SCALING-UP OF THE MSF FRANCE HIV/AIDS PROGRAMME in CHIRADZULU, MALAWI, THROUGH DECENTRALISATION AND TASK-SHIFTING 1993-2012

MSF OCP 2012
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Contents

MAP OF MALAWI

ABBREVIATIONS

AIDS: Acquired Immune Deficiency Syndrome
AIDSEC: AIDS Secrétariat
ANC: Ante Natal Care
ART: Antiretroviral Therapy
ARV: Anti Retroviral
AZT: Zidovudine (Azidothymidine), an antiretroviral drug used to treat HIV/AIDS
CAD: Community ARVs Dispenser
CAME: Campagne pour l'Accès aux Médicaments Essentiels (French abbreviation) = (MSF) Campaign for Access to Essential medicines
CD4 or T-cells: Cluster of differentiation 4
CO: Clinical Officer
CROI: Conference on Retroviruses and Opportunistic Infections
DBS: Dried Blood Spot
DHO: District Health Officer
D4T: Stavudine, an antiretroviral drug used to treat HIV/AIDS
FUCHIA: Follow Up Care of HIV and AIDS
GTZ: Deutsche Gesellschaft für Technische Zusamenarbeit (German Agency for Technical Cooperation in Development)
HIV: Human Immunodeficiency Virus
HAART: Highly Active Anti Retroviral Therapy
HAS: Health Surveillance Assistant
IEC: Information Education Communication
IPD: In Patient Department
IT: Information Technology
MDR: Multi Drug-Resistent
MoH: Ministry of Health
MoU: Memorandum of Understanding
NVP: nevirapine (antiretroviral)
NACP: National AIDS Control Programme
OI: Opportunistic Infection
OPD: Out Patient Department
PMTCT: Prevention of Mother To Child Transmission
PWLA: People Working and Living with Aids
RUTF: Ready to Use Therapeutic Food
SAMBA: Simple AMplification Based Assay
SMA: Six Month Appointment
STD: Sexually Transmitted Disease
3TC: Lamivudine, an antiretroviral drug used to treat HIV/AIDS
TB: Tuberculosis
TDF: Tenofovir DF, an antiretroviral drug used to treat HIV/AIDS
UNAIDS: Joint United Nations Programme on HIV/AIDS
UNICEF: United Nations Children's Fund
VCT: Voluntary Counselling and Testing
XDR: Extremely Drug-Resistent
WHO: World Health Organisation

 ***Extract from interviews conducted in 2011, 2012***

 ***Extract from MSF archives or press clippings***

PEOPLE INTERVIEWED AND THEIR POSITION AT THE TIME OF THE EVENTS

- **Dr Guillermo Bertoletti,** MSF France Malawi Medical Coordinator, then Field Coordinator, then Head of Mission, 1993 to 1995; MSF France Desk manager from 1997 to 2001; Deputy Director of Operations then Director of Operations from 2001 to 2007
- **Dr Jean - Hervé Bradol,** MSF France President from 2000 to 2008, author of "Médical Innovation in humanitarian situations: the work of Médecins Sans Frontières"
- **Dr Christopher Brasher,** MSF France Desk manager, from 2001 to 2004
- **Emmanuelle Chazal,** MSF France Medical Department Advisor on Patient Education and Training from 1999 to 2007
- **Frazer Chimbuzi,** MSF France Malawi HIV/AIDS Program Counsellor then Head of Counseling Department, from May 2000
- **Dr Sylvie Goossens,** MSF France Malawi HIV/AIDS Programme Medical Coordinator, from September 2005 to July 2007
- **Gaëlle Fedida,** MSF France Deputy Desk Manager from 2004 to 2005, Desk manager, from 2006 to 2008
- **Annick Hamel,** MSF France field coordinator in 2002, then Liaison officer CAME, then in charge of the Village Unit set up, from January to June 2007.
- **Mike Kalemera,** MSF France Malawi HIV/AIDS program counselor from 1999 to 2010, then Head of IEC Department
- **Michaël Le Paih,** MSF France Malawi HIV/AIDS Programme Head of mission, from September 2007 to July 2009
- **Megan MacGuire,** MSF France Malawi HIV/AIDS programme field epidemiologist May 2007-July 2009, MSF France East Africa Regional Epidemiologist from November 2009 to January 2012
- **Charly Masiku,** MSF France Malawi HIV/AIDS Programme Clinical officer, from 2007 to 2010 then Deputy Medical Coordinator.
- **Esnat Mbanda-Mbanda,** PWLA, MSF France Malawi HIV/AIDS Programme tracer then tracer supervisor, then IEC officer from 2002
- **Maryline Mulemba,** MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003.
- **Tamika Munyenyenbe,** MSF France Malawi HIV/AIDS Programme Epi data officer, from 2002
- **Dr Elisabeth Szumilin,** MSF France medical department Aids advisor, from 1998

SUMMARY

In 2001, Médecins Sans Frontières France had been present in Malawi for 14 years, seven of them implementing HIV/AIDS prevention activities in the southern districts of Mwanza and then Chiradzulu from 1997 on, where 20% of the population was estimated to be HIV-positive. In August 2001, in Chiradzulu hospital, the MSF team started a programme to provide free access to Highly Active Anti Retroviral Therapy (HAART) to HIV/AIDS patients.

For years, those who were sceptical about the relevance of dispensing ARVS to poor populations with high HIV+ prevalence had been advocating that the constraints imposed by poverty—lack of health structures and trained human resources to organise treatment programs, lack of money to pay for ARVs—were insurmountable.

Therefore during the first years of the Chiradzulu programme, MSF aimed at proving that treating patients with ARVs in poor-resource setting was actually possible. Acknowledging the scope of the epidemic, the main objective throughout these years remained to treat and keep alive as many patients as possible.

Indeed within 10 years, the number of monthly enrolments evolved from a handful of patients in 2001 to more than 200 in March 2004 and more than 600 on average in 2011. At this date, almost 30,000 patients were included in the cohort, among them 23,000 on ARV treatment.

Scaling-up

This was made possible thanks to the **simplification** of the treatment approach, to the **decentralisation** to peripheral health-care structures, and to the **task-shifting** of certain essential tasks from medical to para-medical and even to non-medical staff.

As early as 2002, biological testing and follow-up of patients were reduced compared to the extent usually implemented in developed countries. This quickly led to many more patients being enrolled. Later on, biological follow-up of patients was reintroduced when tools appeared that were easier to use.

During the first year, the programme was limited to a specific external HIV consultation at Chiradzulu hospital. Then during 2002 and 2003 it was extended to the ten district health centres where MSF teams started to implement regular mobile clinics, with the objective of reaching patients from all over the district.

From 2005 to 2008 a second scaling-up phase consisted of progressively training clinical officers and nurses from MSF, then from the Ministry of Health (MoH), to treat opportunistic infections, to follow up stable patients on ART, and then to initiate new patients on ART.

From 2007 onwards, efforts were also directed towards a reduction of the number of medical consultations by establishing the Six Month Appointment (SMA) system. The system's premise was a medical consultation every six Month only for stable patients, who would collect their drugs in the meantime from non-medical staff.

By 2009, every health structure in the district was in a position to provide the whole range of services for HIV/AIDS patients, from testing to Prevention of Mother-to-Child Transmission (PMTCT) and treatment of TB co-infected patients.

Innovate to simplify

At each stage of this scaling-up, beyond decentralisation and task-shifting themselves, innovative initiatives were developed to adjust the different activities of the program to the scope of the cohort and to the constraints of the context.

The epidemiological data system FUCHIA was set up to monitor the activities and to generate further questions for operational research.

Specific activities were established to compensate for the limits of medical follow-up. Counselling and tracing activities were developed to ensure better adherence to the treatment by patients and were regularly adapted to the evolution of the medical protocols, the growth of the cohort, and the operational set-up.

Research was supported on quick diagnosis tools to count CD4 or measure viral load that would facilitate follow-up of the patients by non-medical staff.

Several studies were implemented whose publication contributed to publicise the MSF Chiradzulu programme as a pilot HIV/AIDS project. In addition to MSF and other organisations' advocacy such studies also contributed to lowering of ARV prices, thus giving access to treatment to more patients.

While in the first years some individuals did not feel comfortable with practices that were not in accordance with HIV treatment orthodoxy, the operational innovations were welcomed and implemented with enthusiasm by MSF's staff. The field teams that had been feeling helpless for years, unable to avoid AIDS patients' death due to lack of ARV treatment, were particularly relieved.

Funding issues

Despite a genuine commitment from the management team and board of directors to the scaling-up of the Malawi program, there were some institutional questions regarding the cost of the HIV programmes. This questioning progressively lessened from 2003 on, as international donors' funds like the Global Fund, PEPFAR and 3X5 initiatives were created to take charge of part of the costs of HIV treatment.

However, since the occurrence in 2009 of the first shortage of ARVs in Malawi, the economic crisis together with the refusal of the Global Fund to fund Malawi's Round 10 request have cast a shadow on the future of HAART provision in the country.

So far MSF has managed to fill the drug gaps for the patients of the Chiradzulu programme. But beyond this issue other questions remain about the sustainability of the programme, which are related to more structural problems.

Ensuring the future

Since the beginning, MSF has been considering handover of the Chiradzulu programme to the MoH as the final objective. However, the deadline of this handover has been postponed several times as some doubts persisted regarding MoH capacity to take over.

Indeed in the hospital and in most of the health centres, despite being trained, the MoH staff are barely in a position to manage HIV/AIDS patients without substitution by MSF staff. Lack

and high turnover of staff, low or unpaid salaries, and tough social conditions are still fuelling absenteeism.

In 2012, ten years after it started, the MSF Malawi HAART programme is reaching a turning point. Once and for all MSF is recognising that it has become a public health rather than a humanitarian–type programme. Thus MSF has decided to try to find private sources of funding for the different activities and to handover to the MoH, in stages, a cohort that will probably reach 50,000 patients within five years.

The following study is an attempt to tell the story of this program, from its very beginning until 2012. It focuses on the history of scaling-up through decentralisation and task-shifting, describing the different steps, difficulties, and controversies experienced. The main text of the study is composed of an edit of extracts of documents and staff interviews. There are also a chronological timeline, a map, a list of abbreviations, and a list of interviewees.,

Full version of some quoted documents and annexes can be accessed by clicking on the hyperlink. This has been done in an attempt to preserve the main documents related to this programme.

SCALING-UP OF THE MSF FRANCE HIV/AIDS PROGRAMME IN CHIRADZULU, MALAWI, THROUGH DECENTRALISATION AND TASK-SHIFTING 1993-2012

In Malawi, the first cases of HIV/AIDS were officially reported by Blantyre's Queens Hospital in 1985. From that date to 1993, 29,194 AIDS cases were reported. Of these, 92% were adults and 4% children below five years (annex 1).

Soon, the country faced a major epidemic. In 1993, the number of people infected with HIV/AIDS was estimated at between 700,000 and 1.1 million (7 to 11% of the population). Differently to other African countries, in Malawi the spread of HIV infection was increasing at a more alarming rate within the rural population than in urban settings. From 1985 to 1993, HIV sero- prevalence among pregnant women tested at urban antenatal clinics (Lilongwe, Blantyre and Mzuzu) increased from 2% to 30%. In 1998, 26% of antenatal clinic attendees tested HIV-positive. Outside of major urban areas, HIV prevalence among antenatal women tested increased from 6% in 1992 to 22% in 1999.

In the meantime, in 1987, the AIDS Secretariat (AIDSEC) had been created under the Malawi Ministry of Health (MoH) in order to implement the National AIDS Control Programme (NACP), and had established several short-term plans, including blood screening and HIV education programmes. In 1989 a five-year AIDS plan was announced. However Malawi had been under the rule of President Banda for thirty years, during which time little attention was paid to the escalating AIDS crisis, as HIV and AIDS were considered taboo subjects. Therefore AIDS education and prevention schemes were poorly carried out.

Until 2001, no HIV treatment was available in the country. Medical action regarding people suffering from AIDS was limited to treatment of opportunistic infections and prevention.

THE LONG WALK TOWARDS ARV TREATMENT

> This mission, even so, was the best mission I'd ever been on. I felt like I'd participated in something that was almost historic.
> **Maryline Mulemba, MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003 (in French)**

Since 1987 MSF had been working in the Mozambican refugee camps in three districts of the southern region of Malawi: Nsanje, Mulanje and Mwanza, Its teams were in charge of epidemiological surveillance, preventive health care (immunisation, sanitation) and curative health care (nutrition and case-management during outbreaks) in collaboration with the MoH.

In 1993, while a peace agreement had been signed in Mozambique, there were still 1.2 million refugees living in camps, including 359,668 in the southern ones where MSF was working.

Though there was no proper estimation available regarding the prevalence of HIV/AIDS among the camp population, it was quite obvious for any observer that the disease was as widely spread in the camps as in the general population of Malawi.

In the refugee camps we were doing nutrition, vaccination, hygiene and sanitation, and managing epidemics. We were not even doing primary health care consultation. We weren't working in the hospital anymore. But we went there frequently because many of the sick people in the camp needed to be hospitalised. You had to be blind not to see that AIDS was a huge problem.
Dr Guillermo Bertoletti, MSF France Malawi Medical Coordinator, then Field Coordinator, then Head of Mission, 1993 to 1995; MSF France Desk manager from 1997 to 2001; Deputy Director of Operations then Director of Operations from 2001 to 2007

Shocked by this situation, and wanting to "do something", the MSF field team independently started to support the MoH staff by providing condoms and organising information sessions about the epidemic within the camps.

We kept thinking that we had to do something but we didn't know what. The Head of Mission convinced Paris we should at least do what we called at the time a "dissemination of information about AIDS". I was the field coordinator in Mwanza and I became a kind of" travelling AIDS coordinator" so that I could take the message to all the refugee camps. I had a driver, a film projector, a screen, and a small budget. We set off with our library of films about AIDS made with Zambian actors. The message was delivered mostly through drama groups. We distributed condoms and talked about AIDS
Dr Guillermo Bertoletti, MSF France Malawi Medical Coordinator, then Field Coordinator, then Head of Mission, 1993 to 1995; MSF France Desk manager from 1997 to 2001; Deputy Director of Operations then Director of Operations from 2001 to 2007 (in French)

In January 1994, these activities were formalised in an MSF "AIDS Control Programme." (annex 2) . This programme was initially directed towards the refugees in the camps of Nsanje, Mwanza and Mulanje districts, in southern Malawi, but it was never implemented in the Mulanje camps since this camp was soon closed.

The overall goal of the project was: "*to reduce HIV transmission through information, education and communication and to sensitise the community about the condom so that they should accept its use while its availability was being increased by the programme.*"

The initial specific objectives were to improve awareness and knowledge about HIV/AIDS (information), to increase condom acceptability and availability, and to reduce sexual transmission of HIV. These were extended as implementation of the activities progressed.

The target audience was "*well defined existing groups of people, familiar to the community and already working with the communities directly or indirectly*": health staff, teachers and students, drama group members, section leaders in camps, health committee members in camps, MSF staff, and Red Cross Volunteers.

Throughout 1994 and 1995 all the refugees were repatriated to Mozambique, so the Malawian health authorities asked MSF to direct its HIV/AIDS education and prevention activities towards the Malawian population in Mwanza district. Because of the intermingling of the Mozambican and Malawian communities, a substantial proportion of the Malawian population living around the camps was already de facto benefiting from the programme. With 162,500 inhabitants, this rural district was one of the most important places in terms of truck driver and sex-worker concentration, and the HIV prevalence among blood donors was 22% in 1994.

Having worked there for many years the MSF team had established good relationships with the local authorities. Moreover MSF was already actively involved in all AIDS

activities developed for the Malawian population in the southern districts. MSF was a full member of the Regional AIDS Network Steering Committee as well as a permanent member of the Strategies Sub-Committee of the network. In August 1994, together with the new President of Malawi and all his ministers, the MSF team had even participated in a "march against AIDS" following the first Conference on HIV/AIDS to take place in Malawi.

In 1995 MSF's activities were refocused toward the population of the Mwanza district and health staff training was developed. In addition to running Information Education Communication (IEC) activities in the schools and communities, the team would support MoH staff in preventing transmission of HIV/AIDS in the hospital and in several health centres, through management of sexually transmitted disease (STD), hygiene, and blood safety activities etc.

The Mwanza district health officer, with whom I became friends, said to me: "Bravo MSF! You did everything you could for the Mozambicans and you leave us in the shit with our malnutrition and AIDS." I had made an effort to get to know the national health activists, I participated in the demonstrations, the marches, etc. When I saw how weak Paris' proposal was for the first intervention, I said to them that in my head I saw a clock tick-tocking while people were dying [...] There was a lot of resistance and fear. Paris felt that if we didn't have perfect hygiene in the health facilities, that if we didn't deal with STD prevention, it wasn't worth talking about doing something to fight AIDS.
Dr Guillermo Bertoletti, MSF France Malawi Medical Coordinator, then Field Coordinator, then Head of Mission, 1993 to 1995; MSF France Desk manager from 1997 to 2001; Deputy Director of Operations then Director of Operations from 2001 to 2007 (in French)

Considering the scope of the epidemic, way before even ARV (antiretroviral) therapy was discussed the team was concerned by the possible scope of the HIV programme that MSF would have to develop in order to work in such a poor environment.

The team was also thinking about a handover of the activities within a few years, and had already taken up contact with an NGO in this regard.

Letter from Dr Guillermo Bertoletti, Head of Mission MSFF in Malawi to Dr Karim Laouabdia, Director of MSFF medical department – 7 January 1995
If we start supporting health facilities in the hygiene area, where to stop? There are some health structures where even water is not so easily available. Are we going to dig boreholes? Are we going to build latrines? I am not saying I disagree, even more, I like the idea. It is just that we've never thought to start such a huge programme with all what that means: engage again expatriates (a nurse plus a log), local employees, cars, building materials, etc etc. Now if you say yes, most welcome, we are ready to start.
If we follow the thought line expressed through the actual proposal, the interpretation is that our aim is to prepare the community for future development of areas such as Home Based Care Programmes and that we are also gaining experience vis à vis the AIDS patients even to take in charge the medical care of them (something that Philipe Biberson [MSF France President] asked me sometime ago while we were discussing about the project.) [...]
After having achieved our 95/96 objectives, hand over to a local NGO all the aspects of IEC and to MoH the areas of STD and sterilisation. Discussions have been started with Demoda, a Malawian NGO interested in starting IEC activities in the district, and it is our hope as well the wish of the MoH (Regional level) to be in conditions to take care of the other areas within the next two years, specially concerning STD supplies and condom availability.
Once these two areas are closed as programmes for MSF, we will be free to evaluate the needs (probably for 97 things will be better and Malawi doesn't need any more our help) and to decide whether or not the continuation of our activities in the already mentioned areas (home based care and medical care of AIDS patients in hospitals).

Since 1997, an MSF team had been implementing a home-based care programme in the province of Surin in Thailand. In 1998, an MSF medical doctor started to support consultations in an HIV clinic where patients were treated for opportunistic infections, and some of them received a bi-therapy funded by the authorities of Surin province.

The effect of this bi-therapy would not last long and would provoke serious side-effects, but it was better than nothing. It was a pilot project at a small scale and remained for several years the only project where an MSF doctor had direct contact with patients on ARVs.

Meanwhile, in July 1996, MSF's medical directors had decided to provide all MSF missions with AZT in order to prevent contamination of expatriate medical staff having been exposed to infected blood.

"AIDS a new pandemic leading to new medical and political practices" in *"Medical Innovation in humanitarian situations: the work of Médecins Sans Frontières" – Dr Jean-Hervé Bradol & Dr Elisabeth Szumilin*

Antiretroviral drugs made their first appearance in an MSF HIV prevention kit in the mid-1990s, following an accidental occupational exposure to blood. Mutual aid was also discreetly provided to infected colleagues, friends and lovers. MSF employees with opportunistic infections were given access on an individual basis to treatments that were unavailable and often very expensive in their own countries. AD hoc networks sprang up to stay with dying friends and loved ones. Refusals to grant visas on the grounds of sero - positivity were circumvented with the organization's complicity. Later, when the first triple therapies appeared, they were sent "under the counter" to colleagues in countries where they were unavailable. Such actions were limited in number, but they highlighted the fact that MSF needed to get involved in treating the disease.

In late 1996, tri-therapy became available in developed countries and thus MSF started considering the introduction of tri-therapy ARV treatment in some of its own AIDS programmes.

FROM MWANZA TO CHIRADZULU

AFP – 9 October 1997 (in French): According to the U.S. Federal Census Bureau, life expectancy will drop to 29.5 years in Malawi by 2010, or 52% less than the initial projection without AIDS. Life expectancy is currently 36 years in this country (Statistics 1996) versus the original estimate of 50 years.

In January 1997 the MSF programme expanded to Chiradzulu, a southern district of Malawi close to Blantyre, the economical capital of the country, with an estimated population of 282,158 people. The objectives and activities were similar to those of the Mwanza district programme: reduce the transmission of HIV through preventing iatrogenic incidents in the hospital; improve the management and follow-up of STDs; eliminate transmission of HIV through blood transfusions. These activities were implemented in stages in the main hospital and its 11 related health centres.

Community IEC work was also developed within the population in order to improve awareness and knowledge about HIV (sex workers, youth, prisoners, police), voluntary counselling and testing (VCT), and to increase acceptability and availability of condoms.

In 1998, the MSF team started to support the staff of the Chiradzulu hospital in treating patients for opportunistic infections, particularly cryptococcosis and Kaposi's sarcoma. For the latter, they were also able to test patients. In December 1999 an HIV clinic, called the BOMA clinic, was opened in Chiradzulu district hospital with consultations one day a week.

In the meantime, the programme's objectives were clarified and its structure was strengthened. At its core were the integration and the linking up of all its components with the activities of the MoH, the final goal being an MoH handover sometime in the future. However the lack of human resources in the MoH system, absenteeism due to low salaries, sickness and even deaths amongst the medical staff—as heavily hit by the epidemic as the rest of the population—appeared to be a major constraint.

End of mission report - January 2002- Odhiambo Dola, Field Coordinator Chiradzulu

After 2 months the Head of Mission called for a general planning meeting because the project document, which was developed by the previous Head of Mission for Mwanza and Chiradzulu, was not clear and we could not see the direction of the programme. The meeting took almost 3 day with brainstorming in groups and plenary, defining the objectives, tools to be used, indicators and resources needed. I considered this meeting as the foundation of MSFF program in Malawi because later all improvement we made on the program were based on this initial meeting. (...) Some of the most important challenges in period between 1999 and 2002 were the involvements and motivations of MoH partner staffs without allowance. Lack of human resources in the MOH/P system and their frequent death probably due to immune suppression was quite alarming.

In Mwanza, the MSF team was not managing to run the programme satisfactorily. While IEC activities were going quite well, there were many difficulties in changing basic practices that would help to improve the prevention of AIDS within the hospital (blood testing, hygiene etc) and to decrease stigmatisation of the patients.

Moreover the relationships with the District Health Officer and the hospital director were deteriorating. Therefore, when it was decided to focus all the resources on one district and to move forward to actually try to treat the patients, it appeared that it would be more efficient to chose Chiradzulu district where the health authorities were keen to work with MSF.

Medical department** – Visit to Malawi – 12-25 October 1998 - **Dr Elisabeth Szumilin

This mission needs clinicians, interested in the care for patients. Malawi is one of the two countries in Africa where MSFF wants to know better what we can do for the management of HIV/AIDS patients. Therefore the human resources needed are clearly clinicians, not doctors more interested in public health.

A lot can be done in term of training by simple clinicians, at the bed of the patient, during clinical meetings, in the health centres. However and above all in Malawi which has had already a bunch of training on a bunch of conditions, this training has to follow the MSF, WHO and Malawian recommendations (they are alike). A lot also has to do with changing the attitude towards AIDS inpatients. We are not here to give lessons, but to show that even a dying person can be taken care of. Touching the patient, speaking to him and his family, seeing him regularly does not cost anything but it is what we have to do to improve the general attitude towards these very sick persons.

Improving the bedding conditions would be a super plus.

MSF Malawi Activity report 2000

[...] Since mid 1999 more resources were allocated to the Mwanza project to be able to reach our objectives.

Unfortunately this decision didn't have a lot of impact in the implementation of in patient care.

At first some activities have been transferred to Chiradzulu district and expatriate as well as national staffs reallocated.
The final decision of closing the project was taken in September and the rest of the team was gradually removed.[...]
Conclusion: The year 2000 has again been very successful in term of all the work done in the community. Our different partners in the community appreciate a lot our presence.
Unfortunately our collaboration with the MOHP inside the district hospital was becoming more and more difficult. Complete lack of communication with the DHO and the matron makes our presence in the hospital impossible.

