs, MSF assesses additional sources through its own internal validation process or purchases originator products locally or from Europe.

A small supply of drugs is kept in the district hospital pharmacy while bulk supplies are maintained at an MSF storage facility. At this point in time, drug dispensing at mobile clinics is still time-consuming and a better system needs to be developed.

Rapid increases in patient numbers have been a major challenge to overcome, especially at the beginning when caseload and drug needs were difficult to predict. When inclusion criteria were relaxed, the number of patients qualifying for ARVs and corresponding supply needs shot up. While the reserve buffer stock supplied immediate needs, extra orders had to be placed to provide dramatically increased quantities and avoid treatment interruption.

As exact drug demand is difficult to forecast, local buffer stocks and strong links with the producers needed to be built. A particular challenge was suppliers' requirement of three months' notice to fill orders. However, the use of FDCs has reduced the number of products that needed to be managed and made supply easier.

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

Community involvement

In Chiradzulu, the need for strong community participation has been recognised since the project began. Between May and August 2002, 85 community chiefs received HIV education. In addition to informing them about disease progression, prevention and care, the aim was to let them know about the availability of treatment so that they could disseminate this information in their communities. Chiefs also promote prevention by supporting the distribution of condoms.

In addition, some people living with HIV/AIDS and receiving HAART have formed a peer support group, which fulfils a variety of roles, including adherence counselling and community education.

Programme monitoring

At every consultation, medical information is collected on a standardized form, which is then fed into an MSF/Epicentre-designed data management system called FUCHIA. The system produces standardized reports, including key epidemiological indicators such as morbidity and mortality. The patient keeps a copy of the form as part of their personal medical file.

Patient outcomes

Patient outcomes have been positive. 74% of patients are still alive and taking treatment (this total figure includes the first group of patients admitted in late

Table 5: Patient outcomes, March 2004*

	Adult	Children <13	Total
N° patients commenced ART since beginning of programme	2105	212	2317
N° patients alive, followed and still on treatment	1680	174	1854
N° patients deceased since beginning of programme	209	21	230
N° patients lost to follow up	159	10	169
N° patients who stopped treatment	57	7	64
N° patients that 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	12 months	18 months
85 (n= 188)	178 (n= 192)	180 (n= 29)

(* Patients for whom complete data were not available are not included.)

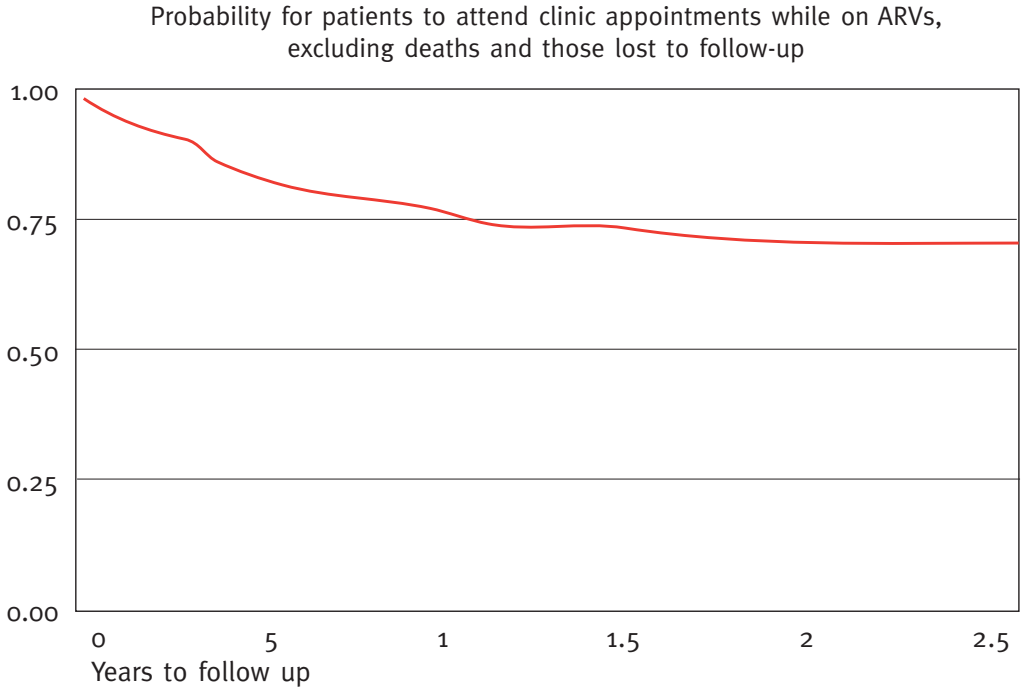
Source: MSF-France Chiradzulu.

2001). Fifteen per cent of patients have been on ARVs for more than a year.

Of 2,312 patients who have started ART since the beginning of the programme (and for whom complete data exists), 230 have died and 169 have been lost to follow-up. In addition, 99 experienced side-effects from the ARVs severe enough to require changing at least one drug.