We had told the two DHOs (District Health Officer) in Mwanza and Chiradzulu: "Make an effort because the day we start ARVs we will begin in only one of the two districts and leave the other." Mwanza pretty well dropped us. The Chiradzulu DHO, a woman, was quite enterprising, she pushed us and she supported us. She wanted us to start. When we held the meeting that they both attended, the Mwanza DHO asked us for four vehicles, whereas the Chiradzulu officer said "Give me a generator to run the operating room and the sterilisation machines." **Dr Guillermo Bertoletti, MSF France Malawi Medical Coordinator, then Field Coordinator, then Head of Mission, 1993 to 1995; MSF France Desk manager from 1997 to 2001; Deputy Director of Operations then Director of Operations from 2001 to 2007 (in French)**

In 2000, two counsellors were integrated to the program in order to motivate people to get tested. At the time they could at least direct those who needed treatment for opportunistic infections toward the Chiradzulu hospital HIV clinic. But they had no ARV therapy to offer to those who had tested HIV-positive.

The HIV prevalence was just getting higher and higher in the country and lots of people didn't have the right information. And there was lots of stigma coming out, so it was very difficult for one to accept to get tested for HIV. Even people who were already in the hospital wards, they thought of going back home without having an HIV test. So the challenge was to motivate the people to see the importance of getting tested for HIV. When they did we had an HIV clinic where our doctors, nurses and clinical doctors, were looking at opportunistic infections, and treating them. So the task that I was really doing, was just to motivate people to come for HIV test, I was able to do the test, give them their results and leave them to the appropriate areas for treatment. **Mike Kalemera, MSF France Malawi HIV/AIDS program counselor from 1999 to 2010, then Head of IEC Department (in English)**

We were doing the testing but we did not have any treatment. In 2000 we had no free ARV treatment here. Maybe some were available in some private hospital but of course they were very expensive. The rich could afford it but a poor person who was living in the village, depending on family could not get access. So that was a challenge to get people tested. Patients would say: "Ok I'll be tested but what next? If I'm found HIV positive what are you going to offer me. You are telling me that I'm HIV positive and that I have to wait and die." We did not know that one day we will have the treatment but of course at that time we were hearing that there was some treatment available in western countries. But in Africa there was none. **Frazer Chimbuzi, MSF France Malawi HIV/AIDS Program Counsellor then Head of Counseling Department, from May 2000 (in English)**

FIRST STEP: TREATING MSF STAFF

More and more of MSF's national staff members were dying from AIDS due to not being treated, and the team couldn't tolerate remaining so helpless.

At the June 1999 General Assembly in Paris, the Head of Mission of the Malawi mission publicly revealed her anger at seeing her staff dying from AIDS and not being able to give them any treatment while ARVs were already available, though at a high price, in certain private health structures in Malawi. Her statement triggered many

discussions in the association and convinced more people that it was time to move ahead.

In April 2000, the Malawian media announced that thanks to an agreement between Glaxo Wellcome and the government of Malawi, ARVs were now available in several public and private hospitals in Blantyre: Queen Elisabeth Central Hospital, the 7th day Adventist hospital (Malamulo) and Mwaiwathu Private Hospital. Every patient had to pay 10,000 kwachas (USD200) per month plus the fees for the CD4 test.

When I did the first AIDS information-education session for our staff, the driver who used to drive me to the sessions came to me to say that unfortunately the information had reached him too late ... He died of AIDS a few months later. We managed to put another driver on treatment and we kept him on as a mechanic. He was able to live longer. The drivers, the hospital staff, they all dropped like flies.
Dr Guillermo Bertoletti, MSF France Malawi Medical Coordinator, then Field Coordinator, then Head of Mission, 1993 to 1995; MSF France Desk manager from 1997 to 2001; Deputy Director of Operations then Director of Operations from 2001 to 2007 (in French)

December 1998. MSF Monthly Activity Report. Chiradzulu District
(...) We lost one Community Nurse from the Hospital, one Nurse/midwife from Milepa H/C, an ambulance driver and a hospital servant. They all died in the hospital due to TB and/or AIDS. (...)

I fought to get antiretrovirals at least for our staff because we were losing a staff member or one of their family every week!
The ethical argument presented against was that you could not bring in drugs that were not available in the country for staff only. But if you looked at that close up it didn't make sense anyway. We, representatives of a medical organisation, able to pay for medicines for our staff, continued to go to the cemetery every week, all the while that antiretrovirals were already in private clinics in Malawi. It was unbearable to have people dying one after the other, knowing that the technical capacity was there, that MSF had the means to pay for the treatment, but that in the end, because of a decision which said that it was not part of the package of care, we could not do it! [...] It was the director of human resources who pushed a lot and tipped the balance overall.
Maryline Mulemba, MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003 (in French)

Eventually, in January 2001, ARV therapies became officially available to all MSF staff and their immediate family. In reality, the MSF team in Malawi had already been giving ARVs to its sick colleagues for more than a year, and treating them for opportunistic infections for several years.

TOWARD ARVS FOR ALL HIV-POSITIVE PEOPLE

- **Internal debate**

The MSF Movement's official position, exposed in a policy paper written by the medical directors of the [five] operational centres, stated that while it was possible to prescribe ARVs in middle income countries like Brazil, Thailand or South Africa, it was not possible to do so in other African countries where prevalence was at its highest.

This position was challenged within MSF France where most of the members of the board of directors and the management team were convinced that the French section should start prescribing ARVS.

Since late 1997 the former Head of Mission of the Malawi programme had become the manager of this programme on the desk, and together with some operational department colleagues had been advocating for the introduction of ARVs in MSF's AIDS programmes.

Two objectives were established: demonstrate that it was possible to treat patients with ARVs in countries with poor health structures, but also actually treat as many patients as possible, with a good quality of care.

However, some people remained more cautious regarding introduction of ARVs. They would present various arguments against, from the financial one—that by prescribing ARVs MSF was risking financial collapse—to medical and ethical questioning of the risks of prescribing ARVs at such a large scale.

MSF movement's Policy Paper VIH SIDA, published in "Medical news" August 2000

Antiretroviral treatment

In the industrial world, antiretroviral (ARV) triple therapy has greatly reduced the number of opportunistic infections and prolonged life. Cost, compliance (it has to be taken life-long), monitoring side-effects (liver and kidney function among others) and monitoring effectiveness (viral load measurement, CD4 count)make ARV therapy inaccessible for the majority of HIV patients in the developing world.

Antiretroviral therapy requires an adequate health infrastructure and comprehensive medical and social support. There are middle-income countries (Brazil, Thailand) where the health infrastructure functions satisfactorily and where a therapeutic follow-up of HIV/AIDS patients under ARV therapy can be implemented. Affordability of drugs remains a major constraint.

MSF considers provision of treatment with ARV as pilot projects. Provision of essential drugs for other diseases should be guaranteed before considering provision of ARV. Research is needed to identify regimens of proven efficacy adapted to resource-poor settings. Follow-up, monitoring compliance and sustainability have to be addressed. MSF should develop knowledge in this field.

Minutes of the MSF France Board meeting 27 October 2000 (in French)

- *The policy paper on HIV*

Jean-Hervé Bradol (Chairman of the Board): the response to the HIV policy paper should be measured but clear. It would be possible for example to use the practical proposals that we are making to the teams that are ready (and arriving in November) to bounce-back, pro-actively, and well-argued in documenting these proposals in an issue of Medical News.

Francois Bourdillon (Board member): The Board hopes that antiretroviral treatment programmes for people with HIV will be established in 5 to 6 missions. In this context, it seems essential that a policy paper on HIV care emphasises this political will, acts as an encouragement to the establishment of such programmes, and provides answers to questions. But when you read the text [in the policy paper] carefully, the message seems fundamentally contrary to the one MSF is trying to find. It also seems necessary that the text on treatment is not drowned in discussion of security, prevention policy, and management of AEB.

Michel Janssens (Board member): but we must also reconsider the organisational chain that made possible the production and distribution of such a policy paper as it is.

All policy papers define policy. It is unacceptable that policy be defined solely by the medical technology. I hope that in the future all policy papers will be submitted for approval to the Board before publication.

Marc Gastellu (Medical Director, MSF France): this corresponds to how our actions developed historically, first focused on prevention then on non-transmission to reach a transformation in '98 by putting the emphasis on treatment. The Board thus is seeing a paper in 2000 that was already developed in 1997; so there is a mismatch; but this paper was nevertheless a step forward from its precedents.

Jean-Hervé Bradol (Chairman of the Board): it is not possible to present this paper as a step forward because it is strictly speaking inadmissible and I think this kind of consensus does more damage to

the entire MSF movement than to a distinct position held by our section which would also be more realistic if we expected to have begun treating patients.
Didier Fassin (Board member): to move forward, the simplest way would be to write a more modest paper, in the vein of an operational protocol, with the current state of our knowledge on this subject as its point of departure, knowing that our knowledge will evolve.
Francois Bourdillon (board member): The title could have been "Proposals by MSF for therapeutic treatment strategies for HIV patients."
Didier Fassin (Board member): yes, thus contained, and clearer and faster, this paper would have allowed us to test the feasibility of our action and leave room for adjustments based on the results.

At my first operations meeting in 1997, I was asked what my goals were for Malawi. I said the introduction of ARVs for the treatment of patients.
It took four years. One obstacle was finance. When I first signed a cheque for the purchase of ARVs for MSF, we were at the stage when it cost USD10,000 per year for treatment, and we had decided to commit for life with these patients. Wasn't the management of AIDS treatment going to push MSF over the edge? We were moving forward hesitantly because there were not many people who knew what to do. As yet there were no free ARVs in Malawi, and we wanted to introduce them to a district bordering on Mozambique, at the risk of attracting patients from that country. What would we do? Refuse the sick? On top, there was no doctor in the entire district of Chiradzulu, so you had to invest heavily in health facilities, the twelve or fourteen peripheral health posts. There was no public transportation. But patients had to come to the centre every day because the drugs had to be taken under supervision.
Dr Guillermo Bertoletti, Medical Coordinator, then Field Coordinator, then Head of Mission, MSF F Malawi 1993 to 1995; Desk MSF France from 1997 to 2001; Deputy then Director of Operations 2001 to 2007 (in French)

The Board of Directors passed a budget that allocated a considerable sum. They said that whatever the costs of ARVs - at that time several thousand dollars per year per patient - the teams were to start prescribing them. It was a gesture to encourage the teams to begin. At first there were very small numbers of patients, very small cohorts. So the real obstacle for MSF was not financial. In fact the debate, which first spread through MSF and then also the external medical-scientific community, was: "Should we do this, or should we not?" Public health policy rules for introducing new treatments suggest that we went slower than what actually happened. In the late 90s, there were groups of doctors and notable public health pundits who said it was going too fast, that there needed to be clinical trials, that there wasn't enough data to undertake things immediately. **Dr Jean-Hervé Bradol, MSF France President from 2000 to 2008 (in French)**

Through 2000 and 2001, the conjunction of several events progressively swept away the barriers to prescription of ARVs.

In late 1999 the MSF Campaign for Access to Essential Medicines (CAME[1], or Access campaign for short), was created. Together with other activist groups CAME started to fight for a significant decrease in the prices of aids drugs, mainly through a demand for flexibility in applying intellectual property regulations and the development of simplified protocols.

Then in February 2000 the Indian pharmaceutical lab CIPLA announced its marketing of a tri-therapy combination treatment, Triomune[2] for USD350 per patient per year. Later on, Cipla would grant MSF a discount down to USD50.

In November 2000, with a view to introducing ARVs in MSF AIDS programmes, the relevant heads of mission met for a workshop to share their knowledge and to brainstorm possible strategies to treat patients with ARVs.

Minutes of the HIV workshop – 13-17 November 2000

The programmes were initially designed with the aim of treating those patients in front of us. The aim of demonstration was secondary, particularly in terms of ARVs. Their effectiveness had already been proven. Trying to make a demonstration in a faultless way ends up holding you back significantly due to the fear of error.
[...] There is rarely an urgent need to put a patient on to antiretrovirals. Adherence is an essential factor in achieving efficient treatment. The patient-caregiver trust relationship, the patient's understanding of the situation, and the right to make choices expression of choice are, undoubtedly, necessary (but probably not enough). Treatment started in haste, misunderstood, has a high risk of being rejected by the patient. It is preferable to wait until after several consultations (2 or 3 pre-requisite visits) for starting treatment.

- **Convincing the government**

As a strategy, the MSF Malawi team chose to first introduce ARVs in its programme for HIV-positive pregnant women, which it had been running since 1998 in Chiradzulu district to manage STDs and VCT.

However it took months of negotiations to get the official agreement of the health authorities to start prescribing ARVs. Indeed at that time, the Government of Malawi was receiving no international funds to finance ARV purchases. Therefore they considered it unethical to have ARVs freely distributed in Chiradzulu while they could not be provided across the whole country.

At that time we had begun to care for HIV-positive pregnant women and we said to ourselves: if you give the treatment to the kids and their mothers die in the background, it is not ethical. So I started to negotiate with the government to let us do a pilot project and to prescribe antiretrovirals. At MSF headquarters they were convinced quite quickly that we would be able to get going. However, it took me at least six months before the government of Malawi signed the agreement.
They were saying to us "We don't have the means to do this for everyone and so if we let you do it in Chiradzulu, we will have problems from an ethical point of view. So we can't let you start." I used the following argument: "You have to start somewhere and prove that it is possible, and then you will get funding for the whole country."
Maryline Mulemba, MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003 (in French)

As the negotiations continued to drag on, the MSF programme manager and the medical department's HIV/AIDS advisor paid a visit to the Malawian health authorities. They announced that MSF had decided to prescribe ARVs to pregnant infected women (PMTCT) but also to other AIDS patients in the district of Chiradzulu, and that it would close the programme if it was not allowed to implement its decision.

At the very same time, the verdict of the legal procedure launched by 39 pharmaceutical companies to stop the government of South Africa from importing cheaper versions of AIDS drugs was returned. The pharmaceutical firms lost the case and the door opened for importation and procurement of the cheapest drugs, at least from South Africa[3].

Maryline, Head de Mission said to me "Come with me, because I think we'll have the resignation of the whole team on our hands if we cannot start treating those who are sick." With Elisabeth Szumilin [from the medical department], we arrived carrying a blue MSF bag full of antiretrovirals. I knew the first Secretary of Health very well and I went to see him with that blue bag. He asked me what I was doing with with my bag, had I just arrived or was I leaving for somewhere. We had a very honest relationship and I told him that the bag was full of antiretrovirals that I was

bringing in to the country illegally! And I added: "If you do not give us permission to start ARVs, I will end up leaving anyway. Whether you have to kick me out for illegal introduction of ARVs, or my team resigns and I'll be gone with them."
At the same time the pharmaceutical lab lawsuit against the government of South Africa was happening and everyone's eyes were on it. He said to me "Calm your team, give me three or four days." He was the one who came down to Chiradzulu and told me we could start. And it was this same day that the verdict was reached in the South African trial, which allowed the lowering of prices for antiretrovirals. **Dr Guillermo Bertoletti, Medical Coordinator, then Field Coordinator, then Head of Mission, MSF F Malawi 1993 to 1995; Desk MSF France from 1997 to 2001; Deputy then Director of Operations 2001 to 2007 (in French)**

Thus the MSF Malawi 2001 Plan of Operations was made much more ambitious than previous ones and included:

- **Antiretroviral therapy for a limited number of HIV-reactive [positive] patients**
- **Organise palliative home based care for terminally ill patients[4]**
- **Start ARV in mothers to reduce mother-to-child transmission**
- **Improved drug access in collaboration with CAME**

In May 2001 MSF and the Ministry of Health of Malawi signed an agreement granting MSF permission to do a pilot for provision of ARVs for HIV/AIDS patients and also for mother-to-child transmission.

A five- year Memorandum of Understanding (MOU) was signed. On this basis MSF launched the programme "Chiradzulu District HIV/AIDS Project - Piloting ARV use at district level June 2001 - June 2006" (annex 3).

In August 2001, the MSF team initiated ARV treatment in the first patients in Chiradzulu district.

A BIG LEAP INTO THE UNKNOWN

I was very scared, but I thought that there was no other choice. It was urgent. At that time, the only usefulness of this mission politically and health-wise was to make a fundamental example. A percentage of patients was going to die with treatment but a much higher percentage would be saved. We did not know if it would work in practice but in theory the drug was supposed to save a big section of those people who would otherwise never get up out of bed again. On the other hand, it was necessary to provide an example of large-scale treatment to demonstrate that it was worthwhile to treat this population, that they were not condemned to death and that you could get results, as had happened a few years ago with the epidemic in the North. (...) The reasoning was relatively easy, which suited me because I'm not an ideologue who will trust an ethical point of view emerging from out of nowhere. But in practice it was a stance that was very difficult to maintain.
Dr Christopher Brasher, MSF France Desk manager, from 2001 to 2004 (in French)

In the very beginning ARV treatment was only available in the Chiradzulu Hospital HIV clinic, while in the health centres MSF had been undertaking, for several years already, different types of HIV prevention activities to reduce HIV transmission as well as treating opportunistic infections.

The objectives of this programme for 2002 were the following:

MSF F Malawi Aids project Annual plan 2002
General Objectives

To improve the level of health services offered in the District especially for HIV aids patients.
To Lobby for improved ARV drugs access in Malawi.
Specific Objectives

1. *To improve general care of sick people in the district health facilities with a specific attention to Aids patients.*
    - *To offer counselling and testing services as well as psychological support for the sick.*
    - *To guaranty good quality care for all patient hospitalised in the District hospital*
        - *General care and nutrition care for the malnourish children)*
    - *To offer specific care for symptomatic Aids patients though HIV clinic*
        - *(Prophylactic treatment, management of opportunistic infections, food support)*
    - *To offer ARV treatment for a limited number of patients to be able to develop know how about HAART (Highly Active Antiretroviral Therapy) use at district level in poor setting country*
2. *To prevent HIV transmission:*
    - *In the Health structures setting (implementation of universal precaution)*
    - *Through screening and treatment of STI.*
    - *Through Mother to child transmission project*
3. *To initiate in the community change of behaviour leading to reduction of HIV transmission through traditional leaders and youths:*
    - *Condom promotion*
    - *Promotion of Voluntary counselling and testing centres*
    - *Information about Mother to child transmission*
    - *Recognition of traditional believes promoting HIV spread*

At the beginning, there were fears that the HIV clinic would be overwhelmed by HIV/AIDS patients from all over the district and even from Mozambique. Therefore only those coming from villages situated within three hours' walking distance from Chiradzulu were granted access to ARV treatment.

A selection committee composed of MSF and MoH staff, mainly doctors, was in charge of examining every case eligible for HAART. Patients with less than 200 CD4 and in such an advanced stage of the disease that they risked not surviving in the coming weeks were accepted in priority.

In the very beginning blood samples were taken in the Chiradzulu HIV clinic and CD4 levels were tested in the laboratory of the Queen Elisabeth Hospital in Blantyre. But MSF quickly set up basic laboratory facilities in Chiradzulu hospital.

During the first months, there were only small numbers of ARV candidates coming to the HIV clinic. Even the initial objective of enrolling ten patients per week was not reached. The selection committee therefore appeared superfluous and was removed. From then on, it was up to the medical doctors to decide whether to put patients onto ARVs or not.

Many of the very sick patients, with very low immunity, were already having serious opportunistic infections (often unrecognised), or failed to cope with the sudden inflammation provoked as a side-effect of the ARVs. Within the first year more than 20% of the patients on ARVs died.

Actually, it took almost a year for the 80% who survived to get better on the drugs, and to become "living evidence" in the eyes of their community that ARVs were effective to keep people alive and in a state of health allowing them to live normally.

For years we had told them so often that they could only die of AIDS, that they didn't believe

they could survive thanks to ARVs. Some of our staff, although we were providing the drugs, died because they refused to be tested. They didn't believe in it. It was when they started seeing the first patients who were almost dying and who then began to get better thanks to ARVs that people began to say the treatment finally worked and that it was perhaps worth it to go get tested and benefit from the treatment. But it was very slow. People who were almost dying, they were put on antiretrovirals and three months later, they were running through the streets. This was super-positive for the teams. It was like a miracle, the shift from the period without and the period with antiretroviral drugs. The arrival of antiretroviral drugs also removed the taboo from the test. We went from people who were afraid to get tested to people who would go for testing to get access to treatment. **Maryline Mulemba, MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003 (in French)**

In the MSF Malawi 2001 activity report, the implementation of the ARV programme during the first six months was described as follows:

Médecins Sans Frontières France – Chiradzulu District- HIV Aids Programme – Year 2001 – Maryline Mulemba, Head of Mission, February 2002

Organisation:

The ARV program has started in August 2001.

All patients followed up at the HIV clinic that are living near the hospital and have a guardian or a PLWA of whom they have disclosed their status have their CD4 count checked.

After 6 months of implementation we would also consider patients who don't want to disclose their sero status because of stigma in their community.

All the patients who have got less than 200 CD4 whatever their WHO staging are and the patients Stage 4 with CD4 less than 350 are pre-selected.

The doctor presents them to the committee (composed of DHO, Matron, DC, MSF field co, MSF Head of Mission, MSF compliance nurse).

The Committee decides on the inclusion. (Evaluate who is starting first and put some on waiting list if no places are available for inclusion).

We include a minimum of 5 patients per week

The patients selected by the committee have some laboratory base line test done (Full blood count, Haemoglobin, liver function test and sputum).

If the laboratory tests are compatible with the start on therapy, they are referred to the counselling compliance team. One, two or three sessions are organised for each patient for them to be able to understand the treatment and to be able to take the drugs.

Once the compliance team is comfortable with the understanding of the patient they provide him the drugs prescribed by the doctor.

The drugs are provided for two weeks. Patients have to come back to the hospital to get the drugs every two weeks for the first month then they can get them monthly through any of the HIV clinics of the district.

Patients are taught how to use the treatment chart that they have to fill each time he takes a tablet.

The guardian is supposed to assist in each drug intake.

The treatment chart is a tool for the patient to help him remember the drugs he has taken.

During the first month each patient is visited once at his home to be sure that drugs are properly taken. This will change. Only patients having difficulty in understanding during the compliance visit will be visited.

Every two weeks if the patient has got side effects, the doctor sees him for proper management. Each patient is taught about the severe side effects and is asked to come back to the hospital at anytime if this happens.

At D14 [Day 14] and D28 [Day 28] and every 3-months, the patient goes again for laboratory check ups (Haemoglobin, FBC, ASAT).

LIMITATIONS OF BIOLOGICAL TESTS AND FOLLOW-UP

Confronted with the expectation of a huge number of patients, the team had to go through a period of definition of simplified operational strategies and technical and medical protocols.

It was almost impossible to ensure the supply of equipment and the regular maintenance of machines in a rural district in Malawi, one of the poorest countries in southeast Africa. Moreover the testing process would take time and slow down the enrolment of new patients while there were so many sick people to treat.

Therefore the coordination team and the programme manager in Paris quickly acknowledged that it would not be possible to have ARV candidates take all the biological tests usually implemented in the USA and Europe. Follow-up once under treatment too had to be as least dependent on biological tests as possible.

At first, when we wanted to put patients on antiretroviral therapy, we had to measure the transaminases, do quite a lot of lab tests, but in the end when we were doing a little research we realised that it wasn't changing things much for our patients, and so we said we would stop the lab tests and that we would start ART and we would see what would come of it!
Maryline Mulemba, MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003 (in French)

In less than a year: we decided to be less cautious in the biological monitoring of patients. We thought that it would work or it would fall apart and that we were going to put them on treatment since that was the only thing to do, so too bad for laboratory tests. If we hadn't dropped the testing we would have had to make everyone come back too often. Backed by our committee of French experts, we decided that there was no need to have 36,000 laboratory tests to treat infected people.
Dr Elisabeth Szumilin, MSF France medical department Aids advisor, from 1998 (in French)

At headquarters there were divided opinions about the practical aspects of the ARV programme's implementation. The MSF Malawi Head of Mission and the programme manager were convinced that simplification of the protocol and a reduction in biological tests were necessary to move forward. They were aware of simplified, pilot AIDS projects such as the one initiated by Partners in Health in Haiti, which was delivering treatment through community-based programmes.

However others within MSF – mainly doctors – remained sceptical. Most of MSF's expatriate medical staff were general practitioners and had poor knowledge and experience regarding HIV/AIDS. At first glance, this could have been seen as a barrier to the programme's development. But surprisingly it was more the "AIDS expert" medical staff that were reluctant to take the risk of treating patients with ARVs without regular biological follow-up.

Almost all the expatriates were reluctant to treat patients without regular biological monitoring. With our system in Malawi at every interview and every point of contact with the patient, it boiled down to saying, "You'll go on treatment." There were few or no checks-ups. We were asking the expats to work blind and without the time to reassure them that they were doing what needed to be done with respect to each patient in a situation with no clearly defined limits, no course of action established. And our doctors were not AIDS experts, so they had to get know this disease. They had reason to be afraid.
I remember an expatriate doctor, who was however a specialist in this field but resisted a lot. He kept returning to more complex models that were not going to work in this context and moreover which would not enable us to put a lot of people on treatment. I struggled with him. He didn't resist openly. He even made an enormous effort. But he did not agree, did not trust our approach, and you could feel this.

I had the chance to go to Haiti to see Paul Farmer, an American physician who is quite well known, who had organised a seminar for a few days with experts to take stock of AIDS. He was in the process

of setting up an AIDS programme with the usual battery of laboratory tests. But the machines to do these tests were broken, so his team decided to continue to put people on treatment anyway, which was the counter-thesis to Farmer's starting position. I asked my "resistant" expat doctor in Malawi to come with me, hoping to convince him. On the evening of the second day we were drinking a beer in silence, he was tired of me and I was a little tired of him ... and after a moment he said "Okay, you won ". What he saw in Haiti convinced him. **Dr Christopher Brasher, MSF France Desk manager, from 2001 to 2004 (in French)**

As MSF was at the stage of research on operational and technical approaches, it regularly organised technical workshops gathering heads of mission and medical coordinators of the various HIV/Aids programmes[5], members of the medical department and outside experts, in order to share and compare experience and lessons learned.

But potentially every meeting with managers of other MSF HIV/AIDS programmes could also put the team again in a state of uncertainty regarding the Malawi programme.

In these workshops, we worked on technical issues: How do we do it? CD4 or not ? Viral load or not ? Which first line? How to follow-up side effects? etc. In fact we didn't have much knowledge since we were working with generalist doctors. It was a choice on my part to not have only HIV-specialist doctors, because we worked in health centres. So it was important to not introduce techniques that weren't adapted to the country. **Maryline Mulemba, MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003 (in French)**

Each co-week was a disaster. The field workers from the small AIDS missions, like those in Cambodia which dealt with only thirty patients, all had a lower workload and their care was much more aligned with Western treatments. They spoke with our Malawi team and all the confidence of the team in what it was doing risked collapsing every time it was faced with the dominant paradigms within MSF and medicine in general. Each time, it was a challenge. It was very fragile. **Dr Christopher Brasher, MSF France Desk manager, from 2001 to 2004 (in French)**

In the field as well as at headquarters, the MSF teams were supported and advised by a committee of French medical experts, composed of medical practitioners with vast experience in the treatment of HIV/AIDs in Europe. Their opinion would also weigh in on the debate within MSF, and help convince those who were having doubts.

Minutes of the meeting of the Board of MSF France, Friday, September 24, 2004 (in French)

Evaluation (Michel Rosenheim, Department of Infectious and Tropical Diseases Pitié-Salpêtrière Hospital in Paris)

Michael Rosenheim: I was very impressed with the MSF mission; I find it quite remarkable. The country has a geographical area and population roughly a fifth of France with a habitat that is "densely rural." The country has a high fertility rate and one of the lowest GDPs, and a limited life expectancy. 15 to 20% of the population is HIV positive.

The programme has worked to simplify the management: it has also sought to avoid the use of quotas and to increase the number of patients in an adapted way. Therapeutic education is very effective, adherence is significant (there is a 25% loss to follow-up – due to death or dropout). The results match international standards and 5,000 patients are treated.

Questions:
The definition of treatment failure is not yet simple or clear enough.
Are CD4s useful?

How can pregnant women be encouraged to test?
How is neonatal diagnosis accommodated? (to avoid monitoring for 18 months)
What are the alternatives to breastfeeding?
A model that can be proposed
More than the country's economic level, it seems that its epidemiological character is what should shape our action: from this point of view, our action seems appropriate for the situation in Malawi.

Doctors working in HIV in France helped us to build our treatment approach. They helped us select the molecules relevant in our context, especially those which had clinical rather than biological side-effects, so that we could diagnose them more easily. They helped us to build the algorithms for managing side-effects, and opportunistic infections etc.. At that time, this specialist committee was very active.
Dr Elisabeth Szumilin, MSF France medical department Aids advisor, from 1998 (in French)

The visit made by Michel Rosenheim of the Department of Infectious and Tropical Diseases of Pitié–Salpêtrière Hospital in Paris in 2004 was very helpful. Michael made sure that everyone was roughly aligned on the simple reasoning that I maintained. The fact that it came from him was very helpful in letting me move ahead quietly and without someone knocking on my door every five minutes. **Dr Christopher Brasher, MSF France Desk manager, from 2001 to 2004 (in French)**

ENSURING ADHERENCE

- **Counselling**

Due to the simplified set-up of the medical follow-up, a good understanding of the treatment amongst the patients was critical to the functioning of the programme.

If the patients did not take their treatment properly they would develop resistance to ARVs that could hamper any further treatment for them in the future. This could also facilitate the spread of ARV resistance within the community and thus put the programme at risk.
Patient education and counselling were organised to address this.

We realised very quickly that we would not have the means to conduct biological monitoring and therefore we had to make sure that the patients took their treatment. So from the beginning, we wondered: "How can we make it that the patients take their treatment regularly? How can we get them through the first critical months?" Then straight after that we had to consider "How are we going to do this over the medium term and how will it work long term?" Adherence was already one of the key issues of the programmes. **Maryline Mulemba, MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003 (in French)**

Counselling was already in place. It was a politically correct activity. There were counsellors trained throughout sub-Saharan Africa for the testing, to essentially then say to people that they would die, since there was no affordable treatment. With the introduction of ARVs, it was necessary to modify the content of the counselling sessions. It was not easy for the counsellors because there was a paradigm shift. **Dr Christopher Brasher, MSF France Desk manager, from 2001 to 2004 (in French)**

For MSF, therapeutic education was a relatively new activity that had been previously developed mainly to ensure TB patients' compliance by counselling them for their

long-term treatment (6/8 months to several years for MDR TB patients). Competencies needed to be developed in this domain.

Since I had been in charge of training I had worked mainly on problems of adherence to TB treatment and how therapeutic education for the patient could partly help resolve problems. When we started the AIDS programmes, obviously we asked ourselves the same question for HIV treatment. We said, "For long-term treatment, life-long treatment, chronic disease, we will have to be able to support people, support them in the management of their treatment."

In Malawi, they quickly set up at national level training of counsellors for pre-and post-testing. This training was well done, it was recognised and validated, with a diploma on top. So all our counsellors, early in the Chiradzulu programme were already working pre-and post-test. They had a good background in listening, in relating humanely. So logically, it was from this pool that we drew when it was time to begin counselling and support for patients on antiretroviral therapy.
Emmanuelle Chazal, MSF France Medical Department Advisor on Patient Education and Training from 1999 to 2007, (in French)

At the Chiradzulu hospital HIV clinic and at the Voluntary Testing and Counselling Centre (VTCT) the MSF staff, already involved in pre- and post-test counselling, were trained in the more complicated part of patient education relating to management of HAART. This training was mainly done "in situ" by the medical staff within the team.

Normally, it was the expat nurse who was doing the education and I was doing the translation. So in a way I was learning from her how to inform the patient about the treatment. And after 2-3 months the information we could use became clear to me. We also designed a flip chart that we could use to help patients and to get the information clearly. After 6 months I was more comfortable, I had training from the experienced nurse and I was able to do the work alone, to pass the information about the treatment to the patient. I was also able to train other counsellors. So in a way that's how we did. In 2004 all the counsellors had actually been trained. **Frazer Chimbuzi, MSF Chiradzulu HIV/AIDS programme Counsellor for May 2000 (in English)**

The change came first about the understanding of the drugs. It was new, it was more medical terms, which were very difficult to even translate into our vernacular language so that somebody from the village could really understand this. And there were lots of misconceptions to do with the ARVS. People would say: "No, I hate these drugs! When you start them, you die". It was things that people were used to believe and it was the role of the counsellor to take care of that and to grow out of these misconceptions so they can see there is a benefit in that. If somebody started, how could we make sure his compliance was integrating well? That was another challenge to gain the trust from the patient. We didn't have any measures to verify that what he was telling us was true. So the counsellors took charge to try and educate people both during health talks and during one to one talks in the counselling rooms. **Mike Kalemera, MSF France Malawi HIV/AIDS program counselor from 1999 to 2010, then Head of IEC Department (in English)**

- **<u>Defaulter tracing</u>**

At the beginning of the programme, the MSF counselling team was in charge of tracing defaulters, the patients that did not show up for their follow-up consultations. But the presence of these teams in the villages stigmatised the patients that were traced and caused difficulties for them in their communities.

Therefore, in 2004, the position of tracer was created. The tracer was recruited from amongst People Living with AIDS (PLWA) groups in the district who knew the communities well and had more discreet access to the patients.

I argued against the efforts to promote the maintenance of treatment. I thought this should come from outside, that it should be organised outside of MSF, by Malawians who were by not paid by MSF. But I didn't have an idea as to how this could be done. **Dr Christopher Brasher, Desk programme manager MSF France 2001-2004 (in French)**

People were looking at the MSF car with European people from somewhere outside the country going to somebody's home. It was a bad intrusion to some of these patients. Then it was decided to use people who were in the support group and one person was given a contract. We gave the position to people who were very much conversant with the district setting. When they were informed where actually one was coming from, they had in their mind "ok they are talking about this area" and they had the picture of where actually this patient was coming from. In some cases, they used to know this place was not available in the district so maybe that was a false address. So it was easy. The burden of tracing was taken out of the counselling team after the tracing team had started its work. **Mike Kalemera, MSF Chiradzulu HIV/AIDS programme Counsellor from 1999 to 2010, then IEC officer from 2010 on (in English)**

In MSF they told me: "We want you to do this: tracing people in the community who started treatment and did not come back." I tried little by little, to settle in my mind: "the aim of MSF is to keep our lives healthy. So if these people are defaulting, I think they're not reaching their potential." So I tried to go in the community, looking for these people through the addresses they have given when they have started their ARVs.
Because of the stigma at that time, I was making sure nobody should know what I had come for. I would come to the village and discuss with someone who was married. The husband or the wife did not know. Even the mother didn't know. They would say: "if I would disclose this test to my mother, she will chase me out. If I disclose to my husband, he will leave me." So, little by little, I would try to encourage these people. **Esnat Mbanda-Mbanda, PWLA, tracer then tracer supervisor, then IEC officer from 2002 on (in English)**

- **Information, education and communication**

In the first years of ARV implementation, MSF's VCT and IEC activities changed. Messages were adapted for more focus on informing people that they could be treated for free with ARVs in Chiradzulu district.

End of mission report Maryline Mulemba, Malawi, November 1998 - March 2003

IEC:
The IEC programme needs to continue to focus on improving knowledge of the community for them to be able to access care.
Support PLWAs for them to be able to function.
PLWA group is very motivated. They are now voluntary counsellors and they are doing a great job for the community as well as for the support group.
We need to be very careful not to spoil this dynamism.
MSF is not paying them (no money for community)
Continue supporting them during meeting.
MSF can play a role to connect them with other groups.
With UMOYO Network (they will access funds from the global fund for support for PLWAs). Chiradzulu PLWA support group could access this money with MSF helping them to define their needs.
UNFPA will start income generating activities with the Ministry of Commerce targeting people living with AIDS (PLWAs).
They will start over the year in Chiradzulu. Make sure that the group is one of the beneficiaries.
IEC could also have the interest to know your sero status for preventive aspect.

Condom promotion not linked with abstinence and faithfulness needs to be continued strongly. The country can't change their priority with condom.
All the other parts of this program need to be handed over by the end of the year.

Before I was working with MSF, I was in a support group. We started this support group for the district. We were 5 of us, meeting all HIV positive people, both men and women. We were encouraging HIV positive living. Some people were thinking it was witchcraft. We had to go in the community to show them that it was not.
As I was going on with the support groups, MSF came there and took some volunteers. We went for a training of community counselling. From there, after 6 weeks we were back in our centres. We were doing pre- and post-test counselling to the patients who were in need of getting the HIV test. After they had discussed, the client would say: "now I'm ready, I can be tested." And we would ask the nurses to take blood for us.
When we would go back in the morning, we would go to the health centres for post-testing for the patients. Those who were HIV positive were referred to the clinic. Those who were HIV negative, were encouraging them to keep themselves proper and not to catch the virus and to come again after 3 months because of window period.
I was working both counselling pre and post-test. I was taking the samples to the district hospital and sometimes I was even addressing people in the community that were doing PMTCT. **Esnat Mbanda-Mbanda, PWLA, MSF France Malawi HIV/AIDS Programme tracer then tracer supervisor, then IEC officer from 2002 (in English)**

When I joined MSF in 2000, there was an IEC officer, doing IEC activity. The focus then was on prevention: talking about HIV/AIDS and the care that were available. And then when the HAART programme started, the focus changed because now it was about talking of curative.
We had our partners in the district that were doing better. So we removed IEC from our MSF program and then it was being done by Ministry of Health. **Frazer Chimbuzi, MSF France Malawi HIV/AIDS Program Counsellor then Head of Counseling Department, from May 2000 (in English)**

On the one hand, it seemed obvious that we had to go out and recruit patients, thus ensuring that people knew that treatment existed and they could come to see a doctor.
But to move forward it quickly became very complicated. We had to explain everything, to change attitudes ... In my opinion we couldn't get involved in that. We just had to facilitate that people had the means to come and hear that they could get treatment. I thought that going beyond what was outside of what was possible and that it would bog us down. I kept each initiative in check with simple arguments. It was very frustrating for people who were working on this, they must have found me brutal and simplistic.
Dr Christopher Brasher, Desk programme manager MSF France 2001-2004 (in French)

In 2003, all non-curative activities like VCT and IEC were handed over to existing partners in the district.

SUPPORTING THE HOSPITAL

The MSF involvement in Chiradzulu hospital remained important, as it was a referral structure for complicated HIV/AIDS cases and also because the MoH at that time had little resources; MSF managed the HIV clinic, health care for HIV-TB co-infected patients, nutritional support, VCT, tracing, support to four wards (men, women, paediatrics and TB), and a laboratory and pharmacy for drugs for opportunistic infections.

Hospitalisation and staff working conditions in such an old and small building were chaotic. In 2001, the mortality rate in the hospital was 19% for men and 17% for women, of which 57% and 65% respectively were attributed to AIDS.

Eventually, the EU financed and constructed a 400-bed hospital which opened in 2005.

Dr Christopher Brasher, Desk manager, report of first visit to Chiradzulu Hospital in May 2002

The general hygiene & staffing levels at the hospital are poor, unfortunately. The older buildings date from 1923 and cannot be improved greatly. The wards are not that clean & the mattresses & beds in poor condition, with two patients to a bed the rule in paediatrics. The morning handover is poorly done but a fantastic & potentially life-saving exercise. I wonder if we couldn't help with visual aids (white or blackboard maybe?). Impressive are the efforts undertaken to use the limited space available for the various aspects of patient care (mothers' awaiting labour room in converted closed-off veranda, counselling room at the end of the TB ward, nutrition centre in what was a radiology building, HIV outpatients dept. in two annexed rooms of the pharmacy). Waste separation (needles from medical waste from non-medical waste) is well done & the Montfort incinerator & needle pits are well maintained & used correctly.

FIRST ATTEMPTS FOR PREVENTION OF MOTHER-TO-CHILD TRANSMISSION (PMTCT)

In developed countries, AZT treatment had been given to HIV-positive women during their pregnancy since 1994 to prevent mother-to-child transmission (MTCT).

In Malawi MSF had been supporting Chiradzulu hospital since 1998 in activities targeting HIV-positive pregnant women, such as hygiene and health education, counselling and testing, and STD management during the antenatal visit.

At the time no specific AIDS treatment was being proposed since ARVS were neither available in Malawi nor in MSF programmes.

MSF Malawi Activity report 2000

3;4 Prevention of mother to child transmission

The midwife in charge of the implementation of this programme arrived in July

3.4.2 Materiel and organisation
Health education is now well established. Specific topic on reduction of MTCT has been introduced.
Promotion of use of VCT is also emphasis in the unit.
Condom promotion has started really well. MOHP staff and the mothers are now very convincing of this action.
Mothers and women coming for family planning are asking for it.
Still it is difficult to improve the quality of the antenatal and family planning because of lack of nurses in the unit.
The MOHP promise two nurses permanently every day. MSF will add one.
STD management will be integrated as soon as the staff will be available.
One room has been allocated to do counselling in the unit. Counselling has started in October.[...]

3.4.4 Objectives to be reached
Improve promotion of VCCT during family planning.
Integrate STD management during antenatal visit.
To increase the staff available to give the service.

In 1999 clinical studies showed that giving a single dose of nevirapine to HIV-positive pregnant women during delivery could a priori prevent 50% of newborns from being

infected with HIV. This regimen was positively welcomed by the MSF teams as it was inexpensive and much easier to use in the poor settings where MSF was implementing its HIV/AIDS projects.

Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial – The Lancet, Volume 354, Issue 9181, Pages 795 - 802, 4 September 1999

Summary

- *Background*

The AIDS Clinical Trials Group protocol 076 zidovudine prophylaxis regimen for HIV-1-infected pregnant women and their babies has been associated with a significant decrease in vertical HIV-1 transmission in non-breastfeeding women in developed countries. We compared the safety and efficacy of short-course nevirapine or zidovudine during labour and the first week of life.

- *Methods*

From November, 1997, to April, 1999, we enrolled 626 HIV-1-infected pregnant women at Mulago Hospital in Kampala, Uganda. We randomly assigned mothers nevirapine 200 mg orally at onset of labour and 2 mg/kg to babies within 72 h of birth, or zidovudine 600 mg orally to the mother at onset of labour and 300 mg every 3 h until delivery, and 4 mg/kg orally twice daily to babies for 7 days after birth. We tested babies for HIV-1 infection at birth, 6—8 weeks, and 14—16 weeks by HIV-1 RNA PCR. We assessed HIV-1 transmission and HIV-1-free survival with Kaplan-Meier analysis.

Findings

Nearly all babies (98·8%) were breastfed, and 95·6% were still breastfeeding at age 14—16 weeks. The estimated risks of HIV-1 transmission in the zidovudine and nevirapine groups were: 10·4% and 8·2% at birth (p=0·354); 21·3% and 11·9% by age 6—8 weeks (p=0·0027); and 25·1% and 13·1% by age 14—16 weeks (p=0·0006). The efficacy of nevirapine compared with zidovudine was 47% (95% CI 20—64) up to age 14—16 weeks. The two regimens were well tolerated and adverse events were similar in the two groups.

- *Interpretation*

Nevirapine lowered the risk of HIV-1 transmission during the first 14—16 weeks of life by nearly 50% in a breastfeeding population. This simple and inexpensive regimen could decrease mother-to-child HIV-1 transmission in less-developed countries.

Minutes of MSFF Board of Directors meeting – 29-30 January 1999

Epicentre must investigate the feasibility of a programme to prevent perinatal transmission of HIV. According to Francis Bourdillon, the situation in Malawi merits an attempting prevention of mother to foetus transmission. Trials to be presented in Chicago next week confirm the efficacy of AZT in short-term treatment before delivery (1-2 months), even in the case of continued breastfeeding.

Therefore in 2001 MSF chose this protocol to start PMTCT activities within its HAART programme. At that time these activities were limited to the hospital.

However in the following years, partly through observation of the behaviour of the pregnant women in the programme and partly through international medical studies and WHO recommendations, MSF realised that the "single dose nevirapine to the mother during delivery" protocol had serious drawbacks.

First, WHO stated that because mothers could transmit the virus to their babies during breastfeeding they should be asked to stop breastfeeding after six months, a period that was considered long enough to protect the baby against other common infant diseases. However clinical trials showed that while babies were partly protected from HIV by this method, they were dying from other diseases like diarrhoea since they were not protected any longer against them by their mother's milk. To compensate for the lack of milk protein after early weaning, MSF started to provide ready to use food (RUTF) containing milk. But then the mothers who stopped breastfeeding and gave

RUTF as supplementary feeding to their child were stigmatised by the community, and eventually gave up the treatment.

In April 2003, MSF mobile clinics commenced PMTCT activities in health centres and an introductory training for 38 MoH staff was implemented.

Malawi Visit Report, 12-19 May 02- Dr Christopher Brasher "Desk" Responsible for Programs –MSF France

Mother To Child Transmission (MTCT)

It is difficult to calculate accurately the impact of this program at this early stage. However, given the stigmatisation of (non) breast feeding (= sero - positive) & the low % of mothers attending medical structures to give birth we cannot talk about the impact in terms of public health. The question will be if the number of infections prevented is worth the effort. If it is not, it is equally important to describe the failure well. We will need to wait for at least another two years to have enough results at 18 months of age to comment with any confidence.

MSF France mission in collaboration with the Malawian Ministry of health plan of scaling up access to antiretroviral therapy- Chiradzulu district 2003

Prevention of mother to child transmission of HIV

Globally, the problem with reducing mother to child transmission is the poor uptake of ante-, intra- and post natal services by mothers. To prevent vertical infections in identified pregnancies , two main interventions are implemented in Chiradzulu: (i) Nevirapine is given to the mother and the baby (or HAART to the mother alone during the whole pregnancy according to her clinical and biological status) (ii) replacement feeding is offered and if breastfeeding is preferred, early weaning is advocated for and supported by the provision of a peanut-based paste (PPN) as an alternate food when the infants reach the age of 6 months. 2003 was the consolidation phase of the decentralization of those activities. Each health centre has been supported twice monthly and provided with Nevirapine, PPN and CD4 count tests.

Although, in the district hospital, less pregnant mothers have benefited from VCT services in 2003, more of those found reactive have accepted to join the prevention program (from 41% in 2001 to 88% in 2003). The overall number of mothers showing interest in the PMTCT has increased in 2003 (from 90 to 267 from 2001 to 2003).

Yet the number of full dose actually absorbed has been estimated to have been a lesser success. Of the mothers enrolled 54% (144/267) have been lost to follow-up. 28% of babies have benefited from a maximum preventive therapeutic action (76/267).

In 2004 MSF decided to deliver PMTCT to pregnant women with a CD4 lower than 350 instead of 200 in all its AIDS programmes, because studies had proven that transmission was higher for women with a CD4 lower than 350. At that time, MSF had more capacity to test CD4 than the MoH which was only starting its HAART programme and kept the 200 threshold for PMTCT enrolments.

In the meantime, clinical trials had shown that taking a single dose of nevirapine could drive resistance and could therefore challenge the possibility for the mother to further treat herself with this drug.

WHO issued new recommendations for a combination therapy to be given during pregnancy, delivery and immediately post-partum. This new regimen was also supposed to limit the risks of resistance. But its implementation was very complicated.

Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants - WHO 2004

Antiretroviral resistance following short-course prophylaxis for preventing MTCT

Viral resistance may emerge during ARV treatment and occurs more frequently with single and dual-drug regimens. Viral resistance is a potential problem for women after short-term exposure to ARV drugs to prevent MTCT and for infants who become infected despite ARV prophylaxis.

Satisfying ourselves with just giving a single dose of nevirapine to the mother during delivery could result in creating resistance to the drug. At the time we didn't have many alternative medicines, so in taking the risk of creating resistance we were also taking the risk of depriving the mother of possible ARV treatment thereafter. We were also taking the risk of depriving the baby, if PMTCT was not effective or if it became HIV-positive later.
Also, if you content yourself with treatment just during delivery, the risk of transmission re-emerges during breastfeeding. And an African woman who doesn't breastfeed risks stigmatisation.
Dr Myrto Schaefer, Head of Mother and Child Health Project Unit, MSFF Medical Department (in French)

There were also structural barriers to the correct implementation of the PMTCT process. Indeed its integration into antenatal care at the hospital was going too slowly. At that time HIV testing was not implemented within the antenatal services of the MoH, which were poorly attended by pregnant women. Moreover, most of the women did not even imagine they could be infected, as their husbands would not inform them of their own status even if they were themselves aware of it. Therefore these women did not go for a test. And those who were aware of their status were not necessarily informed that they could be treated to avoid viral transmission to their newborn. Therefore, very few pregnant women were being tested and thus detected as eligible for PMTCT.

The PMTCT process was split across several consultations and the women often couldn't manage to attend all of them (antenatal, maternity, postnatal, HIV clinic etc ...) within the same day. Moreover there was no link or follow-up between these different consultations.