In patients that had baseline CD4 measurements, the majority were severely immunocompromised at treatment initiation: 12.6% of patients had CD4 counts under 50 cells/ml, while 38% had CD4 counts of 50-200 cells/ml. Mean CD4 gain was strong: 85 cells/ml after six months (for 188 patients), 178 after 12 months (for 192 patients), and 180 after 18 months (for 29 patients). The vast majority of patients who did not have baseline CD4 tests were at WHO stage III or IV at time of treatment initiation.

Graph 3: Proportion of patients remaining on ARVs, according to commencement date.



Source: MSF-France, Chiradzulu.

There is no access to systematic viral load testing in Chiradzulu. However, to monitor the programme, an evaluation was undertaken of viral load measures of half the patients who had been on treatment for at least six months. Viral load measurements were taken on 477 patients. Eighty five percent (407) of patients had undetectable levels of virus (less than 400 copies). This indicates that HAART is producing good virological results for patients in the Chiradzulu programme.

LESSONS LEARNED: TREATING MORE PATIENTS WITHIN LIMITED HEALTHCARE STRUCTURES

The Chiradzulu programme is still evolving. Learning through experience, the Chiradzulu team has already successfully employed a number of strategies which couldn be used to increase the numbers of patients under care in other poor rural settings with limited health care infrastructure.

The following are some specific approaches that have proven successful for scaling up on a regional basis:

Simplification:

- use of fixed-dose combinations (FDCs), which simplified the treatment regimens, reduced the time needed for patient education and generally facilitated compliance to treatment;
- decentralization of point of care from district hospital to community health facilities, which increased the reach of the programme;
- re-allocation of tasks amongst health staff professionals, which enabled existing and supplemental staff to handle larger caseloads. An example of this strategy was the training of nurses and clinical officers to take on some tasks formerly performed by doctors; and
- reducing dependence on laboratory monitoring for initiation of treatment. Lack of access to monitoring does not have to be a barrier to treatment for patients: in Chiradzulu, the requirement for a CD_4 count before initiating treatment was dropped for patients in WHO Stages III and IV. (*See table 6 for more details on steps to simplify treatment protocols*)

Aggressive drug procurement:

- initial labour-intensive efforts to register both generic and brand-name suppliers mean that the programme will be more sustainable over the long term, as the overall drug cost has been kept to a minimum. Choosing drug suppliers has also become much easier with the advent of the WHO prequalification process.

Some future challenges

- **Clinical monitoring** — at the health centre level, clinical algorithms need to be developed urgently to allow nurses working in isolated locations to follow patients within existing structures and with existing resources. HAART needs to be integrated into standard outpatient departments.
- **Laboratory monitoring** — there is a need for more affordable and easier-to-use CD_4 and viral load monitoring tests. The need for a viral load test is particularly urgent as it will allow patients to be switched to second-line combinations at a time when their viral load is rising but before they fail clinically.
- **Paediatric formulations** — current treatment regimes 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** — in the coming two years, the programme will face the challenge of growing numbers of patients failing first-line treatment. There is therefore an urgent need to advocate for lower prices of second-line drugs and development of new FDCs.

Table 6: How treatment protocols have changed

Before simplification	After simplification
HIV 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 4, OR HIV stage I-II-III plus CD4 count ‹200, OR pregnant women in PMTCT program plus CD4 count ‹350, OR HIV stage I-II-III plus CD4 count ‹15% (for children).
Applicants' eligibility reviewed by selection committee.	Clinicians and counsellors make assessment and decide on inclusion.
Selected patients attend two ARV counselling sessions before treatment.	First counselling session in groups of 5-6, second session is one-on-one conducted one week later at hospital or two weeks later at health facility.
HIV clinic in district hospital open three days per week.	HIV clinic in district hospital open five days per week.
First-line protocol: AZT/3TC/NVP.	First-line protocol: fixed dose d4T/3TC/NVP (change made to assist adherence through use of FDC).
First-line available in four pills.	First-line available in triple FDC, two pills per day.
Only clinicians performed diagnosis and treatment of opportunistic infections, and followed-up stable HAART patients.	Nurses trained in opportunistic infection diagnosis/ treatment and in follow-up of stable HAART patients, 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 only performed once per year once HAART is initiated (or upon clinical signs).

The table shows the differences between MSF protocols at the start of its programme in Chiradzulu, and changes it made later to facilitate expansion of numbers of patients on treatment.

Endnotes

[1] HIV sentinel surveillance report 2003, National AIDS Commission, November 2003.
[2] Ministry of Health and Population, Malawi. "Treatment of AIDS, the two year plan to scale up antiretroviral therapy in Malawi." February, 2004.
[3] 2001 figure. United Nations Development Programme, "Human Development Report 2003", July 2003.
[4] During the period when it was in operation, the selection committee never refused treatment to a patient.

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