Within MSF, opinions were divided on the PMTCT issue. There were questions about the actual impact in terms of public health. Some thought that the single dose nevirapine protocol was satisfactory since for them the main objective of PMTCT was to prevent the baby from being contaminated by his HIV-positive mother. Others, and among them the desk manager, were ethically opposed to what they considered as a discriminatory protocol. They wanted to prevent transmission to the child during delivery, but also to treat HIV-positive pregnant women with ARVs even if they were not sick yet. However at the time there were many barriers to this approach.

The only treatment that seemed appropriate to me was treatment for life for HIV-positive pregnant women who wanted it. As for those who didn't want it, they took the risk ... But back then it was unthinkable. No one accepted it. We were not yet treating all the people who were sick, so it wasn't the time to treat pregnant women who were still in good health! The one thing that was conceivable was mono-therapy to fight transmission to the baby. It focused on saving the baby. But for the mother, we took the risk of sacrificing her. I was in complete disagreement with this approach. We were holding the population in total disregard. Ethically, I thought it was indefensible. But I knew that for political reasons, both at the level of MSF and the Malawi authorities we were obliged to pretend a little to be happy to do what was accepted at the time. So we did it. But personally, I couldn't believe it and I did not want to put resources behind it.
Dr Christopher Brasher, Desk programme manager MSF France 2001-2004 (in French)

The impact of the programme remained weak and the PMTCT activities were handed over to the MoH in January 2005 for the hospital and in July 2005 for the health centres.

MSF France Malawi Fiche Projet 2004

(...) PMTCT

A thorough evaluation of this program shows it is a failure. Women included in the program do not represent 5% of the population and the proportion of losses to follow-up between enrolment and delivery and babies' HIV test are respectively 25 and 75%. Until now there is no significant difference in the HIV prevalence among babies who have received the full intervention and those who did not receive ARVs. Therefore we will disengage from this activity as such next year. Pregnant women will still be treated under the current HAART program.

The PMTCT program pre-existed antiretrovirals and had raised great hopes. We said to ourselves: "We cannot put patients on anti-retroviral drugs yet, but if we can ensure that the newborns are not infected, it's something." Nevirapine appeared to be the miracle cure, inexpensive and uncomplicated to implement, so we threw ourselves on it. And then we quickly realised that it was a nightmare because in Malawi as in all poor countries, there was no structure of managing pregnancy. So women did not come to deliver in hospital, and did not come to get tested. And those who came for testing did not come for the results. Nor did they come in for regular monitoring.

We managed to test two or three children at 18 months. We also lost many, because the mothers were transmitting the virus through breastfeeding. We had still tried to promote artificial feeding, checking the quality of available water in their homes, giving them the equipment to treat it and so on. But during this era we were afraid, if we put the mothers on antiretrovirals and the babies still developed AIDS, that we would create resistance and not be able to do anything more for them. The Medical Coordinator who worked with me was quite visionary. He said that we had to embark on research, but back then we didn't dare. Therefore we busted our brains on this project for almost two years, only to finally abandon it.

Maryline Mulemba, MSF France Malawi HIV/AIDS Programme Head of Mission from December 1998 to March 2003 (in French)

FIRST STEPS OF SCALING-UP: OUTREACH ACTIVITIES TO HEALTH CENTRES

It quickly became clear that the initial set-up based on hospital activities only would not allow MSF to take charge of all the patients eligible for ARV treatment. It became critical to decentralise the programme in the health centres, where MSF had been implementing testing and treatment of opportunistic infections for several years already.

This first stage of decentralisation was implemented step by step. In early 2002 the "three hours' walk limit", which had been one of the criteria to enrol patients, was removed.

Over 2002, the follow-up of the patients was progressively relocated to health centres in order to reach the HIV-positive people living at a distance and facing difficulties to come regularly to the Chiradzulu HIV clinic.

Once a month, a mobile clinic composed of both MSF and MoH staff would set up, first in three out of 10 health centres of the district then, in 2003, in all 10 health centres. The patients would come to be tested and to start HAART, then for their medical follow-up and drug supply. A MoH clinical officer was integrated to each MSF mobile team in order to be trained and would alternatively work in the hospital HIV clinic in Chiradzulu receiving an MSF allowance.

Throughout 2003 the MoH nurses in the health centres were trained to treat opportunistic infections. In 2004, in five out of 10 health centres, nurses too started to be trained in the management of stable patients.

In the meantime in October 2003, the Global Fund[6], created in 2001, started to allocate funds to states to purchase ARVs. Once Malawi's application for HIV treatment was approved an agreement was signed with UNICEF as the HAART drug procurement agency.

Beyond training MoH staff, MSF also contributed to the national plan by writing guidelines on opportunistic infections, ARVs and treatment.

As early as October 2002 the MSF France board of directors had discussed the MSF strategy of implementation of ARVs in all its HIV programmes, and more particularly about possible and efficient methods to scale up the number of patients treated with ARVs. They had recommended to increase the number of patients under HAART and to explore collaboration possibilities in order to simplify the process. They had even pushed to go further by implementing the task-shifting of some activities to groups of patients. But it took several years to try to implement this last step.

Minutes of MSF France board meeting 25 October 2002

AIDS: How to increase the number of patients with access to ARVs in our programs?
Presentation (Michel Janssens)

MSF has six missions with an AIDS program. Each program absorbs twenty new patients per month. It seems urgent at this stage to consider what can be done to significantly increase the number of new patients treated. (...)

Elise Klement: Even if we follow large cohorts (2000 in Cambodia) few patients are on treatment. There are fewer than 323 patients in each program (a figure from Surin in Thailand). We need to change the scale of our response to meet demand without having to recreate the criteria for choosing who to provide care for (this being a step that is very difficult for teams).

Debate.

Francois Bourdillon: (...) Why can MSF not go further? Due to lack of doctors, or machines, for fear of not being able to manage a significant flow of patients ... We have 4-5 years to ensure that we demonstrate the proof that treating patients in a precarious situation is feasible. And that governments can embark on treatment successfully. To do this we must jointly address general policies and practical obstacles in the field.

Maurice Negre: my fear focuses on the likelihood of MSF finding competent doctors willing to work long-term enough to produce the proof. Because it must be noted first that the treatments are more complicated but they are also simplifying (alot has changed since combinations appeared as a single tablet). We need to prove a level of excellence, to set an example.

Christian Losson: 4-5 years to prove ourselves seems to me very long because the international environment does not lend itself to this, given that the pharmaceutical laboratories continue to lobby and have also gained some retreats in position vis a vis Doha. (...)

Elise Klement: our goal is not to remain for life in these programs but to train national staff (who can then train our own volunteers. (...)

Elizabeth Szumilin: Usually we take the most serious cases and assign the others for future months. Everything related to the information necessary to promote adherence to treatment takes a long time: the teams prioritise this aspect of quality at the expense of quantity. (...)

Christophe Fournier: (...) We must not simply focus on the enrolment criteria because it is not this that limits the number of patients. We spend too much time on the qualitative aspect and on contact with patients: the relationship must be opened up in terms of the doctor! This is one of the solutions that would allow the queue of patients who need access to a consultation to grow. We must rethink the idea that the same clinician should follow the patient from beginning to end. We need to create city-hospital networks, strengthen relationships with patient groups, with doctors and nurses practitioners of a good level. (...)

Francois Bourdillon: (...) We must have the courage to say that not all patients can be monitored by the team of expatriate doctors, and that local staff that can do the monitoring which is not so complicated when adherence is good.

Michel Janssens: We must work to simplify the protocols in the field because every three months the treatment changes and everything has to be re-explained. (...) We don't take the risk of simplifying the protocols but I think we should, and space out the monitoring intervals for people who are doing better. To get better adherence we should decrease the sweet talking and try to reduce the number of tablets.

Elizabeth Szumilin: But they have only to take two tablets, one in the morning, one in the evening! The difficulty is that local doctors work with us in the morning in the public hospital and keep consulting privately in the afternoon to make money, where they prescribe different treatments that correspond to local supply. In other words when we want to transfer the monitoring of one of our patients to the local medical sector, the whole treatment has to be changed. (...)

A person in the room: in Malawi, people now feel more confident and they also have more perspective and distance in terms of individual monitoring which one's trying to space and delegate.

Elizabeth Szumilin: but in Malawi, people come every week whereas doctor is telling them "Come back next month". But they return the following week even though they're progressing well and the doctors don't manage to state clearly enough: "You are well, let me take care of those who are managing less well". We try to establish the role of the nurses, the patient groups who distribute drugs, but by developing the notion of triage, which would specifically guide those in need into the care of a clinician. (...) In Malawi, they're thinking about giving the medication for three months, but we know that spacing generates a lower adherence to treatment although this remains to be seen ... Personally three months seems too long to me. So my idea is to train a patient in every village so that he can explain the side-effects, how they evolve, to put a cap on access to the clinician and then the consultation could be done every three months. In short the idea is to develop a dynamic that is at the level of the health centre. (...)

Recommendations: The Board supports the objective of increasing the number of patients treated in our missions, the Board recommends to reduce clinical follow-up to mobilise expatriate doctors onto those cases that cannot be treated by someone else. The Board also recommends exploring how to organise collaboration with peripheral actors (with associations, nurses, patient groups ...)

The possible operational and financial impact of the implementation of the project provoked a lot of tension and even controversy at headquarters. During this period, the programme manager would purposefully provide his colleagues in the headquarters with only minimal information about the program's financial and ethical issues and its progress. His aim was to avoid being blocked by those who would have been reluctant to endorse the risks he was actually taking in running the project and in the objectives he had for it.

At headquarters, everyone has the right to question everyone, which is fine, but it can paralyse any action. So sometimes, to move forward, we had to hide what we were doing a little. I refused visits from headquarters to Malawi several times to avoid destabilising the field team at a time when they were managing to swing those expatriates with doubts in a positive direction. In the same way we really had to hide from the desk the implications of the program for three or four years, because it wouldn't have been approved. So we remained evasive on the long-term vision and budgetary outlook and ethics. We used to get the program approved to continue every six months,

using very simplistic arguments. We had full support and carte blanche from the deputy director of operations, who had been Head of Mission and manager of programmes in Malawi - it was he who had made the decision to begin ARVs. But he did not have much power. (...) Of course, it was necessary to account for everything, but it was also a must to avoid being held back. There was always the chance that the Board would oppose it.. We could not afford to make a mistake, because it was controversial. So we had to make small presentations all the time, give enough information so that people felt more or less comfortable, without revealing all and taking the risk of going as far as open confrontation and a clash. It worked.
Dr Christopher Brasher, Desk programme manager MSF France 2001-2004 (in French)

Chris wanted to put a maximum number of people on ART. He told us that if we didn't do it we would be letting people die. It was really stressful. But there was real reluctance within the operations department and the medical department and demanding questions about how we were balancing "quality versus quantity." I have memories of operations meetings where Chris was really upset. He was a little all on his own against the pack.
Annick Hamel, MSF France field coordinator in 2002, then Liaison officer CAME, then in charge of the Village Unit set up, from January to June 2007 (in French)

At that time while the total operational budget of MSF France was 66.6 million Euros the Malawi programme budget was 2.5 million. It was continuously growing, provoking fears on how to manage the future. Planning the budget was not an easy task, as it was almost impossible to forecast the number of patients that would be included in the programme, thus the increase in terms of drugs and staff salary expenses.

However by then, HIV projects were starting to be financed 100% by private funds that had increased considerably within a few years. Over 2002 and 2003, in addition to the Global Fund, two other initiatives had been launched: the "3X5" initiative by WHO and UNAIDS with the objective of having 3 million patients on antiretroviral drugs by 2005; and the US President's Emergency Plan for AIDS Relief (PEPFAR) that included funding of ARVs although until recently the US had still been considering their prescription as impracticable in Africa.

The MSF movement had decided not to receive any of these funds, believing that they should be granted to and managed by ministries of health in their respective states. At the same time MSF's CAME kept advocating for lower prices for HIV/AIDS drugs.

Rapport financier MSF France 2005 (in French)
MSF France Financial Report 2005 (23)
In the field we're seeing the arrival of money from the "Global Fund" (funding maintained by the US, created under the initiative of the United Nations). The governments of the countries in which we operate are urging the hospital authorities to enrol patients in their structures. Nevertheless, the ministries of health are poorly prepared and lack trained human resources that are also supervised.

There were problems at headquarters: too much money one year and not enough the following year, as usual, things that had nothing to do with Malawi. The fact that we could not predict the budget because in six months it could go 300% over or under meant it was very difficult to get it through. But it wasn't our fault: we could not predict what was going to happen. The arrival of drugs from the Global Fund, in 2003, brought with it more problems than solutions for us at the time. We had just negotiated an exponential jump in budget and suddenly we lost 80% of it, collapsing because of the drugs. It was tough to have to fight for budgets each year. The sums were astronomical and we were far from precise in our projections. Manipulating millions was not standard work for an MSF desk. Only the emergency desks did that, but with a system that enabled them to have a global perspective more quickly than we could have on Malawi.
Dr Christopher Brasher, Desk programme manager MSF France 2001-2004 (in French)

MONITORING THE HIV/AIDS PROGRAM

In order to be able to follow up each patient and to cope with an increasing cohort, as well as to draw out some data-based evidence of the success of the ARV pilot project, MSF needed to establish a database system that would be both reliable and adapted to poor settings. It was decided to start with the electronic monitoring system FUCHIA (Follow Up Care of HIV and AIDS) that had been tailored for the MSF HIV program in Cambodia.

From April 2002 FUCHIA was installed in the Chiradzulu program. With the support of epidemiologists from Epicentre[7] it was upgraded step by step as scaling-up of the cohort and the workload of the team advanced. However it remained complicated to run such a system.

There was this famous commentary: "Africans, lacking a watch, won't be able to take their medications properly..." which summarised the view that was generally shared regarding treatment possibilities for AIDS patients in Africa. So it was imperative that we justify and validate our action using scientific means. We had to have the patients monitored epidemiologically, so we asked Epicentre to take it on.
Dr Christopher Brasher, Desk programme manager MSF France 2001-2004 (in French)

At that time FUCHIA was centralised only at the hospital, with the MSF clinic that was in Chiradzulu Boma centre. In 2003, the project decided to decentralise, and because at the time there was not a national monitoring and evaluation system they used carbon-copy versions of the FUCHIA follow-up form. And so what that meant was that every time a patient was seen, the FUCHIA form was duplicated, and one would go with the patient, and one would go to a central location for data entry, which, when you're talking about a few thousand patients, that's fine. But when you're talking about tens of thousands of patients, it becomes a little bit of a lunacy.
Megan MacGuire, MSF France Malawi HIV/AIDS programme field epidemiologist May 2007- July 2009, MSF France East Africa Regional Epidemiologist November 2009 - January 2012 (in English)

I started with MSF in April 2002. My background was HIV data management. The only one person who had a little knowledge on the issue, the Head of Mission, introduced me to the FUCHIA, so that I should start entering the data. It was a very tough job because I couldn't know where to start. The staff had started writing FUCHIA forms in around March 2001, but I started entering them in the data system in 2002 April only, a year later. So I had to take up all the forms written during this year, in addition to the current ones. I was under pressure because by then, Paris was waiting for the results. Then patients were scattered in the health centres. So at first two medical mobile teams would go around all the health centres. But those teams increased following the program's growth and so did our team. Later on, MSF decided to introduce the enrolment of HIV patients in the health centres. By then, our own workload was increasing very fast. We had to employ more staff so that they should help in the management of the data. Some moments were quite difficult because nobody knew how the program would be moving. So we tried many things, we made many errors in many ways, and little by little knowledge had to come. It was only in 2006, that I was sent to Kenya for the FUCHIA training. I had to wait almost 5 years for this basic training that should have been given to me at the very beginning!
Tamika Munyenyenbe, MSF France Malawi HIV/AIDS Programme Epi data officer, from 2002 (in English)

In 2004, the Ministry of Health set up its own system, named Mastercard, a complete paper-based system that collects and keeps data on paper, as opposed to the MSF FUCHIA system which digitises data once it has been collected on paper.

The Master Card system started to be set up in every health structure in the country except in Chiradzulu district where MSF had decided to carry on with FUCHIA. As the scaling-up of the program advanced, this specificity would become a hindrance to MSF's efforts to integrate its activities into the MoH system.

The problem was that in 2004 the national monitoring and evaluation system started the paper-based system. However, MSF chose not to adopt that system in either the centralised or decentralised sites. At the hospital site, the Ministry of Health did put a parallel system in and it's still in place, which is absolute lunacy, where the patient goes to see the HIV clinic and then, when they go to pick up their drugs, a master card is filled out by a data clerk from the Ministry of Health. We've tried to stop several times, or tried to integrate as much as possible, but it's been very difficult.
Megan MacGuire, MSF France Malawi HIV/AIDS programme field epidemiologist May 2007- July 2009, MSF France East Africa Regional Epidemiologist from November 2009 to January 2012

ADVOCATING FOR CHEAPER DRUGS AND A NEW MODEL OF CARE

To be able to provide as many patients as possible with HAART, MSF had to ensure that the prices of the drugs would continue to go down. Therefore, during this period, the battle to get affordable drugs was the core agenda of the CAME. The example of the Malawi program providing evidence that it was possible to treat a large amount of patients was used to push forward the vital necessity to lower the prices of the drugs.

Once antiretrovirals were introduced we created the first document on the work of MSF in Malawi, to provide arguments to the Campaign for Access to Medicines. This essentially marked the debut of generics, but I'm not talking about combination formulas. We didn't have Triomune, we were still at the stage of separate molecules. But we were already negotiating in Malawi with representatives of Rambaxy and Cipla, the generic manufacturers. **Annick Hamel, MSF France field coordinator in 2002, then Liaison officer CAME, then in charge of the Village Unit set up, from January to June 2007 (in French)**

In July 2002, at the 14th International Conference on HIV/AIDS in Barcelona, the MSF presentation on "Access to HAART in MSF programmes" included the Chiradzulu experience .

The XIV International AIDS Conference : Access to HAART in Medecins Sans Frontieres programmes Medecins Sans Frontieres and Epicentre

Abstract no. TuPeB4660

Background: HAART was initiated during 2000/2001 in HIV/AIDS programmes supported by Medecins Sans Frontieres in South Africa (University of Cape Town), Malawi [Chiradzulu District Hospital (H)], Kenya (Homa Bay District H), Cameroon (IRD U36 Military H), Cambodia (PBN Sihanouk H), Thailand (Surin Provincial H, Thai Network of PLWH), Guatemala (Roosevelt H). We analysed results 6 months after initiation. Methods: All protocols follow WHO and western recommendations. After at least 3 drug counsellings, ARV triple regimen is proposed to patients severely immuno-compromised. ARVs are free of charge. Supply is based on the local market competition including quality-assured registered generics. During the first months, patients return for drug resupply/counselling and clinical check-up at

frequent intervals. A CD4-cell count is performed every 6 months. HIV viral load is not available in most settings. Prospective data collection system was implemented. Results: As of December 2001, 580 patients started HAART (43% women, 9% children <13 years old). Among them, 125 adults (median age 32 years) started in June 2001 or before (South Africa, Cameroon, Thailand), of whom 76% were ARV naive. At baseline, median CD4-cell count was 18 cells/mm³ [inter-quartile range (IQR): 6-64] and HIV viral load (n=39) 253,000 copies/mL (IQR: 64,900-990,000). At 6 months 103 (82%) remained on treatment, 12 (10%) were dead, 8 (6%) had stopped and 2 were lost to follow-up. After 6 months on treatment, median changes in weight and CD4 were +5.4 kg (IQR: 1.0-8.5) and +94 cells/mm³ (IQR: 54-155) respectively. A viral load control was available for 34 patients: 33 had < 500 copies/mL. Overall, 21 patients (17%) developed adverse events requiring a change in regimen. Conclusions: MSF has scaled up pilot projects to give access to HAART to an increasing number of patients. The short-term results provide further evidence that HAART is feasible with acceptable benefit in low and middle income settings.

During the same conference Fred Minandi, one of MSF's first patients in Malawi to receive HAART, described his daily life.

Fred Minandi's statement to the 14th international conference on HIV/AIDS in Barcelona in June 2002

I am one of the first patients to benefit from free treatment in Malawi and if I am here to talk to you about it today, that's because I am receiving treatment.
Some of you will say that Africans cannot take medicine properly because they don't know how to tell time. I don't have a watch, but I can tell you that since I began my triple therapy, I have never forgotten to take a single dose.

As a pilot program which could be accepted as an example to set up other ARV programs in poor African rural settings, the MSF Chiradzulu project had to be described and analysed in scientific and medical journals.

In 2004 the MSF Chiradzulu program was described as a model for ART delivery in a WHO publication. In April 2006 an "efficacy assessment" of the Chiradzulu program, carried out by MSF and Epicentre, was published in the Lancet.

Even before this publication organisations involved in AIDS projects came and visited the MSF Chiradzulu project in order to learn from MSF experience, as they were starting to receive funds for ARV treatment programmes.

"Antiretroviral therapy in primary health care: experience of the Chiradzulu programme in Malawi" Case study Médecins Sans Frontières Malawi and the Ministry of Health and population, Chiradzulu District Malawi, WHO 2004

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.
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.

"Scaling up of highly active antiretroviral therapy in rural district of Malawi: an effective assessment" Laurent Ferradini, Arnaud Jeannin, Loretxu Pinoges, Jacques Izopet, Didakus Odhiambo, Limangeni Mankhambo, Gloria Karungi, Elisabeth Szumilin, Serge Balandine, Gaëlle Fedida, M Patrizia Carrieri, Bruno Spire, Nathan Ford, Jean-Michel Tassie, Philippe J Guérin, Chris Brasher. The Lancet, Vol 367 April 22, 2006

Summary.
Background - The recording of outcomes from large-scale, simplified HAART (highly active antiretroviral therapy) programmes in sub-Saharan Africa is critical. We aimed to assess the effectiveness of such a programme held by Médecins Sans Frontières (MSF) in the Chiradzulu district, Malawi.
Methods – We scaled up and simplified HAART in this programme since August 2002. We analysed survival indicators, CD4 count evolution, virological response and adherence to treatment. We included adults who all started HAART 6 months or more before the analysis.HIV-1 RNA plasma viral load and self-reported adherence were assessed on a subsample of patients, and antiretroviral resistance mutations were analysed in plasma with viral loads greater than 1000 copies per mL. Analysis was by intention to treat.
Findings - Of the 1308 patients who were eligible, 827 (64%) were female, the median age was 34-9 years (IQR 29. 9-41.0) , and 1023 (78%) received D4T/3TC/NVP (stavudine, milamivudine and nevirapine) as a fixed-dose combination. At baseline, 1266 individuals (97%) were HAART-naïve, were at WHO stage IV, 311 (33%) had a body-mass index of less than 18-5 kg/m2, and 208 (21%) had a CD4 count lower than 50 cells per µl. At follow up (median 8-3 months, IQR 5.5-13.1, 967 (74%) were still on HAART, 243 (19%) had died, 91 (7%) were lost to follow up, and seven (0-5%) discontinued treatment. Low body-mass index, WHO stage IV, male sex, and baseline CD count lower than cells per µl were independent determinants of death in the first 6 months. At 12 months, the probability of individuals still in care was 0.76 (95% CI 0.73-0.78) and the median CD4 gain was 165 (IQR 67-259) cells per µl. In the cross-sectional survey (n=398), 334 (84%) had a viral load of less than 400 copies per mL. Of several indicators measuring adherence, self-reported poor adherence (under 80%) in the past 4 days was the best predictor of detectable viral load (odds ratio 5-4, 95% CI 1.9-15.6)
Interpretation – These data show that large numbers of people can rapidly benefit from antiretroviral therapy in rural resource-poor settings and strongly supports the implementation of such a large-scale simplified programmes in Africa .

In a way we participated in developing the program for introducing antiretrovirals nationally. It wasn't very difficult. On the contrary, MSF was actively asked to help. Antony Harries, an Englishman, who was sort of the HIV advisor to the Ministry of Health, engaged with us a lot to explain what we were doing and describe the results.

Annick, Hamel, MSF France field coordinator in 2002, then Liaison officer CAME, then in charge of the Village Unit set up, from January to June 2007. (in French)

Subsequently we had a study published in *The Lancet*. This marked the end of the demonstration phase, when we were able to show that it was worth the effort. *The Lancet*, they got it right away! It's an article now quoted all the time, a reference for the era and the treatment, which showed that it was doable. This kind of article was still uncommon then because people thought not only that this type of program was not feasible but that it was useless, that people were not going to take the treatment and were going to die anyway..
Dr Christopher Brasher, Desk programme manager MSF France 2001-2004 (in French)

HANDS-ON DECENTRALISATION AND TASK-SHIFTING

The ethical dilemma was "do I heal 10 million people affected with HIV with a 3% loss, or do I heal 300 with a 0.1% loss? "
Gaëlle Fedida, MSF France Deputy Desk Manager from 2004 to 2005, Desk manager, from 2006 to 2008 (in French)

At this stage, the MSF Chiradzulu project could be considered as having demonstrated that treating HIV/AIDS patients with ARVs in a poor-resource country was possible. The first challenge of the program, the decentralisation to health centres, had been met. The second one was then to dramatically increase the capacity to include all patients in need of HIV care and HAART as quickly as possible while maintaining the quality of care.

This scaling-up required an increase in terms of human resources. But considering the weaknesses of the medical staff in Malawi, this objective could not be met with the current MSF model of HIV care management, which was reaching its limits. It became obvious that the programme had to be redesigned.

It was time to apply the ideas that had been reflected on from 2002: to delegate the clinical responsibility for patient enrolments to the nurses and to increase the involvement of paramedical staff in the non-medical follow-up. This would strengthen the capacity to consult and follow up high numbers of patients. Other ambitions included shifting some tasks to stable and experienced patients.

MSF France Malawi Mission in collaboration with the Ministry of Health: Plan of scaling up access to antiretroviral therapy Chiradzulu district – 2004

Conclusion:
Since the beginning of the program, in August 2001, 4346 patients have been started on ARVs and by the end of 2004, 3425 are still alive. The cohort of mature patients is growing with more than 900 patients receiving ARVs for more than a year and more than 200 for more than 2 years.

The monitoring and evaluation data of the program indicate good quality of care and efficiency of the program (treatment, HIV clinic cares, mobile team care, VCT, counselling).

Those good survival outcomes confirmed by a virological survey, demonstrate the success of the program. The results of the study found showing that 85 per cent of patients with more than 6 months therapy, included in the study had an undetectable viral load 85%.

However some aspects of the program must be improved, like the tracing, the IPD, some part of the laboratory services.

Before significantly increasing MSF resources, it is important to develop further an integral strategy of partnership and collaboration with the MOH as the government's ART scale up rolls out. Advocating for the decentralization of ART to improve access and adherence for patients at the health centres level remains an important aim of our program. To meet this challenge, a training plan targeting nurses working in health centres has been designed and is being implemented. The ultimate goal is to both allow a proper management of AIDS complications daily in the whole district and to be able to use MSF team only for complicated cases. Until this is achieved, clinics continue daily in the hospital and twice monthly in the peripheral structures.

The best way is to work more on the involvement of MOH staff in the mobile team, in the laboratory and in the IPD.

We realised that what was presented as decentralisation was more like delocalisation. That is to say, it was the MSF team that went to the health centres, as well as patients but the health centre staff were hardly involved.
So it limited the number of people who could be treated and put onto antiretroviral therapy. MSF only visited with the mobile clinic once every two weeks and this severely limited the possibilities for treating people—whether for opportunistic diseases or to put them on ART. In fact, the equation was quite simple: too many patients and clearly not enough medical staff. So we had to allow local paramedics to perform a replacement role.
Annick Hamel, MSF France field coordinator in 2002, then Liaison officer CAME, then in charge of the Village Unit set up, from January to June 2007 (in French)

The Global Fund had already started and all the officials who had previously pressed to get a share saw this pressure come back like a boomerang: "What are you doing? You have the means, the drugs, and the money and [yet] the number of patients is not increasing." So when we arrived with our rationale for expanding the program ... it was music to the ears of the country's public health bosses! They didn't have the personnel, they didn't have the knowhow, they didn't have the organisational models. Nobody did. It was all still being invented.
Dr Jean-Hervé Bradol, MSF France President from 2000 to 2008 (in French)

TOWARDS DELEGATION TO MOH STAFF

In 2004, as the MoH was receiving drugs from the Global Fund and the National Plan for the treatment of AIDS cases was planning a scaling-up of AIDS activities, MSF considered for a while handing over some of its activities in order to focus its own teams on scaling up.

However in 2005 despite an increase in MoH staff in the district health structures, it was still MSF staff that was running the HIV clinic in the Chiradzulu hospital, as well as mobile clinics giving consultations every week in the ten health centres of the district.

While the handover of the VCT activities was implemented to plan, an attempt to handover the Chiradzulu BOMA HIV clinic to MoH failed. After a few months MSF staff had to come back to bridge the gap created by absent or unmotivated MoH staff.

Médecins Sans Frontières Chiradzulu, Plan of Action for 2005)

The primary goal of our involvement has been met: donors and government have been convinced that the treatment of AIDS cases is feasible, even in a rural set up. The national scale-up plan will bring new resources in the MoH. New drugs, least of which antiretrovirals (although limited to the first line yet), new training possibilities and possibly new staff should arrive in districts soon. This national plan engulfs most activities that MSF is usually dealing with: VCT, PMTCT, treatment of OIs and ARV provision.
The strength of the MoH capacity in Chiradzulu has already been greatly improved by the recent staffing adjustments. The number of nurses has been more than doubled, clinicians are twice as numerous and the lab staffs have been multiplied four-fold. It will enable the Ministry to be more active in areas where MSF had to substitute. Those are particularly: the HIV/ARV clinic of the hospital, the PMTCT program and some of the most technical laboratory investigations, e.g.CD4 counts.
The spirit in which we view these handovers is not a challenging one. MSF wishes to give renewed support to the MoH in case of new shortcomings, e.g. in case the quality of the care given to patients is objectively reduced.

MSFF Malawi Annual report 2005: Reducing mortality due to HIV in Chiradzulu district

Difficulties in the hand-over of hospital HIV clinic

Because the MoH appeared to be in a position to take responsibility [Drugs, including ARVs were provided by NAC and Global Fund and staff had been working with MSF, hand in hand, for already 3 years] in April, the HIV clinic in the hospital had been handed-over. MSF continued to help with more complicated patients in special clinics [In the hospital, MSF has focused its efforts on medically complicated cases. Special day clinics have been set up for patients on second line treatment, patients suffering from Kaposi Sarcoma and children. For the latter, special attention was given to the adherence counselling process, involving the child and the guardian.]
MSF continued however to share the nursing and ARV dispensing activities with the MoH and ensured the complete service related to adherence counselling. Because of frequent absenteeism, lack of motivation in some members of the MoH team, NAC requested MSF in August to get back into HIV clinic supervision.

The main adverse effect of those decisions has been to reduce our ability to monitor program outcomes. Patients initiated on ART then have been registered using the national system and not with the monitoring system established by MSF since 2001 (FUCHIA).

Hand-over of PMTCT and HIV testing to MoH
With the advent of a national scale-up plan of PMTCT activities, MSF handed-over its share of the program in CZ. From April, the MoH has taken complete responsibility.

We have handed all VCT activities to MoH staff in health centres. Extra human resources are still needed inside the hospital. The provision of test kits has been irregular, forcing MSF to complement often.

I started on the second of January, 2004. I was hired as a clinical officer, mostly to work in the health centres. We were starting to go to the health centres at the full scale. When I was starting, I was the only one who was going to the health centres on a full-time basis. We had one clinical officer always working in the hospital, and then he came and joined the team that was working in the health centres. There were some clinical officers who were working at the HIV clinic, and there were some that were working directly in the ward when the patient [was] admitted. There was the mobile team, which was comprised of one clinical officer, who was full-time, and an additional clinical officer who was coming on a rotational basis. So it was a team of mostly two clinical officers and then one medical doctor who was covering up in the health centre, and one psycho-social counsellor, and also one nurse.
We had ten centres, in total, the whole of Chiradzulu. We were visiting a health centre on a two-weekly basis. On Monday we would go to work at one centre, the next Tuesday we would go to the other, the third one to another one, until we would have finished the whole ten health centres. So that was five working days. So in two weeks, we would go to all the ten health centres. And then we would start all over again and then you have completed a month.
Prince Nkoma, Clinical Officer, MSF Chiradzulu HIV/AIDS programme from 2004 to 2011 (in English)

- **Temporary suspension of enrolments**

Paradoxically the reorganisation period started with a suspension of patient enrolments. Indeed, with 8000 patients in the cohort and among them 4000 under ARVs, and over 250 new ARV enrolments per month, the MSF team had become overwhelmed by the workload. Therefore in March 2005 it was decided to stop enrolments at the health centres, to evaluate the situation, and to design a system to organise the human resources and programme management in order to enrol and follow up patients in better conditions. A few months later, enrolments of very sick people, already included in the pre-ARV cohort, were restarted. In order to keep a stable cohort, the number of new enrolments was limited to the replacement of defaulter patients who had died or stopped treatment. In April 2006 enrolments of new patients started again.

"Operations Meeting: Gaelle Fedida (Malawi Desk Manager) - AIDS" March 22, 2005 (in French) (31)

How far do we go with enrolments? What are the limits? The criteria? The teams seem to have reached the operational limits of the Chiradzulu AIDS program: either we put more resources in or do we stop? Our initial target was to be able to put 6,000 patients on ART and especially not to set limits, by adopting a pro-active and willing attitude. The teams' observation is that we've reached the peak for consultations, with an estimated 8,000 patients of whom 4,000 are on ART. It is a programme with significant ambitions (simplifying access to treatment, training nurses) but the level of resources could endanger programme quality. But summing up, once these ambitions - how do we treat a big number of patients? - are met, we are faced with: how do we manage to keep them alive? The general feeling is to continue enrolling the most serious patients in the order that they come. Everyone agrees on stopping enrolments into the ARV treatment program in Chiradzulu from here on, and thus stop testing. On the other hand the core question remains, and remains undealt with. The debate has been postponed and will be revisited during coordination week (...) Decision: temporarily suspension of enrolments. Await the FUCHIA results for analysis of mortality, to better define future enrolment criteria.

- **The geographical question**

Since it started, the MSF program had taken charge of many patients who were not Chiradzulu residents. Many of these patients would come to the MSF/MoH structures because they were the only places in the country where they could receive free healthcare.

In 2005, the MoH started to treat HIV/AIDS patients for free all over the country. Therefore in order to alleviate the burden of the increasing number of enrolments in MSF's Chiradzulu programme, the desk decided that patients not from Chiradzulu district should be transferred to the health centre closest to their home in their own district. Unfortunately the MoH had so far opened only one or two public health structures in each district to the provision of HAART treatment; they were providing basic health care and prescribing just first-line treatments.

The Medical Department advisor on AIDS disagreed with the desk's decision, while the field team felt reluctant to enact it. They argued that specific cases like patients on second-line, or those suffering from opportunistic infections or even children, would have no guarantee of the quality of care they would receive in the public health centres.

MAP (Mise à plat) décisions – 2006

Boma (Chiradzulu Hospital HIV Clinic): transfer out over 300 patients to their own district. Normalise this clinic to function like the health centres. This clinic should evolve into ambulatory care for complex cases out of the IPF.

The condition for resuming enrolments was that all patients who were not from Chiradzulu district could no longer be treated by MSF. So the new cases that presented but were not the district were referred to the nearest health centre. Patients who had been treated for some time by MSF were also referred to the centre closest to their home. Initially, everyone came to Chiradzulu because it was virtually the only district where patients were treated for free. Gradually, many centres opened in Blantyre and surrounding districts. But here, in the first instance, care was not always free. Then, the staff there were only trained to initiate treatment and to take charge of first line patients. But we

already had second line patients, very special cases like those with Kaposi's sarcoma, children, all sorts of cases that were really very specific and not covered anywhere other than at MSF. From a medical and human perspective, from the moment that we got involved in start treatment, we had to continue to treat these patients. It was not possible to tell them overnight: "We can't accept you anymore. Now you will have to pay 500 kwacha to be treated elsewhere." We tried to not take new cases from outside the district, but the patients who had been treated by us for a long time already and who were really difficult cases, or very poor, we kept them on, we couldn't do otherwise.
In the field, we were all on the same wavelength. Elisabeth from the medical department was on our side. But there were big discussions with the desk. Every week they asked us, "So, transferred patients, what's the current number? How many patients do you still have from other districts who are treated in Chiradzulu?" And every time we'd get yelled at because there were too many. This went on for six months at least. In the end the desk let it slide. And so we retained a certain reserve of patients (perhaps a thousand, I no longer know how many they were) who came from outside the district.
Dr Sylvie Goossens, MSF France Malawi HIV/AIDS Programme Medical Coordinator from September 2005 to July 2007 (in French).

- **Fears and internal resistance**

For a while the Malawian authorities, who were in the early stage of the implementation of the national HAART program, expressed doubts regarding the pace of the MSF decentralisation and task-shifting plan. The MoH was quite aware that the understaffed health centres would have difficulties to cope with the ARV management tasks that MSF planned to hand over.

However, according to the desk manager at the time, their resistance was not as strong as that coming from within MSF.

In this phase, there were many restraints placed on us at the beginning by the authorities in Malawi. But within MSF itself we weren't united to defend the message. There were even messages that bypassed the desk and went directly from Paris to Blantyre or even Chiradzulu, both to the MSF teams and to the health authorities to explain that this business of scaling up was craziness. There was a *mise a plat* meeting at headquarters involving the relevant people, one big shouting match. External barriers, ultimately, are more natural and more able to be dealt with than first having to fight with the office next door to get your job done!
Gaëlle Fedida, MSF France Deputy Desk Manager from 2004 to 2005, Desk manager, from 2006 to 2008 (in French)

In the field MSF staff was pushing hard for scaling-up of the program, because they were witnessing people among their relatives and neighbours suffering and dying, and desperately in need of HAART.

In the operations department, at the beginning, many considered that MSF had already fulfilled its initial objective via this pilot project: demonstrate the feasibility of delivering HAART in a poor country. The scaling-up plan was considered with reluctance, many arguing that it was not up to MSF to manage all the HIV patients in Chiradzulu district but up to the MoH, since it was now receiving money from the Global Fund to implement its national program. There was also a fear that the scaling-up of the program would impose a burden on the MSF budget.

Then the desk manager asked the president of MSF France to pay a visit to the Malawi program in order to convince the Malawian authorities about the consistency of the scaling-up and decentralisation project. She was also hoping to convince her colleagues within the operations department to overcome their fears.

The national staff were 300% behind it. They had been already for years, most of them being also sick themselves. They saw the results clearly and what was going to be achieved in the coming years with scaling-up to a global/overall cohort, and in the care for each individual, with a nutrition component, taking on cohorts of children etc. I would go as far to say that initially it came in part from the medical staff on the ground who said, "But ultimately, could we not take more patients by simplifying?" It's not necessarily doctors in headquarters who had the brilliant idea ... It came from discussions in the field. (...) In the summer of 2005 I had a discussion with the Director of Operations on the subject of scaling-up and decentralisation, and he blocked everything by saying "No, it's becoming crazy, the Malawians have to make do, we cannot do everything on their behalf, we are not the Ministry of Health etc..." He said, "Enough now! Malawi will cost us 10 million. We have five AIDS programs, so it will cost us fifty million!" (...) I then asked the MSF F President to come with me to Malawi to talk about our goals with the Minister. And when we got back, it was more than evident that the Minister had said 'yes'. The President's visit provided the final push in-house and on the ground with the authorities.

Gaëlle Fedida, MSF France Deputy Desk Manager from 2004 to 2005, Desk manager, from 2006 to 2008 (in French)

The day we arrived in Malawi, at the first meeting with the staff there, we began by congratulating them on the number of patients that had been treated. But it fell completely flat. We were wrong-footed straightaway. They said "Ok, we're happy like you are. But the problem is that we know all those people who aren't receiving ARVs. We live with them, some are family, we can't completely forget them! We are very proud of what we did, but we know we're mid-term and that it would be catastrophic if there was no broader development effort." We also had a meeting with a patient group/association. I gave the spiel, and once again I'd misfired. These patients, a little more politely than the staff, said: "Thank you doctor for all that MSF has done for us, but people are dying all around us! What can we do to overcome this?" (...) We visited the people responsible at national level for the fight against AIDS. From the Minister of Health, the political boss of the fight against AIDS, the technical boss of the fight against AIDS, we got a verbal pre-agreement to move forward. The political boss of the struggle against AIDS told us that his life was a nightmare, because the Head of State and the Prime Minister were on his back. (...) Knowing already something about the Malawian health system and our operational capabilities, Gaëlle and I decided to go ahead, without knowing how we were going to expand the district, knowing that people from outside the district would also come to us. (...) When we returned from Malawi, we did a debriefing at the operations meeting. Almost everyone was against it!

Dr Jean-Hervé Bradol, MSF France President from 2000 to 2008 (in French)

There was a questioning of the medical relevancy from the headquarters. The questions which were asked, we as a team didn't have the ready answers and that was something that delayed the process. It was true that we were not ready to move our part. Looking at the human resource capacity that we had it wasn't enough to do more but the team was very strong. We used to write some papers to justify what actually we would like to do. There was a doctor from Sri Lanka, who took a step to try to draw up the strategy: how can we manage to do it and how can it help the community at large if we do that. So there was lots of support from the field, lots of support from the coordination and it was easier to accept it from Paris as well because we had to understand the issues right here from the field. So when people went to Paris to present it, they had lots of backing of which it was easier to have the go ahead on the process. It was very well supported that the decentralization proved to be a very good idea that MSF managed to do.

Mike Kalemera, MSF Chiradzulu HIV/AIDS programme Counsellor from 1999 to 2010, then IEC officer from 2010 on (in English)

Despite the resistance, the desk went ahead and decided to start the implementation of the second phase in the decentralisation process, called "task-shifting". The objective was to train MSF then MoH nurses to take charge of stable patients and to

initiate new patients under HAART. At the end of the process all the tasks were supposed to be shifted to the MoH staff in the health centres.

End of mission/Handover report – Michelle Chouinard, Project coordinator decentralisation April-December 2007

The increase in teams increased the number of days we spent in each HC. Therefore, we a) decreased the number of booked patients on clinic days, b) decreased the waiting time at the HC for the patients. However, after a period of stabilisation, we again started to see heavy workload for the teams from May. It was not uncommon for a team to have 100+ booked patients in a day, not counting the new patients and unplanned patients (coming late or early). The benchmark we established for the COs at the time was 40 patients/day, for the nurses 60 patients/day. In both cases, the patient bookings far exceeded these numbers, especially for the COs [Clinical Officer]. So, September 1, we increased the mobile teams to 5 (1 CO, 1 Nurse, 1 Counsellor per team), plus 3 flying COs, 3 flying Nurses. The flying staff is assigned to the teams with the highest workload on any particular day. However, 1 flying CO and 1 flying Nurse need to be considered to replace annual leave and sick days for both the HCs and the Hospital. If no one is on leave they will work at the Hospital or HC depending on where workload is highest. We also have a relief Counsellor that is shared between the Hospital and HCs.

Strategic framework for the continuity of HIV/AIDS response in Chiradzulu district – Letter from MSF F Head of Mission and Programme Director to the Minister of Health of Malawi, 16 November 2005

(…)In total MSF France services in the district amount to a budget of 2 million Euros this year, including 80 staff members. All these actions have been initiated in agreement with NAC and MoH services. As we agreed in August, we deem necessary to remain a "pilot" district in Chiradzulu to design innovative ways to respond to HIV pandemic. The national program could benefit, towards its donors, in taking advantage from MSF financial capacity to support a rural district in comprehensive care to more patients as possible.

In order to assure the consistency of access to ART and to good quality of care for the population of Chiradzulu district, we recommend the subsequent actions to be taken:

- *To control the global inclusions on ART in the district.*
- *To standardise the protocols, process, the data collection and analysis*
- *To continue to offer a systematised adherence counseling to every patient.*
- *To resume decentralisation process in the district as per MoH objectives presented in the 5 years plan by :*
  - *Distributing the 150 new treatments per month available from MoH equally between hospital and health centres, which allow us to restart ART from the health centres also for new diagnosed patients. It will alleviate the burden of the hospital, facilitate treatment adherence, and give a good willing sign to the population.*
  - *Scale up training of health centre personnel in HIV patients management*
- *MSF continues to focus on medically complicated cases (including TB), procuring human resources and drugs and involving gradually the MoH team for integration in this activity.*
- *MSF will continue to supply OIs drugs in substitution of MoH to meet the needs of patients under treatment, and will advocate the issue to donors.*
- *MSF will reinforce the clinical care supervision in the IPD of Chiradzulu hospital in female, male, TB and pediatric wards. (…)*

- **The nurses' training issue**

The training process for ARV treatment initiation and follow-up started late 2005 for the nurses in five out of the 10 health centres. This phase took more time than expected due to divided opinions on the training content and length. Some people considered that nurses were already sufficiently "professional", needing only a short training in order to be quickly operational. Others were more concerned with the quality of the training.

It began in dribs and drabs. In the beginning, an initial pilot course was scheduled for five or six nurses, which would last several weeks. Then they had to be evaluated. This was then supposed to allow us to scale up the training and have intakes of fifteen nurses rather than in groups of five. And this whole phase was significantly delayed because the training lasted six weeks instead of three, twelve instead of six. Then, the evaluation, it was jerry-built. Some people within MSF put a spoke in the wheels. I don't think they were philosophically anti, but I think they were afraid and didn't dare put faith in the program. There was a very big fight because of it, and a phenomenal loss of momentum in 2004 and 2005 in particular. A whole program had been established, expecting to move from 3000 to 5000 enrolments then doubling in two years, based on the rhythm of the nurses training in all the health centres. I really regret that we lost at least a year if not eighteen months at the stage of nurse decentralisation. **Gaëlle Fedida, MSF France Deputy Desk Manager from 2004 to 2005, Desk manager, from 2006 to 2008 (in French)**

We were going to ask the nurses to do diagnosis and clinical service. If we wanted them to be well trained they needed to be by a good clinician, able to understand what he's talking about and [recognising too] who had a superior level to them. "We had already recruited a good clinical officer. He knew HIV and had already worked a lot with us, well. Also, he had trained as a trainer. And suddenly, Paris decided it was over, we would send him back and replace him with a nurse who had been trained at the HIV clinic, because it needed a nurse to train nurses. I gave up! Eventually we defined steps and modules for training nurses: first, opportunistic infections, then the monitoring of stable patients and finally the start of treatment on antiretrovirals. We had discussed strategies. There was a whole job to accompany these nurses for the clinical officer who dispensed formations in Chiradzulu and the health centres. He came with the MSF mobile clinic to the health centre and he took care of a queue of patients with the nurses-in-training. It wasn't assembly-line work with 60 patients, but quality work taking the time to think, or talking together before seeing the patient, then discussing with the patient etc. They were trained one by one and gradually tasks were transferred to them. We started to allocate them certain patients that they then took over for their consultations.
Emmanuelle Chazal, MSF France Medical Department Advisor on Patient Education and Training from 1999 to 2007 (in French)

By then in Malawi there were less than two hundred trained physicians and a few hundred clinical officers, trained for four years-. Therefore the MoH asked MSF to train its medical staff. MSF France refused to accept medical interns from the MoH training course's HIV program arguing that MSF's objectives were to treat patients and not to train doctors.

We accepted that Malawian doctors come to work with us. We said to the MoH, "Give us the manpower." But they would reply: "We don't have enough doctors. Don't come to us to recruit any more of them. You are very skilled in AIDS, so help us train them." MSF Belgium was even considering getting right into the Ministry's curriculum by proposing that student doctors come on rotation as trainees for a few months in Thyolo. They wanted to establish a practical training unit. MSF France didn't agree at all with that. We said: "The Malawians just have to organise themselves in terms of the training. We, we take the real sick, who need to be treated carefully and you don't do that

with apprentice doctors." We didn't want the responsibility of issuing a certificate with MSF's signature to validate medical staff skills in Malawi. We didn't want to become part of the institutional structure. But we still had a good relationship with the ministry and an MSF doctor would still go regularly to give lectures in the medical faculty.

Gaëlle Fedida, MSF France Deputy Desk Manager from 2004 to 2005, Desk manager, from 2006 to 2008 (in French)

In the meantime, MSF's mobile teams were reorganised. In March 2006, the nine-person team was split into three smaller teams of one counsellor, one clinician and one nurse per team. The rotation schedule was changed from clinic visits twice a month to clinic visits up to seven times a month in the busier health centres, dividing the patients per reasonable number of consultations per clinician with the nurses managing the stable patient reviews.

In the first quarter of 2007, enrolment and HAART initiation figures had almost reached the overall numbers of 2006 for the project, and the staff workload kept on increasing. Then a flying mobile team was created to pick up the extra workload of the three already existing teams. In September, this arrangement was complemented with two extra mobile teams.

By late 2007, all stable patients were managed by MSF nurses at Chiradzulu hospital and in the five health centres by the newly trained MoH staff. The MSF clinical officers continued to manage the complex cases and all patients ranging from new to complex in the five remaining health centres (Bilal, PIM, Mbulumbuzi, Mauwa and Milepa).

End of mission/Handover report – Michelle Chouinard, Project coordinator decentralization April-December 2007

A stable patient is:

- *On Triomune for at least 4 months*
- *Adult above 15 years*
- *Has no OIs*
- *Has no side effects to Triomune*
- *Not pregnant*
- *If female, does not have a child under 13 years on HAART*

A complicated patient is:

- *Kaposi Sarcoma*
- *Pregnant*
- *Child under 15 years*
- *On alternative 1st line or 2nd line treatment*
- *Experiences side effects*
- *Has TB or any other OI*

[...] The increase in teams increased the number of days we spent in each HC. Therefore, we a) decreased the number of booked patients on clinic days, b) decreased the waiting time at the HC for the patients. However, after a period of stabilization, we again started to see heavy workload for the teams from May. It was not uncommon for a team to have 100+ booked patients in a day, not counting the new patients and unplanned patients (coming late or early). The benchmark we established for the COs at the time was 40 patients/day, for the nurses 60 patients/day. In both cases, the patient bookings far exceeded these numbers, especially for the COs. So, September 1, we increased the mobile teams to 5 (1 CO, 1 Nurse, 1 Counsellor per team), plus 3 flying COs, 3 flying Nurses. The flying staff is assigned to the teams with the highest workload on any particular day. However, 1 flying CO and 1 flying Nurse need to be considered to replace annual leave and sick days for both the HCs and the Hospital. If no one is on leave they will work at the Hospital or HC depending on where workload is highest. We also have a relief Counsellor that is shared between the Hospital and HCs.

When we were seeing patients every two weeks, the problem was the following: when you started the patients on ART, it meant you would only be able to see them after two weeks. When they had a problem within these two weeks, it was difficult to see you, simply because you were not there. So people looked at that kind of scenario and said that some patients might die along the way. So we needed to see them every week or maybe to give them the chance to say when they got a problem, they could come and meet the clinical officer at the nearest health centre. Then MSF started recruiting more clinical officers. So then the teams were split into four mobile teams. Each mobile team was composed of a clinical officer, a psycho-social counsellor, a nurse, and the driver. We had one or two medical doctors who were covering up in all those health centres. And then the teams started to grow again so that we could be visiting these places quite frequently.
The major decision that was taken was to train our nurses to be seeing stable patients. That came because the workload was increasing now and then. We had reached a point whereby even if we were visiting the health centres, on an everyday basis, or maybe twice or three times in a week, we were not able to see each and every one. Some people were left. So we thought we can use our nurses after they have gained experience, then they underwent training.
Prince Nkoma, Clinical Officer, MSF Chiradzulu HIV/AIDS programme from 2004 to 2011 (in English)

The decentralised health centres were fundamentally understaffed. Moreover their staff was already managing all the patients with pathologies not related to HIV/AIDS, and the handover increased their workload. Therefore MSF started to pay incentives to the HAART nurses in the health centres. It was also decided to hire extra nurses, called "village nurses", to replace the MoH staff in their regular activities while they were doing the HIV clinic. Once again it raised the haunting issue of MSF doing more and more substitution and thus increasing the difficulty of a future full handover to the MoH. Some hope was invested in the implementation of the national MoH five year training plan[8] that was supposed to provide trained medical personnel to health centres throughout the country. But it progressed slowly, and there were concerns that Chiradzulu district would be the last to be integrated, since the HIV program was already staffed by MSF.

These health centres were pretty well all managed by nurses. But organisation of the teams in the peripheral health centers required medical assistants also. I think that in all the district health centres combined, there was only one medical assistant. We should have worked more diligently upstream with the Ministry of Health so that these health centres were already providing the necessary health workers. Then we might have been able to manage our training plan differently and distribute the tasks differently. (...) When we undertook the transfer of tasks to nurses in the health centres, we wondered: "Will the nurses have the time to do them?" There were two nurses in each health centre. One working day and night for a week, and if there was a birth, she managed it. And the other rested. These women, not all of them young, were always on the go, and in addition they were asked to come and be trained, and make themselves available and to take on an additional layer of work. There was also a high turnover amongst these nurses, and we had to negotiate with the Ministry that those who had been trained were not replaced and relocated otherwise you had to start all over again every fourth morning. **Emmanuelle Chazal, MSF France Medical Department Advisor on Patient Education and Training from 1999 to 2007 (in French)**

The idea was to train nurses to care for patients. In our system at MSF we already had two levels. There were the complicated patients who were seen by doctors and clinical officers, and the stable patients who were seen by nurses. So within the decentralisation we had created a system where the health centres nurses could take care of stable patients—the very stable initially. Then, later, we would train them to take on more and more patients until we found to a good equilibrium in terms of what they could really manage. They are monitored alot. At first they were always accompanied. Then gradually they were left alone, while maintaining regular visits. (...) The government was also of a view to train nurses in health centres to manage HIV patients. So we didn't have to battle with them on that. (...) There were however big discussions on the workload that this represented for the nurses. I think this was the main difficulty. The nurses asked to be paid more because they had more work and patients. This was discussed with the Ministry: was it for MSF to pay, or the Ministry? Finally, we put in place a kind of "special decentralisation" pay scale and MSF gave a type of incentive for the health centre nurses.
Dr Sylvie Goossens, MSF France Malawi HIV/AIDS Programme Medical Coordinator, from September 2005 to July 2007 (in French)

Then two options were considered. The first was to let the Ministry of Health complete the process by training the nurses and medical assistants in the five remaining health centres. However there was no guarantee that the MoH would be able to cope and train the requested staff quickly. Therefore a second option was taken whereby MSF would complete the training and task-shifting in all the district health centres. This second phase started in 2008 but it took more than one year to be fulfilled due to the scope of the training having been underestimated. Indeed, at that time there was a huge turnover amongst the MoH staff working in the health centres, and every fresh staff member had to be trained as the MoH training plan was not efficient enough.

We said to ourselves that we had started the decentralisation process and that it was imperative to be able to continue it since we already had good results and that the road ahead to decentralise to the other five centres i.e. train the MSF and MOH health staff was not so long. So we went ahead at "full power". (...) But it was not decided in advance that we would complete the exercise with decentralisation in all centres, this decision was made at the MAP in October 2007.
Michaël Le Paih, MSF France Malawi HIV/AIDS Programme Head of mission, from September 2007 to July 2009 (in French)

TOWARDS DELEGATION TO NON-MEDICAL STAFF

Already at that time it was clear that task-shifting of care to nurses would not be sufficient to ensure the scaling-up. With the aim of decreasing the workload of the team and to ensure a good quality of care, the team started to explore the possibilities to space the consultations and to delegate more tasks to non-medical staff.

Arriving in the field early 2007, I noticed that as the MSF team always came to do its mobile clinics, the medical assistants and MoH health centre nurses who had been trained were left a bit on the fringe. They didn't get to fulfill their role much, partly because of the presence of the MSF nurse, doctor and medical assistant. And also there had been problems with the training, it had dragged out a lot. So we decided to pick up speed.
Annick Hamel, MSF France field coordinator in 2002, then Liaison officer CAME, then in charge of the Village Unit set up, from January to June 2007 (in French)

- **Dispensing ARVs at village level: the Village Unit experience**

The idea of having HAART dispensed in the community by patients had been raised as early as in 2002 but was actually elaborated over the years 2005 and 2006. The set-up involved a network of Community ARV Dispensers (CAD), non-medical individuals (generally stable patients themselves, called "expert patients") that would be in charge of dispensing the drugs at the village level to consenting, stable patients. Thus these patients would not have to go to the health centre so often, and as a result the staff workload would be reduced. Actually, the final objective was to set up a "six month appointment" (SMA) approach that would consist of providing stable patients a medical consultation only once every six months.

The process was described as followed in the Field Coordinator's end of mission report in December 2007:

End of mission/handover report Michelle Chouinard Project coordinator decentralisation December 2007
Basically, the MoH health worker determines eligibility (see eligibility form) and offers referral to SMA (six month appointment) to patient. If patient agrees, he sees peer counsellor for patient education session to ensure patient understands basic elements of his treatment. The next appointment is with the CAD (Community ARVs dispenser) 2 months later at one of four sites available to the patient in the Traditional Authority (TA) of Nkalo: Mitole, Maoni, Khoromana and Nkalo HC. The CAD only dispenses Triomune that was prescribed by and collected from the MoH Health Worker in the morning and cycles to the SMA site to dispense. If a patient does not show up, the CAD traces him the same day. If twice a CAD traces a patient, he is considered non-stable and referred back to the MoH or MSF clinic. He can be referred back to SMA again once stable.
The SMA is as follows:

- *Appointment with MoH and referral to SMA*
- *Counselling session with Peer Counsellor the same day*
- *At 2 months: CAD*
- *At 4 months: CAD*
- *At 6 months: MSF CO for annual review*
- *At 8 months: CAD*
- *At 10 months: CAD*
- *At 12 months: MoH health Worker for review*

If patient remains stable at every SMA with MSF and MoH, he/she returns to CAD.(...)
The idea is for the CADs to be independent from supervision. However, the DHO has some reluctance with non-medical personnel dispensing drugs and because of this, for several months, the CADs has to be directly supervised by B (...) who is a nurse. Therefore, what was supposed to be a discreet community based activity had a high profile as B (...) arrived with an MSF vehicle to provide

supervision at each CAD "clinic day". Also, this meant that we couldn't really assess the efficacy of the activity, as B (...) was there each time to provide support to the CAD and patient. The CAD activity was considered a medical act due to a short questionnaire they were filling re: possible side effects. We discussed the issue with the Pharmacy, Medicines and Poison Board of Malawi who visited our decentralised pharmacies in all 10 HCs and met the 4 CADs in Nkalo. Following this visit, we received the go ahead to continue with CAD and withdraw the follow up questions re: side-effects. Therefore the CAD are now dispensing without the direct supervision of B (...).

It involved delegating some tasks, a bit in the shape of a pyramid, with the expatriate doctor who delegates to the Malawian medical assistant who delegates to the nurse who him/herself delegates to the health assistant, etc. all the way down to including the patients themselves. It was necessary to get close to the patient, where he or she lived, and to respect those who found that they were stigmatised by coming to the clinic.
It was also necessary to relieve the burden of the health centres nurses to whom all the tasks fell and who carried a heavy workload.
Because, there was still a number of patients who only came once every two months to the health centre to receive their medication. They were seen by a medical assistant or eventually by a nurse, just to say to each other, "How's things?", "OK", "Have you had any problems?", "No". And then we gave them their two months' worth of medication. This involved dozens of patients, who each took a quarter of an hour of staff time. (...) We had chosen N'Kalo because there was a nurse there who had completed the training and was very motivated. There was also a patient support group which was quite active. People from here were on-side and motivated, and present in sufficient numbers to keep the health centre operating. Because, it was no longer a question of putting all the health centre staff onto HIV care and leaving other pathologies unmanaged.
We held meetings with patient support groups and local authorities, to see if they were on-side or not. Then we recruited patients and trained them. They had to know enough to ensure that the patient presenting to them was stable enough to give him his medication, but without wanting to play doctor and trying to treat other diseases. Then with Mike, one of the senior counsellors within our MSF team, we established the follow-up procedure by going with them when they made the first drug distributions.
Annick Hamel, MSF France field coordinator in 2002, then Liaison officer CAME, then in charge of the Village Unit set up, from January to June 2007 (in French)

Though somebody from headquarters was sent to specifically implement this new approach, establishing the Village Unit system took much more time than planned. As the CAD had no medical background and no legal link with the MoH, MSF needed the green light from the Pharmacy and Poison Board of Malawi. It took several months for the Board's agents to come and make their assessment, and give their green light with recommendations.

It was only in August 2007 that we really had authorisation, on the condition that we adhered to their recommendations: the expert-patients had to come to pick up the pills in the morning at the health centre and in the evening bring back those which hadn't been issued. We really needed the expert-patients to be at least connected to the people running the health centre pharmacy. But this decision really took a long time at Lilongwe level and we had several months' delay before it got going.
Michaël Le Paih, MSF France Malawi HIV/AIDS Programme Head of mission, from September 2007 to July 2009 (in French)

However there was one insuperable barrier to the implementation of this project: most of the patients refused to enrol in the village unit system. Even after the supervising nurse had stopped driving to the village in an MSF car, the patients remained afraid of being stigmatised, lest they be spotted with the CAD or heading off to the place where the ARVs drugs were dispensed.

Another reason for failure was that the approach had been imposed by headquarters and implemented too hastily compounded by inadequate training for the

CADs. Therefore, and as most of the Nkalo patients kept visiting the health centre regularly, the approach was not extended to other villages.

The idea was good, but very quickly privacy concerns were raised. At that time in Malawi stigma was still strong, so people hid their status. Having someone come to the village and meet certain villagers leads other people to ask questions: who are they? What are they doing? Etc. We had tried to find them a small room in a school, but it wasn't discreet. In fact, patients came once or twice and realised that they were beginning to be asked questions and finger-pointed. So they no longer came. Once, one of the officers told me he only had one visitor of the five that were expected. And he realised that this patient had been hiding behind the school building until no-one else was there, to go inside undiscovered.
Dr Sylvie Goossens, MSF France Malawi HIV/AIDS Programme Medical Coordinator, from September 2005 to July 2007 (in French)

Documents in preparation for the MAP - VU History 2007"

ARV dispensing at the village level

- *In total 68 patients were followed-up by the ARV dispensers since they started to work end of December 2006. Of the 68 patients, 51 were seen twice and 17 only once, representing a total of 119 consultations. More patients could not be booked up to now to the ARV dispensers because they either didn't fulfil the criteria or because they refused to be followed-up by an ARV dispenser. Until more stable patients are transferred from the MSF cohort to the MoH cohort, and until we get a clear authorization from the MoH to go ahead with the ARV dispensing at village level, it will not be possible to transfer more patients*
- *Almost half of the patients (31) had to be referred to the nurse at their first consultation with the ARV dispenser: 5 due to bad pill count, 3 because they were pregnant, 5 because they needed counselling and 18 because of medical reasons (main complaints being numbness, cough and headache). Of these 31 patients, 24 came back to the ARV dispenser for follow-up consultations, and 9 didn't return because of medical reasons.*
- *None of the patients was erroneously not referred because of the constant presence of the training nurse (bright) for legal matters (see below).*
- *Only 4 patients didn't show up at their date of appointment and had to be traced by the ARV dispensers. None of the patients died.*

In a way, doctors or medical people don't hesitate to hammer home their instructions to an HIV patient: "You must come back in a week" or "we need you to come back in three months." As a result, patients are very informed about what they must or must not do, and it pushes them, without doubt, to return a lot more to the health centre, to make quite sure that they are well and that they are doing things well. They want to keep a medical link.
Michaël Le Paih, MSF France Malawi HIV/AIDS Programme Head of mission, from September 2007 to July 2009 (in French)

Everything needed to be ready and started on a date specified by Paris. So as usual, it was thought that the training could be done in two shakes, the day before for the day after. For the expert-patients they repeated the training designed for the nurses with the same messages and same content. It was the classic default of any training that wants to show absolutely everything that can be seen as sexy. In my opinion the training wasn't appropriately pitched or thought through. The team's objective was to show that the famous Village Units worked. So they needed to do the training and get started as soon as possible. **Emmanuelle Chazal, MSF France Medical Department Advisor on Patient Education and Training from 1999 to 2007 (in French)**

The setting up had been too hasty, and not talked through enough. It was like, "MSF has arrived with its plan so everything will be great." In fact we set things up without really trying to test the waters well, to see how we might do it in the best way, what would work or not, if people really wanted

it or not. I didn't stop saying it was going too fast. The national staff were consulted. But I don't know if they felt really comfortable to give their real opinions.
Dr Sylvie Goossens, MSF France Malawi HIV/AIDS Programme Medical Coordinator, from September 2005 to July 2007 (in French).

- **Six Month Appointment**

However, the SMA system survived the failure of the Village unit experience. Step by step, it was adapted to fit with the patients' constraints and requests.
Instead of the CAD/expert patients, it was decided to rely on a pre-existing category of MoH staff: the Health Surveillance Assistants (HSAs). These non-medical staff present in every health centre, were already delivering TB drugs under the supervision of the National TB program of Malawi.
Therefore, MSF just had to train them in the basics of HIV pathology and management of ARV distribution. Moreover as many patients were HIV-TB co-infected it made sense for them to collect both their ARVs and TB drugs from the same agent.

However, officially the Medical Council did not allow HSAs to dispense drugs; but they were used in all the medical structures to do so. So MSF followed this.

End of mission/handover report Michelle Chouinard Project coordinator decentralization December 2007
Keep in mind that as the MoH now has many HAS per HC, there is a possibility to negotiate with the DHO to train HAS and put them on the incentive plan. The reason to consider this is that HAS are included under responsibility of the national Medical Council, whereas our CADs are not. The MoH was open to the idea of HSAs as CADs but as we were not yet ready to move ahead with SMA we didn't discuss seriously. Elisabeth is Environmental Health Supervisor in Chiradzulu and supervises the HSAs. She, along with the DHO, should be part of discussions if decision is to move forward with HAS instead of expert patients as CADs.

Head of Mission Referral document for Malawi covering period of June 2009 – December 2010- Martha Huckabee
The one thing that is sort of holding this up is the role of the HSAs in our project. Currently in Malawi, HSAs are not "allowed" by the Medical Council to dispense any drugs. Like in most clinics that dispense ARVs, the HSAs do dispense drugs in Chiradzulu. The standard line is, even though it is not approved by the Council of Medicine, everyone does it because there is no other choice.
In Chiradzulu and in other districts, visits by the Medical Council have resulted in the HSAs being set out of the clinics. This usually only lasts a day or 2 and is the responsibility of the DHO to fix. But it brings up the very real problem: if we want to publish something on the SMA and potential disseminate the information about how the program is ruin a model…then it can be problematic for the Chiradzulu project - but also everywhere in Malawi using HSAs to dispense drugs. […]
It is important to note that MSF had a visit from the Poison Board in 2006 [2007]. The Poison Board regulates among other things, who is allowed to handle drugs in Malawi. They came to Chiradzulu and gave the OK for HSAs to dispense drugs under the supervision of a nurse (this report is in the HOM [Head of Mission] hand over file in the office).

The "new version" of the SMA system, with HSAs, was put in place: every three months the patient would have his/her drugs provided by the HSA in the health centre to cover three months. At the same time the patient would be asked a series of pre-defined questions regarding his/her adherence to the treatment during the three previous months.
Then every six months he/she would have a medical appointment and undergo biological tests if necessary.
If any problems occurred in the meantime, he/she would be welcome for a non-scheduled medical consultation then.

Since the HSAs were already integrated in the National Health System, their enlisting helped to strengthen the sustainability of the decentralised HAART project. However their activities would remain supervised by the MSF team.

Handover/End of mission report MED CO Chiradzulu Malawi – André Munger August 2007 - March 2008

SMA-Village Unit

The Six Months Appointment (SMA) is the new designation for the Village unit. The SMA is a step forward in the task shifting and the decentralization. The target is to relieve, as much as we possibly can, the pressure of the HIV patient from the HC by providing ARV drugs by a non-medical person – a member of the community. This dispensing occurs every 2 months with a visit to the nurse at 6 months and to the CO at 12 months.

At the beginning the idea was to provide ARV drugs for the most stable patients by a non-medical person, a member of the community. Because the MoH was not very enthusiastic about this, the long-term viability was doubtful; therefore we decided to use the HAS for dispensing the drugs.

Nkalo has been established as a pilot project for this, and almost 120 patients were in the program. Unfortunately this number dropped to 20, mainly due to the patients being stuck in the HC following their annual visit to the CO. This was discussed with the supervisor and his focus should be on the revision of the criteria of inclusion with the CO and the nurses.

In the next weeks and months we should stress this process as the final step on the way toward decentralization. Moreover we expect to extend this concept of SMA to all the other HC's.

The HSA was really the most efficient and quick way to try to reduce the workload of the nurses and clinical officers, who sometimes had to see up to a hundred patients a day. The HSA has to, via a demedicalised questionnaire, ask very important questions about how the patient has been "adhering" to treatment for the three months prior. From this short questionnaire the HAS must assess whether the patient has followed the treatment correctly, or slightly deviated from it, or has completely dropped it. So, if everything has gone well, the patient returns this time three months later for a medical consultation. Using the HSA lightens the load of 20 medical staff. In addition they're MOH staff and remunerated by the ministry. It's a way to ensure some longevity.

Michaël Le Paih, MSF France Malawi HIV/AIDS Programme Head of mission, from September 2007 to July 2009 (in French)

In January 2008, 2932 patients were enrolled in the SMA program, which was improving slowly but surely. As of 2010 SMA was available in all MSF-supported facilities. In 2010, 3021 patients were followed under SMA.

In October 2011 there were 3500 patients on the SMA program which represented 7000 fewer consultations per year out of a total of 175,000.

Six Months Appointment – Patient description and early outcomes evaluation - Chiradzulu MSF/MOH HIV Program. 2010

It appears that SMA is slowly starting to absorb some of the consultation volume, 10% of consults are now through the SMA program, though ART consultation in decentralization sites have dramatically increased in the past years, 2-fold from 2007. Therefore the impact may be minimally felt at the field level. (...) There is significant potential to demonstrate the progress of the SMA program and contribute to the much needed evidence of utilised non-medical/clinical workers for HIV care in limited health care resource settings. To further evaluate the SMA program there needs to be a better definition for a primary end point, such as viral load, maybe for a sub-sample of patients. Additionally, a clear operational protocol describing the project implementation structure of means of supervision/monitoring would be useful.

In 2009, the clinical criteria for enrolment were enlarged in order to allow access for more patients.

- **PMTCT and care for children**

In 2005 when the national AIDS program was launched, MSF had handed over the PMTCT programme to the MoH, believing that it could handle it. This handover also allowed MSF teams some room to consider additional activities. Meanwhile the completion of decentralisation of HIV/AIDS care had also brought care closer to the HIV-positive pregnant women.

However this handover continued to be considered a mistake by many who were convinced that reduction of mother-to-child transmission was a crucial approach within a strategy of decreasing incidence of the epidemic.

In early 2007, MSF decided to include every child born to an HIV-positive mother in the HIV programme. The objective was to tackle the issue of follow-up after birth, which is an important challenge in PMTCT.

Then, from March to May 2007, an MSF nurse was charged to make a thorough assessment of the state of PMTCT in Malawi, and more particularly in Chiradzulu district.

"PMTCT pragmatic approach in Chiradzulu District" MSF France, Philippe Le Vaillant – 2007

PMTCT has lasted for some years, before the introduction of HAART [triple therapy, as opposed to the former PMTCT regimen with 1 or 2 ARVS] in southern countries. It has been during a long time the only treatment proposed to fight Aids epidemic. AZT, the first drug put on the market, is known to have good placenta diffusion. Nevertheless, until today no program has shown good results in terms of avoiding new contaminations and capacity of following children until their 18 months.
Some obstacles may explain this failure:

- *The low availability of testing capacities during ANC. We can see that only 17% of PW were tested in 2006 in Malawi.*
- *The low use of maternities by women. Only half of all the births take place in a health facility.*
- *Difficulty to follow a child until he is 18 months.*
- *The shortage of human resources. With 2 doctors and 60 nurses for 100 00 inhabitants, the country is not staffed enough to face current medical problems and Aids epidemic at the same time.*
- *Poor adherence because main recommendations may be fearing women to be included in a program where they are induced to disclosure and breast feeding stop that can be lived as stigma points. PMTCT 5 years plan from MOH put forward twice in the introduction plan the necessity to address to pregnant women and her partners. It seems to be prerequisite to good PMTCT when it may be its first obstacle.*
- *Women not eligible for ART are often young and don't consider themselves as sick, that does not help to make them understand the importance of a PMTCT treatment.*
- *Poor service offer from Family Planning in many countries.*
- *At last, use of single dose Nvp for PMTCT treatment in Malawi is not considered as the best one. Already in December 2004, UNICEF proposed the implementation of a different protocol or ARV for PMTCT. UNICEF in a study called "Current WHO recommendations for use of ART drugs for PMTCT – Evidence from international studies" published by Malawian MoH in March 2005 gives a summary of acquisition of Nvp resistance in mothers and children.*

Myrto Schaefer, Mother and Child Health MSF medical Department, visit report March 2007

During this visit PMTCT was a "hot topic". The desk had sent an additional expat (Philippe Le Vaillant) in order to investigate issues around (amongst others the socio-cultural aspects/barriers) PMTCT; it would be interesting to read what he comes up with, but I do not think that the question of whether or

not anything should be done with regard to HIV transmission from mother to the child can seriously be up to discussion in a HIV treatment programme such as the one in CHZ. To me it is difficult to understand that we want to "face the epidemic in CHZ" (see fiche projet) and are still discussing whether or not we should be involved in PMTCT activities in CHZ. One of the reasons being that treating children will always be complicated and tedious and not having HIV is always a better option than having.
And in fact we already provide HAART for women who are pregnant and know their HIV status and have less than 350 CD4s (that is, at least on paper we do that. It was not possible to get any reliable numbers on that issue. The numbers I had access to showed that 550 pregnant women had been tested positive for HIV in HC and hospital, and only 123 had been enrolled into the program according to FUCHIA, the lab had performed 343 CD4 counts– Philippe Le Vaillant's report will have more details on statistics on PMTCT).
What is not done is:
- Offering HIV testing to pregnant women in the course of ANC (although officially this is supposed to happen through the MoH, this is not happening due to understaffing; when I was there the staff responsible for VCT was on outreach EPI activities for both days of ANC). In the hospital testing is offered to all pregnant women, the lack of testing or suboptimal coverage for testing applies to the HC
- We do not take care of the women not eligible for HAART (again, what happens in the hospital is not clear to me. I am referring to the HC).

At the end of 2007 the MSF team designed a new PMTCT program and established the priorities. Together with the District Health Officer (DHO) it was decided to focus support on health centres rather than on Chiradzulu hospital. It was also decided to set up a "one-stop service" system which means that a woman who is HIV+ can visit the health centre on a single day to access all services.

The MSF PMTCT program started in March 2008 and by the end of 2009 was implemented in all the health centres; it included ANC services, Voluntary Testing and Counselling, initiation on ARVs, PMTCT services, early infant diagnosis, and paediatric follow-up and care for exposed infants. Chiradzulu was the only district in the country that had managed to implement this policy.

The stigma was less acute than a few years before and drug issues had improved. But MSF was still facing the challenge of being able to assess the social-cultural background and the outcomes of the program.

Annual plan 2010, MSF France HIV Care and treatment programme Chiradzulu, Malawi

To continue on the momentum of this One Stop Service, it will be important during the next 6 – 12 months to determine additional steps that can be taken in order to move away from a purely female focus when consolidating services and to look towards developing a family clinic day. Our discussions with traditional authorities, patients and communities will also help us to identify what is appropriate in terms of combining services. There is a very large national level campaign to include men into the PMTCT programs. However, it is not clear if men want to be included. As Chiradzulu is matrilineal, we know that men are reliant on their marriage in order to have access to land, and that it is the women who control the sale and use of agricultural products. Also, divorce in Chiradzulu is a common prevention mechanism whereby women divorce their husbands if they are suspected of engaging in risky behaviour or if they are found to be HIV+. We have also been told by our patients that the elder women in the family can force a wife to divorce her husband if they discover he is HIV+. In light of this socio-cultural situation, it is important to have our operational decisions guided by the needs of both the women and the men in order to assist them in finding ways to access treatment and care and to keep their status private if they desire. This may mean that men should not be involved in PMTCT at the moment.

Malawi 2011, "Fiche projet"

Review activities 2010- Decentralization
The main obstacles in the PMTCT program at the moment are loss to follow up of both mothers and babies at all stages, disclosure and stigma. The monitoring and evaluation of the PMTCT remains

complicate. The planned introduction of a new MoH tool, a master card for exposed infants is on stand by until the new protocol of lifelong treatment for all HIV+ pregnant women is starting.

In 2007 12% of the 17,361 active patients in the cohort were children under 15. Children represented 8% of patients on ART with 44% of them under five years due to the extension of PMTCT.

From 2007 on efforts to provide more children with better treatments were boosted by the PMTCT program.

In December 2007 Dried Blood Spot (DBS) analysis, an early infant diagnosis test, started to be implemented in Chiradzulu hospital. In the following years it was extended to health centres.

Annual plan 2010, MSF France HIV Care and treatment program Chiradzulu, Malawi

As an integral part of the PMTCT program, MSF along with the MoH has finally made DNA-PCR testing available in all health facilities in the district. Rapid testing for HIV does not work until 12 months of age due to the fact that babies are born with some of their mother's antibodies and a positive test on an infant is often incorrect. The only way today to test babies for HIV before 12 months of age is with DNA-PCR. MSF is using the Dry Blood Spot (DBS) method where 4 drops of blood are placed on a pre-designed laboratory card and allowed to dry. Once dry they are transported to the laboratory of Queen Elizabeth Hospital in Blantyre. As Queen's is a teaching hospital with significant support from Johns Hopkins University in the US, these tests are run for free and the turn around time is less than 2 week.

So our current testing schedule for HIV exposed infants is to have a DBS test done at 6 weeks which coincides with the baby's first visit to the health centre. Due to the large number of HIV exposed babies we do not conduct another test until either six weeks after breastfeeding has stopped or if the baby is 12 months of age. This second test is done with a rapid test. If the rapid test is positive, a DBS repeat test is done as confirmation. All HIV exposed infants are put on cotrimoxazole prophylaxis at 6 weeks of age to prevent some opportunistic infection.

Once a child is found to be HIV + they are started on ARVs immediately as the mortality rate for HIV+ infants not on treatment is 50% by the age of 2.

As stated previously, many women choose not to return to the health centres for their children's test results. Again, the explanation given by the MoH is "stigma" however there has been no research on the issue and no one has been able to specify to me what is meant by stigma exactly. Now that DBS is available in all health facilities, we must ensure that mothers are asked if they want their child to be tested in the first place and give them the possibility to opt out. We can also take the opportunity to discuss with all the mothers during their counselling session what their concerns are in terms of their babies getting tested. It is important for us not to assume that we understand the constraints these mothers face, and rather include them in guiding our intervention strategies on the issue of early infant diagnosis.

In January 2008, paediatric fixed drug combination antiretrovirals were introduced in treatment of children.
In 2009 a "paediatric day" was established once a week in the health centres. Consultations specifically for children were implemented on this day. It was also a good opportunity to organise group counselling for them.

In 2010 the new WHO protocols presented PMTCT programmes with the "B+ option": the initiation of life-long ARV treatment for HIV-infected pregnant women with a CD4 count under 350, a new regimen for breastfeeding women and a treatment for infants of HIV-infected mothers up to the age of six weeks. MSF was able to implement these changes within its PMTCT activities (annex 4).

- **Improving adherence**

    - **Staff behaviour with patients**

In 2008 a study was conducted by Epicentre in order to evaluate the reasons for loss to follow up in the period from 2004 to 2007, in order to ascertain the outcomes for the patients.

This study pointed out that after stigma, harsh behaviour by staff was the second reason why patients would not return and gave up their treatment.

"April 2010. McGuire, M., Munyanyembe, T., Szumilin, E., Heinzelmann, A., Le Paih, M., Boulthy, N., Pujades-Rodriguez, M. Vital status of pre-ART and ART patients defaulting from care in rural Malawi. Tropical Medicine and International Health"

Primary reasons for defaulting were similar in pre-ART and ART patients: stigma (42.5%), dissatisfaction with care or staff behaviour (34.4%), perceived improved health (28.3%) and high transportation cost (18.7%). Of the 161 pre-ART and 37 ART patients who scheduled a return appointment, 71% and 65% sought care, respectively.

Philippe Blasco, MSFF Medical department Therapeutic Education and Training Advisor Visit report, August 2007

[...] ARV nurses

They are very experienced as well and seem to know the protocol and the drugs very well. But due to the numerous tasks they have to perform and the important number of patients, they are quite expeditious. They don't have any empathy and they don't create an atmosphere to encourage an active participation of the patient.

They perform a pills count and refill according to the remaining number of pills. If the pill count shows a problem of adherence the patient is referred to counsellors. (...)

Some of the messages given by the counsellor are sometime repeated by the ARV nurse. The distribution of task between the counsellor (or the peer-counsellor) and the ARV nurse needs to be revised and clarified.

In some occasion (for instance a patient who is transferred from the District Hospital to an Health Centre) the exact date for the next appointment is not known by the ARV nurse who dispenses the drugs. Therefore she could not give the correct quantity of drugs with a risk of shortage for the patient. Is it possible to fix the date of the next appointment before dispensing the medication?

Annual action plan 2010, MSF France HIV Care and treatment program Chiradzulu, Malawi

In addition, in response to the findings from the tracers that the main reason for defaulting is the negative way they are treated by the health care staff, the IEC team will develop a program to educate the medical staff about their actions and attitudes toward the patients and the impact that this has on the patient's involvement in ART. There is literature available from other contexts that give[1] interesting examples of the kind of education that is useful. The outcome we hope is to see fewer complaints from the patients about the way they are treated by the staff. This can be monitored doing exit studies and with the suggestion boxes that are in all the health centres now.

    - **Adapting counselling**

The needs for adaptation and re-organisation of their work was a permanent issue for the MSF counsellors, who had to cope with the evolution of drug protocols, growth of the cohort, and the specific social needs of the patients.
Once the pre- and post-test counselling was transferred to MoH staff they had more time to focus on the counselling part of their job.

For our patients to take six tablets in a day was a challenge. So MSF advocated for fixed those combinations at international level and eventually when we received the D4T, 3TC and nevirapine that came in fixed dose combination. So one gets one tablet in the morning , and one tablet in the evening. Then we tried to adapt our counselling education according to the type of treatment that we have at that particular time and we also tried to be more flexible.
In 2004 we saw a good bunch of staff from MOH being trained to do the testing. And when that was done, MSF had to give faith to them. Now all the testing is more the mission of the MOH and we are focusing more on health counseling.
Frazer Chimbuzi, MSF France Malawi HIV/AIDS Program Counsellor then Head of Counseling Department, from May 2000 (in English)

Within the MSF team, a dynamic of information-sharing was developed between medical staff and counsellors, which helped to adapt the quality of the patient education to the changes induced by the switch to new drugs protocol.

In the meantime, MSF had also started to participate to national trainings regarding adherence counselling.

So adherence counselling was something that as a team in Malawi we build from the scratch, looking at what information people had and we had to share. It took us a very long time to start getting the first formalised training in adherence counselling. For a long time there was no national training to do adherence. When they started the national training we used to be involved in training others.
In terms of people's skills in adherence counselling, the MSF Chiradzulu team was quite acceptable. And from other areas in Blantyre, and Mulanje, and some areas in Zomba, some people used to come to visit us to say "what are you doing in adherence counselling?". They would see the materials that we have come up with, to help in the patient education.
Then you could see that the MoH really had the confidence in the team to say, "You guys have already gone down that road and you can help us train others."

Mike Kalemera, MSF France Malawi HIV/AIDS program counselor from 1999 to 2010, then Head of IEC Department (in English)

There were discussions about task-sharing within the MSF mobile teams, particularly regarding counselling. Some thought that ideally patient education/counselling should be done as much as possible by the nurses or the medical staff. But it was obviously impossible to increase their workload.

The controversy surrounded the distribution of tasks and roles: "who does what" within the MSF teams and how to delegate these tasks in the health centres. The MSF teams were composed of clinical officers, nurses and counsellors. We believed that actually we shouldn't have to have a counsellor because it was up to the medical staff to do the work involved in therapeutic patient education in addition to their clinical activities. But the clinical officers didn't have the time because the workload was enormous. We thought that the nurses should at least be able to unearth the small problems associated with poor adherence and talk about them directly with the patient. We had envisaged the MSF counsellors doing the follow-up of the complicated patients that the nurses would be able to refer to them or of the patients who wanted stronger support.
Emmanuelle Chazal, MSF Medical Department Advisor on Patient Education and Training from 1999 to 2007 (in French)

With the increase of the cohort, the counsellors couldn't cope with the workload. In 2007 the HSAs were trained in pre-test counseling and could handle a part of these activities. But this was not sufficient to respond to the needs, and the idea emerged of setting up a group of peer counsellors. These were stable patients, organised in "support groups", that would take charge of the support and counselling of stable

patients. Then the MSF counsellors could focus on the complicated cases. In 2007 and 2008, 19 peer counsellors were recruited to cover 10 health centres full-time.

Philippe Blasco, MSFF Medical department Therapeutical Education and Training Advisor Visit report, August 2007

[…]Peer-counsellors

In last February, 10 peer-counsellors have been recruited and trained. They are now working in 5 Health Centres (2 peer-counsellors per HC). They offer counselling the day of MOH clinic for stable patients and at ARV initiation. They see in average about 12 patients per day (6 for each of the 2 peer-counsellors). Mike is in charge of supervising the peer-counsellors.

I had the opportunity to see only one peer-counsellor, which is not enough to have an objective opinion about the quality of their work. Nevertheless it is clear that they don't have the same experience of the MSF counsellors and need some more support.

In Health Centres the counselling room are often quite small and make difficult the organisation of group counselling. Construction of new building is under process and should give more space for counselling session.

In the coming months the involvement of peer-counsellors will increased since we are going to refer some more stable patients to Health Centres. There is also a plan to have an MOH clinic every day. Therefore some day the MOH and the MSF clinic will be done together. This will allow exchange between the MSF counsellors and the peer-counsellors.

Peer-counsellors are also doing health talk for patients in waiting room, but in many Health Centre the arrangement are not optimal for group discussion. The main topic addressed during these health talks are : transmission, safe sex, positive living, HIV and aids, taking ARV, condom, CD4, health talks are : transmission, safe sex, positive living, HIV and aids, taking ARV, condom, CD4, benefit of HIV test.

We identified patients from all the districts, who were doing fine, those who could teach and counsel their friends. We selected them according to the health centre that they were close to. Most of them were also in treatment. We asked them to support patients but also to provide the counselling and also the education. It works very effectively because they shared from what they had gone through. So this was very powerful. **Frazer Chimbuzi, MSF France Malawi HIV/AIDS Program Counsellor then Head of Counseling Department, from May 2000 (in English)**

In 2007 the national program decided that the HIV counselling service had to be improved and extended. Thus people who were Health Surveillance Assistants (HSAs) were given the chance to be involved in HIV testing and counselling. That was one big change that came along. For the HSAs, adding counselling as part of their job was a challenge, because they already had several activities in their job profile, so to add this one, was very difficult. But the government made it possible to train more and more people. Once trained, they needed to practice. We, as MSF team, had prior experience of what we can do, thus we had to work together with them, give them the skills that we knew, monitor their skills. Soon they were able to handle almost all the counselling activities in terms of HIV counselling and testing. And that was a relief for us, because we had now to concentrate on adherence. But still the cohort grew up, and the issues of decentralization became more acute. So we recruited the peer counsellors. The idea was to involve the patient to do the job. It was a big motivation for them and for the community. These people were living there, and they happened to be given the task to do something. It was a very big motivation for them. They tried as much as possible to give quite a lot of effort to understand, to promote the activity in the health setting, and also to show to the community that it could do more. Now (in 2011) we are talking of 19 people as peer counsellors, who are doing quite a big job at the health centres. They are mostly responsible for the first-line counselling sessions. The alternative counselling sessions, for the second-line, are for the senior counsellors. Some general counselling sessions that had to deal with the emotions which have just come up, and that have been ordered in emergency by clinicians, are still sent to the senior counsellors.
Mike Kalemera, MSF France Malawi HIV/AIDS program counselor from 1999 to 2010, then Head of IEC Department (in English)

As the team was constantly understaffed, the counselling supervisor would often replace missing staff and would thus face difficulty doing his supervising work.

However tools such as guidelines and trainings were developed, and onwards from April 2007 the counselling team started to receive some support from an expatriate psychologist, who helped them set up a continued work plan. From then on the team was also able to receive the support of a local psychologist based in Blantyre to deal with stress, or risk of burn out.

Within MSF some people considered that the message disseminated through the counselling tools and sessions to the patients was exerting too much control and pressure on them.

Notes taken by the Head of Mission on the visit of Rony Brauman (ex MSF president and Director of Studies to MSF's Chiradzulu programme, August 2008

Counselling (tool, tone & MTCT)

- *A bit shocked on the use of tool we are having at least in CZ (the soldier, and the virus in the body) for the kids, and the representation that the child may have for his body a battle field, can pose serious adherence issue.*
- *No advice on eating well (when we know that they eat what they can), neither advices on tobacco cessation, alcohol drinking (unless really the patient is addicted to the point that this is a disease, and hampered adherence to treatment, for example - because the patient can forget).*
- *For PMTCT, according to Rony we shouldn't rush to speak about disclosure and safe sex, at a time when what matters more is PMTCT. It will come with time and further sessions. Otherwise, we will frighten the mother to be. No judgment on an HIV woman if she becomes pregnant. Be only supportive.*
- *Many things are common sense. But too many times, we see that instead of discussing with the patient and informing/answering questions-concerns, the tone is moralist or hygienist: do this and this, don't do that and that.*

More and more children were managed in the MSF program. But for several years, only those going to the hospital HIV clinic were receiving any specific counselling. In 2008 specific tools were developed for child counselling, and this activity was extended to health centres.

The issue of their growing up was totally ignored. In 2008, an advisor came from Paris, to try to see why we can't have more time thinking about the children. And we started thinking about it. We thought that the more our cohort was growing up, the more the number of children in the cohort was growing up. If we were not involving them for sure they won't be involved by anybody else. They grow up, and they will be one of the risks in our community. But now we are totally heavily involved in them. The expat which was sent here was able to take us through the children activities. He was the one who masterminded the whole process and he had to come to train us. He even came twice, to monitor the activity, just to see what was gradually going on in the field and his report gave us an impression that actually we have really changed quite a lot in terms of targeting the children.
Mike Kalemera, MSF France Malawi HIV/AIDS program counsellor from 1999 to 2010, then Head of IEC Department (in English)

The growing number of patients on alternative and second-line treatment presented the counselling team with new challenges. They had to improve adherence of patients in first-line treatment and to work on acceptance of second-line treatments and adherence amongst patients with side-effects.

The number of people requiring second-line treatment was growing up, and because of that, there had been an effort from both counselling and the clinical team to try to see how much we can support these people. We had several discussions to try to see how to get patients involved as much as possible to give the right information at a right time to start a second-line treatment. Second thing is that lately we have seen some long-term side effects coming in, which was not the case before. The

issues to do with the lipodystrophy had not been discussed before. But as we had been in the project for a long time, we noted that this was one of the challenges that people were facing. It was not easy for them to notice that there was a problem because of the changes they were experiencing in their body. So it was also a challenge in terms of the counselling team to convince patients having taken a slight change in the drugs that we needed to get more information from them.

Mike Kalemera, MSF France Malawi HIV/AIDS program counselor from 1999 to 2010, then Head of IEC Department (in English)

In 2010, the entire counselling program was reviewed and protocols simplified. From 2011 on systematic counselling for all patients who had been on ARVs for more than 12 months was stopped. Efforts were concentrated on the first year of treatment. However patients were able to access counselling whenever they felt they needed it.

Malawi 2011 "fiche projet"

Review activities 2010- Decentralisation

Content of counselling messages and the rhythm of counselling were not adapted to the needs of our patients anymore and the protocol has changed. In future, prescribed counselling sessions will stop after one year of ARV therapy. Efforts will be concentrated on patients with adherence problems, treatment failure, social problems and new regimens passing messages adapted to the constraints of the individual patient. The whole package of child counselling was reviewed in 2010, new tools developed and the staff trained in order to improve the quality of children counselling in the project.

- **Strengthening defaulter's tracing**

In August 2006, tracing activities were re-organised and decentralised to the health centres. One tracer was assigned to each health centre and two in Chiradzulu hospital's HIV clinic.
Mid-2007 tracers started to dedicate their morning hours to patient registration (identity, weight/height, preparation of FUCHIA forms, referral to the medic) and their afternoons to tracing:

- **Patients eligible for ARVs who did not come for their appointment**
- **Patients on ARVs who did not come for their appointment**
- **Patients whose CD4 had dropped**

Registration was shifted to the tracers because they were living near the health centre and could therefore manage to start registration early in the morning. They were familiar to the people within their catchment area which they knew quite well.

With this new set-up, tracers were able to reach patients failing to come to their appointments within 72 hours of the set date. In 2007, 2135 patients had been traced of which 7.2% were eventually considered lost to follow-up.

"Tracing report for the decentralisation – February 2009"

Impact on both registration and tracing by tracers – registrars
When the team arrives at the health centres:

- *Clinicians and nurses just go straight into their respective duties e.g. consulting patients and dispensation of drugs because registration is done early in the morning*
- *There is a significant reduction of the number of false addresses given by newly enrolled patients since tracers started registration in mid 2007.*
- *We have a more reasonable number of patients being traced every month than before when tracing was done by one person*
- *Defaulters are traced before their treatment last.*

Additional tracers were employed in the busiest health centres, based on the number of patient bookings. In February 2009 there were 24 tracers.

Patients should be free. They should know that this is their clinic. They should own it. When they come to see any health worker, they should be free to say anything. And also they should be free to express their feelings and also say their issues. For instance they can say: "I may not be able to come next month, why don't you give me two months? ". There has to be that kind of discussion. We should try to make the whole care good for them, to be flexible, to create a more friendly environment. We should be conducive so that when patients come to see us, they shan't be afraid to talk to a health worker. We are there for them. **Frazer Chimbuzi, MSF France Malawi HIV/AIDS Program Counsellor then Head of Counseling Department, from May 2000 (in English)**

In 2009 there were extensive discussions about placing the responsibility of tracing in the hands of the DHO via the HSA, at least in some health centres. But it was decided not to do so in order to avoid aggravating the serious human resources problems the MoH was facing.

- **Enhancing IEC**

The IEC activities were restarted in 2008. For a year they were managed together with the counselling. But the team was overwhelmed and very little IEC activities were developed. Thus in June 2009 counselling and IEC activities were separated between two teams. The IEC team was composed of a former experienced counsellor and one of the first patients of the program who had also been the first tracer and had good experience in IEC. This arrangement was consistent with the will to encourage active collaboration between counselling, tracing and IEC, in order to enhance the link with local communities.

Medical Activity Report 2007-2008 – Chiradzulu project – Malawi Médecins Sans Frontières French section

In 2008, MSF-F has revamped its capacities of community mobilization through MSF-F staff and support groups. Every month with the support of the DC, DHO and the TAs, we conducted gatherings within schools or for the general population to speak out about the epidemic, and with the assistance of support groups, to provide key messages related to treatment, providing testimonies, and addressing the only efficient way to prevent the contraction the HIV, the use of condoms.

MSF Chiradzulu HIV AIDS Program Activity report 2009-2010

By developing lines of communication between tracing and the Information, Education and Communication program (IEC), the issues that patients are struggling with at the community level can become the topics for upcoming community mobilization activities. Tracing may also assist in providing insight into what kinds of support is available within communities in terms of patient support and follow-up and help to determine what strategies can be developed to empower patients and communities to overcome these hurdles.

At that time, Mike was a counsellor and he also take IEC which is in a way linked to counselling, because in both activities we are talking about sharing information with patients. So, sometimes Mike was for IEC and sometimes for counselling. So, it was difficult for the two of us to design what we want as a program and also at the same time trying to support the people. How could we strategise in terms of trying to achieve our objectives? So eventually, in 2009, it was thought that it would be much better to try to separate the two. We tried to have a structure for counselling and also a structure for IEC, so that we tried to focus and invest our time fully, in the activities, and that we were able to reach our objectives. So it has got to do with time management, and also with how do we focus on these two programs.

Mike has been able to design a good IEC activity program, and also he's been able to follow it closely, to see that the objectives we had set up were fulfilled.
At the same time, it has given me also some space, to focus closely on our counselling activity as a program but also to try and focus more on the patients. Bearing in mind that I have the peer counsellors who are also more or less like ex-patients who need more support. We also have the psycho-social counsellors who are more or less senior counsellors, and I have to make sure that they are going to support the peer counsellors fully and then to enhance their working capacity.
Frazer Chimbuzi, MSF France Malawi HIV/AIDS Program Counsellor then Head of Counseling Department, from May 2000 (in English)

By then, the IEC team activities included community mobilisation, health talks implemented by peer counsellors, and information sessions in schools and businesses.

When we hear about a place where they are defaulting too much, we need to go and encourage. We call the chiefs we call everybody through peer assistants. If people hear the sounds of their radio or the music, they come at once. We are even taking the drummer groups. People will understand and come. After we have discussed in the community, we give them chance to ask some questions. They don't have enough information on HIV. We come with the idea that sometimes we should involve the medical people, because they can ask a medical question which we cannot answer. There are some requests from the communities for us to come. There is no chief who denied us. Little by little whenever there's a problem, the chiefs are calling me. Our plan for first year was to tackle behaviour change. Now we see more people coming to the hospital for testing. People are open they are not fearing anymore. But we still see the number of HIV testing positive is increasing. Our programs are not working properly, as we want it to be.
But still, chiefs have been calling us. "What are you doing MSF?"You stopped coming into the community with those medics. We understand MSF is going. But I have problems in the community. Why did you stop?" But we need to buy some gifts for the chiefs, because in Malawi you cannot go to the chiefs without gifts or without an allowance.
Esnat Mbanda-Mbanda, PWLA, tracer then tracer supervisor, then IEC officer from 2002 on (in English)

From January 2010 on, after an assessment, IEC was started with commercial sex workers, a group that had been identified with the highest default rates. The aim was also to further empower them by educating both their colleagues and their clients about HIV/AIDS prevention and issues.

As a team we are going to see if we are really ready to do more in this area of commercial sex workers. It's very difficult to deal with, but it's very important in terms of the nature of their job. It happens to be one of the areas where transmission of HIV occurs quite a lot.
In 2010, we had the chance to offer them HIV counselling and testing. Most of them who tested were HIV-positive. We had about 80, 83% of the group which had HIV-positive. At the country level, it is over 70% of people who are in this business who are HIV-positive. These people are working in risky areas like in the bars. Most of the time they work when they are drunk, which is the area where it is very difficult to make very informed decisions, for such people. **Mike Kalemera, MSF France Malawi HIV/AIDS program counselor from 1999 to 2010, then Head of IEC Department (in English)**

In 2011, it was realised that the IEC messages and strategies were inadequate and needed to be adapted to the new challenges, such as new protocols, circumcision, or PMTCT.

- **<u>Simplification and integration of data management</u>**

As the scaling-up progressed, the data management had to be simplified and organised to facilitate integration with the MoH.
Improvement in data management quality became critical to the provision of accurate and useful information that would help to refine and improve the program (annex 5).

Over the period 2006-2007, the epidemiological department was reorganised. Staff was increased and premises were built. In particular there were issues to resolve regarding reduction of the flow of non-useful information that was collected, extraction of data, data sharing with MoH, and its use for publication (annex 6).

HIV monitoring and Evaluation system Chiradzulu HIV Program (MSF-F Malawi) Laurence Ahoua & Mamadou Balde Epicentre, 01-11 September 2008

Since last year (2007), 5 mobile teams (soon to be 6) are supporting 10 Health centres for HIV medical care. Activities intend to increase for PMTCT and Nutrition. There is currently over 9,000 patients seen per month in the Health Centres and in some of them, an average of 50 to 60 patients seen per day per clinician. Standardised indicators are now produced by EPI on a monthly basis to monitor the programme's expansion and give feedback to the field and coordination teams. To be able to produce such analysis, all information (collected on carbon copies of Fuchia forms) are centralised daily at the MSF Chiradzulu office. All copies of Fuchia forms are filled and kept in the office. To be able to cope with the data entry work without too much backlog, 10 full time data entry operators are entering data in the Fuchia database. At this point, there is a strong need to simplify the M&E system to be able to decrease the work workload and focus on medical care.

Head of Mission referral document for Malawi covering period of June 2009 – December 2010 –Martha Huckabee

On the one hand, MSF cannot give open access to our data base as this is confidential information. However, as we are working in Malawi, in MoH structures, with MoH staff and MoH drugs, and we are managing the care of 8% of their national cohort -– it's also normal that the MoH wants information from us.

There are other problems though. It is not easy to extract data from FUCHIA. The data base is huge and we do not collect all that much information for the data base. On the other hand, some information that is not a part of the standard quarterly reporting can be extracted from FUCHIA and it is very time consuming. Also, Epicentre and MSF want to be sure that the information is used accurately. However, we also discovered that Epicentre is publishing using this data without informing either the desk or the field – and therefore also not the MoH.

The whole thing has become a mess and has been a consistent problem that is worse every time there is a confrontation – which is basically every time the MoH asks us for information.

We are trying to get on paper a blanket agreement with the MoH and HIV Unit as to data sharing. This is being worked on by the legal department and Epicentre. Annette at the desk is also following this closely.

In 2006, we put in the place the means to really establish epidemiological monitoring of Chiradzulu and we built a new hall for the epidemiological department. This shocked people a little, but one had to be realistic about the size of the programme and the responsibility we had in monitoring these patients. We added staff and it also enabled us to produce a few studies and put out some information to re-engage and also to share what we were doing in Chiradzulu with other HIV programs. This really helped us to take decisions regarding the direction of our activities. For example, it allowed us to have fairly rapid feedback on what patients thought of the Village Unit and how quickly the nurses switched eligible patients to the 6-month appointment regime. After two months, we saw that the patients weren't being switched quickly enough. It is via this database that we really started working in depth.

We also wondered if we couldn't limit ourselves in terms of the epidemiological monitoring of patients to two sentinel health centres. It had been under discussion for a long time but no decision had ever been taken. When I left in July 2007, the new epidemiologist was head of an epidemiology department of ten people. We had decided to continue to monitor all patients individually. I think we didn't yet feel sure, we didn't have enough data yet that satisfied us to be able to say "We will continue to do

monitoring, but only in two health centres." We wanted more numbers to support our argument and then argue some more. And then the disease and the treatments became more complicated with time. The FUCHIA forms became more and more complicated to complete because we had to collect more and more complementary information. We also considered simplified forms, but in fact it was all of interest to us and we wanted to record everything: CD4, viral loads, side effects. Obviously, the more it became more complex, and the more patients there were, the less staff took the time to complete the forms and we had to fight for this to be done well. We even threatened, "If you don't complete your FUCHIA forms, we can't keep you on!" But deep down it was recognised that it was useless to set up a system which we could only use to a level of 50%. So we balanced between "we want to know everything" and "we know it's a big workload."

Dr Sylvie Goossens, MSF France Malawi HIV/AIDS Programme Medical Coordinator from September 2005 to July 2007 (in French).

When I arrived in June 2007, the priority was to standardise. So we created a MSF-structured patient ID system, and then we also decided to invest in constructing a patient file warehouse. It meant that every patient had a file that was accessible, as much as possible. The reason for that, at this time, was the decision that MSF was going to be there for a while. MSF was also going to invest in operational research, invest in monitoring and evaluation support, and invest in really making this a strong program. So we organised and really pushed for a standardization of information flow. The challenge was, on top of that, that there was too much information being collected. At this time, we had maybe twice the amount of data fields that are being collected now, and none of it was useful. And the problem that we also faced in this, unlike any other field, is that the FUCHIA entire form is not just data fields for checking off. It's also where the patient notes and prescriptions are written. It's one piece of paper that is an entire patient file of information. And so it had to be utilised by all medical staff. So you had to maintain some level of space to write notes and prescriptions. It's absolutely insane. We knew it wasn't sustainable. So we aimed to reduce the amount of data elements, as well as standardise as much as possible to the Ministry of Health data elements.

[...] MSF reports weren't a reflection of what was required for the Ministry of Health. The database in Malawi was so large, by 2007, that the routine reports weren't easily generated. And so what we were doing is exporting the data to a separate data analytical tool. Therefore in 2007, we asked for the regional epidemiologist at the time to come, and we wrote programs so that we could start standardizing the reporting system, both for MSF and the Ministry of Health. Reflecting on this, it's one of the most outrageous things that we could have done in rural Malawi where we're using sophisticated program techniques to extract basic data elements necessary for reporting.

FUCHIA became so large that we then had to split the databases in December of 2007. So there's a male database and a female database, to this day. What that means is that for any reporting that we have to do, we have to export two separate databases, prepare those files with quite complex steps, and then bring the data together to one file. The level of sophisticated understanding of information to get the system to function in Malawi is unlike anything I've ever seen in my life. And I worked in universities I worked with big research projects.

Megan MacGuire, MSF France Malawi HIV/AIDS programme field epidemiologist May 2007- July 2009, MSF France East Africa Regional Epidemiologist from November 2009 to January 2012 (in English)

It became obvious that the FUCHIA system was reaching its limits in terms of size but also because it was a centralised data collection system applied to a decentralised project continuously caused problems.

Moreover, because of MSF's "hegemony" in HIV/AIDS activities in Chiradzulu, most of the staff were not aware of or trained to use the MoH Master Card data paper system. Therefore, though they were very well trained in HIV/AIDS care, should they decide to apply and work in another district they would be hampered by this gap in knowledge. The transfers of patients from Chiradzulu district to another was also hampered for the same reasons.

In the Chiradzulu District, the Ministry of Health actually can't do its own monitoring system because we haven't implemented it. No one in Chiradzulu knows how to use the Ministry of Health system. Let's imagine an MOH nurse who's been working in one of the health centres is then moved over to another district. She has all this experience in HIV and then she looks at the master card and she says: "what is this? Where's my FUCHIA?" There are major issues about patient confidentiality because the patients carry their files with them. That also means the facility has no record of the patient. That could be a good thing or a bad thing, depending on who you talk to, but it's challenging when it's not standardised across the country. So a patient ends up going home to another district and they need a transfer in to receive care. But don't have MOH tools to validate their transfer. We're not even using the patient passport. **Megan MacGuire, MSF France Malawi HIV/AIDS programme field epidemiologist May 2007- July 2009, MSF France East Africa Regional Epidemiologist from November 2009 to January 2012 (in English)**

In 2008 the MSF team assessed an IT system developed by Baobab, an association specialising in IT innovation adapted to poor-resource settings. Among other functions it would allow management of patient data but also monitoring of ARV stocks. MSF along with the HIV Unit of the MoH was particularly interested in using this IT system to simplify the management of patient cohorts in rural settings.

At the time though there was some questioning within MSF about system sustainability regarding costs and maintenance, so MSF did not pursue Baobab. However most of these barriers are now on their way to being overcome and in the meantime, the MoH has decided to adopt the Baobab technology for its Mastercard system in districts hospitals across the whole country. So far there is no plan to extend this technology to rural health centres.

What is currently planned and ordered by the Malawian authorities is progressive replacement of the MSF FUCHIA system in Chiradzulu district by the MoH Mastercard data "paper system,

It is something postponed by MSF for years because the active files of patients in the health centres are too big to be managed and maintained by a paper based system. Therefore in 2012 the replacement of Fuchia by Mastercard is planned for one health centre only, which patient active file is small enough to fit with a paper system.

MAP for Malawi, October 2009

Mastercard/ Four health centres have been slated to make the switch from FUCHIA to Mastercard (Chitera, Maua, Thumbwe and Ndunde). All of the concerned actors have agreed upon the necessary conditions for this to occur and the data to be included from FUCHIA. This means that we are currently waiting for the HIV unit to provide all of the documents that are required (Pre ART, MasterCard, minimum of 6 months supply of Mastercards forms) and for the DHMT to identify and recruit the staff necessary to take over the registration of patients in these locations.
MSF needs to be prepared to potentially share the costs of training as the district did not receive funding from NAC in 2009 for training. This may not be necessary if this takes place in 2010 but will depend on the budget the DA is given for training.

At the time (in 2008) we were thoroughly committed to switch from FUCHIA to the so-called health centre-based system. It was a system with touch screens etc. It also allowed a cut in the time spent on paperwork by MSF or MOH nurses and clinical officers in the centres, by making them do it in real time, during the consultation. We shared our thoughts on this subject with the Lilongwe HIV Unit which was involved in a project to assist health centres to implement a patient management system that was simplified as much as was possible. Indeed in every health centre in the country the whole data collection system was based on paper records. Every three months, a team of ten or so officers drove to each health centre to collect data: how many patients had been initiated, how many had died, how many were lost to follow-up ... It was an unwieldy system, designed to produce national statistics.

By modernising the system, the HIV unit hoped to have a better quarterly statistical report which would allow, among other things, the drug order to be streamlined. In fact they were hoping to be able one day to come to the health centres with just a USB stick to pick up the information. They would have liked to use technology to leapfrog some of the existing steps. We were therefore also interested in this because we felt that the HIV Unit had this idea and we could give them that extra push. But it was an approach based on very advanced technology that required certain electrical equipment that health centres were totally devoid of so it was difficult to transmit it to the MOH. [...] At the time we were rather excited about the possibility of testing the system in a health centre, but I have the impression Paris might have forgotten that? **Michaël Le Paih, MSF France Malawi HIV/AIDS Programme Head of mission, from September 2007 to July 2009 (in French)**

Baobab was started by this volunteer in Malawi in the 90s, who was a mechanical engineer by training, and created first a unique patient ID system for IPD and OPD at a hospital in Lilongwe, the capital. And then they realised that they needed an ART monitoring system, so it was modelled off out of the Ministry of Health monitoring paper-based system. That is a touch-screen system with built-in checks. Malawi decided to put special bar codes on the back of their ARVs and so Baobab monitors the amount of ARVs, the types of ARVs that are going out. And it also has an embedded automated report for Ministry of Health reporting,
We did a preliminary evaluation in 2008 about the system. I was convinced, but no one else was. And by 2009, they actually came to Paris to present their system. And there were some reservations about it, that I think are warranted, but becoming less and less so.
What would be the maintenance of it? Who is going to pay for the long-term cost? MSF was more or less ready to consider the implementation costs, but not necessarily ready to commit to long-term costs, which is a legitimate point. Additionally, even though it was implemented in Ministry of Health clinics, it wasn't super clear would the Ministry of Health validate this as a national system.
Thirdly, the funding for really scaling it up on a national level was unclear. That's becoming more and clearer at the moment.
Then there was a question on migration. How would we take the FUCHIA system and migrate it to this different kind of system?
And then lastly, Chiradzulu is really a decentralised program. Less than 18% of the patients are followed in the hospital. But the health centres don't have an electrical system, so how would you decentralise the Baobab system? They have now found a solution for that: windmills and car batteries.
To date, Baobab has been scaled up to 22 sites, several health centres, but primarily in district hospitals or regional hospitals. Over 60,000 patients are followed in the system. It has been fully endorsed by the Ministry of Health to the point where it's going to be put into all district hospitals including Chiradzulu.
Another limitation of it was that it was specifically only ART. And at that time, MSF was very committed to having pre-ART, some hospitalization information, PMTCT and labs monitored. So now, Baobab is not just going to be for ART. There's pre-ART, pre-natal care, post-natal care, a EPI for children that would include exposed infants. It's turning into a health information system for OPD.
Additionally, the Centres for Disease Control, which is a funder for monitoring in Malawi, has committed several million dollars to the implementation of it. So a lot of our concerns are actually being addressed. However the long-term financial stability of it is going to be a question that we would have anyways even with FUCHIA or Baobab or another system. We can't project what's going to happen five years from now.
Megan MacGuire, MSF France Malawi HIV/AIDS programme field epidemiologist May 2007- July 2009, MSF France East Africa Regional Epidemiologist from November 2009 to January 2012 (in English)

From 2008 on, the use of the EPI database as a tool for operational research was boosted. More studies (annex 7) were implemented that gave a better understanding of the cohort and over and above that insight to improve the operational process.

Field Visit Report "Overview, assessment and recommendations for HIV monitoring and evaluation" Chiradzulu HIV report. Epicentre regional team, Laurence Ahoua & William Watembo, August 2007

Operational research- Assessment – The size of the MSF-F cohort is easily one of the oldest and largest in Africa, however limited publication and operational research have been conducted; the last OR project was in 2004. A few evaluations have been initiated, specifically by using retrospective data from FUCHIA however information has not been disseminated. The major obstacle is the quality of the database, which requires extensive cleaning. The extensive decentralization to the MoH nursing staff and ARV dispenser program both have potential for useful OR to be carried out for 2008. During this field visit, four proposals were drafted with the regional epidemiologist and field epidemiologist and presented to the HoM and MedCo. The proposed subject on OR will be sent with the report from the field epidemiologist.

Medical Activity Report 2007-2008 – Chiradzulu project – Malawi Médecins Sans Frontières

French section

Research - MSF-F along with the MoH, its department of HIV/AIDS and the DHO has been working on two research protocols in 2008.

MSF-F carried out an internal assessment to trace and ascertain the outcome of the patients who were enrolled in the cohort since the beginning of the project but defaulted between July 2004 and September 2007.

A second operational research project was about to start at the end of 2008. The objective will be to describe the clinical, virological and immunological outcomes of adults and children followed in the program that started ARV either 12 months or 48 months ago and are alive in the MSF-F/MoH HIV/AIDS program. Among the secondary objectives, MSF-F also wants to compare the clinical, virological and immunological outcomes between centralised and decentralised delivery of HAART to adults and children followed in the program who started ARV at 12± 2 months before study start date.

Now that we had a data manager in place, we started operational research projects. The first operational research project that we did was a lost-to-follow-up study. It took place over 5 months, where we evaluated the outcomes of 1700 patients who had left care. We had hired a team of local staff to go door to door to find patients. We presented at CROI[9], and it was published in Tropical Medicine and International Health.

Then we wrote another protocol to look at the outcomes of patients in centralised and decentralised care using, after one year on treatment and four years on treatment, to look at the virological outcomes and differences between the two. We ran that study in 2009. It was approved in 2008. That was presented at MSF/Epicentre Journées Scientifiques, at the International AIDS Conference, and is now in publication at Plus One. We started also to monitor specifically the task-shifting, so each consultation was evaluated by the monitoring system and we just finished the analysis of a three-year outcome evaluation of that. We also embedded the six-month appointment monitoring which was presented partially last year [2011] at the International AIDS Conference. So the idea was instead of having separate operational research, we would embed some of the operational research into the monitoring system but with minimal impact. So we simplified, but we chose very specific data elements that we would monitor for task-shifting and simplification.

Megan MacGuire, MSF F Malawi field epidemiologist May 2007- July 2009, MSFF East Africa Regional Epidemiologist November 2009- January 2012 (in English)

IMPROVING QUALITY OF CARE

Conscious that there would be some loss in medical quality if activities focused only on the scaling-up objectives, i.e. quantitative results, MSF teams enhanced their efforts to improve the quality of care of the various pathologies linked to HIV/AIDS infection: tuberculosis co-infection, malnutrition, and opportunistic infections. New protocols and diagnostic tools were tried and put in place. The staff had to be trained which made the program more complex and increased the workload. The outcomes were various, depending on the cooperation with the MoH and its staff, particularly in the hospital, but dependent also on the involvement and motivation of MSF's staff.

- **Taking on Tuberculosis treatment**

In a high HIV burden context, MSF has been considered it a medical priority to ensure timely and accurate tuberculosis (TB) diagnosis, especially for children and to ensure better management of people co-infected with HIV and TB.
With more than 80 percent of TB patients registered for treatment at Chiradzulu district hospital HIV-positive, MSF decided to get more involved in TB management and to bring technical support to the existing MoH TB programme. Early detection of TB-HIV co-infected patients and their referral from HIV clinics to the hospital started in March 2006. A "one-stop service" was established in each structure where patients could be followed for both infections. At the same time an MSF clinical officer was in charge of supervising MSF's involvement in TB activities in Chiradzulu.
The MSF team started to prescribe the WHO-recommended six month treatment protocol to TB co-infected HIV/AIDS patients under its responsibility whereas the MoH had not yet approved this protocol. As a result, for several months the non co-infected TB patients managed by MoH staff remained under treatment on the longer, eight month protocol.

In the area of tuberculosis, the government was much less reactive than for HIV and we had to fight to be able to introduce the six months' treatment which is not only shorter but also more efficient. In fact we began to prescribe it six months before the MOH decided to do so and against their advice. It was a little sensitive. Initially, we decided to prescribe six months' treatment at for our HIV patients. So in the hospital, there were HIV patients who received treatment for six months and there were non-HIV patients who had treatment for eight months, it was a bit weird. We ended up agreeing that any patient infected with TB would be treated under the six month protocol.**Dr Sylvie Goossens, MSF France Malawi HIV/AIDS Programme Medical Coordinator, from September 2005 to July 2007 (in French).**

In 2008, following several outbreaks of XDR TB in South Africa, MSF implemented a drug sensitivity study (annex 8) with the objective of measuring the prevalence of primary multi-drug resistance in pulmonary smear-positive TB patients. The secondary objectives were to describe the MDR-TB and previously treated patients, the proportion of cases with XDR, and resistance to second-line anti-TB drugs in MDR-TB cases. Within the intake that was completed in 2010, the study found there was a prevalence of only 0.7% of MDR TB and no XDR TB in the district.
Since there was no involvement by the National TB program in MDR TB at the time the study began, MSF committed to provide treatment for all DR patients found during this study via an ambulatory approach.

"MSF France Annual Activity Report Malawi 2009-2010."
As there was no MDR in-patient facility available for the treatment of MDR TB in Malawi, MSF provided rehabilitation to the homes of the drug resistant patients to ensure proper ventilation and reduced exposure to the other members of the household. Also, MSF provided special foods to MDR patients during the most difficult periods of treatment to help with the side effects. Testing and prophylaxis were made available for members of MDR TB patients' households.(...)
During the course of the study, the National TB Program launched their drug resistant program with the opening of a new laboratory in Lilongwe. Therefore, the MoH has access to a lab that can test for drug resistant TB and is now able to provide treatment for drug resistant tuberculosis.

Even after several years TB management remains problematic, as in theory the responsibility is shared between MSF and MoH but the MoH staff put in charge are not supervised enough. In practice this sharing is difficult to undertake because of the lack of collaboration between MSF and MoH staff.

Though TB remains among the top priorities for MSF, the introduction planned for 2011 of GeneXpert, a new diagnosis system has been postponed due to negotiation delays with the MoH.

Across the country, while the number of detected cases increases the number of people treated does not grow in the same proportion, because the MoH healthcare system is not able to manage them.

- **Adapting drug protocols**

For HIV/AIDS the main changes in drugs protocols, by reducing side-effects and limiting the number of pills, have always aimed at facilitating drug compliance and improving treatment quality, thus helping to simplify the process and scaling-up in a number of patients.

These changes in drug protocols were undertaken by MSF following the issue of new recommendations by WHO and the approval of the Malawian health authorities who more or less implemented the same changes in their own national programs a few weeks after MSF. Apart from the replacement of Triomune 40 by Triomune 30 as a first-line treatment and the introduction of Kaletra as a second-line, which wasn't actually problematic for the government, there was no change in drug regimen during the first ten years.

In October 2007, the Deputy Programme Manager on the desk asked the field team to look at the possibility of introducing Tenofovir for first-line. This drug, which has been given since 2005 in Europe and the USA has less side-effects than the current first-line drugs, but it is more expensive. Permission was refused by the health authorities of Malawi mainly because its cost would not allow them to expand its prescription to all districts in Malawi.

MSF's real innovation was mainly in 2004 when it raised the CD4 count threshold to initiate pregnant women on ARVs, from 200 to 350.

Médecins Sans Frontières France – Chiradzulu District, Malawi – Avril 2004
Report from Dr Nicolas Duriez

Table: How protocols have changed

The following table indicates differences between the protocols MSF introduced early in its programme in Chiradzulu, and changes it later made to facilitate expansion of the numbers of patients on treatment.

"Before simplification"	"After simplification"
HAART inclusion/follow-up only at district hospital.	Inclusion/follow-up extended to 11 local health centres, 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 1-2-3 plus CD4 count <200, OR pregnant women in PMTCT program plus CD4 count <350, OR HIV stage 1-2-3 plus CD4 count <15% (for children).
Applicants' eligibility reviewed by selection committee.	Clinicians and counsellors make assessment of inclusion.
Retained patients attend two ARV counselling sessions before treatment.	First counselling session in groups of 5-6, second session is one-on-one and is one week

	later at hospital or two weeks later at health centre.
HIV clinic open 3 days/week.	HIV clinic open five days per week.
HIV clinic conducts ART and opportunistic infections consultations.	HIV clinic focuses on ART, all opportunistic infections reviewed at outpatient department.
Testing only at district hospital.	On-site rapid testing extended to health centres.
First-line protocol: AZT/3TC/NVP.	First-line protocol: fixed dose d4T/3TC/NVP (change made to reduce AZT-related haematological toxicity and to assist adherence through use of FDC).
First-line available in 4 pills.	First-line available in triple FDC, two pills per day.
Only clinicians performed diagnosis and treatment of OIs, and followed-up stable HAART patients.	Nurses trained in OI 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 centre 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 signs of clinical deterioration).

Management of HIV/AIDS Chiradzulu project, September 2004

Patients must:

- *Be HIV positive (even children)*
- *Be medically eligible*
- *Be **free of any diseases:** all OI MUST be stabilised.*
- *Have undergone 2 ARV counselling sessions in no less than 1 week*
- *Be living in Chiradzulu*
- ***NO LAB TESTS ARE NEEDED** (apart form CD4 in early stages)*

Adults

- *Stage I / II and CD4 < 200/ml*
- *Pregnant women stage I / II and CD4 < 350/ml*
- *Stage III / IV no CD4*

Children

Older than 18 months: All Stages with HIV test and CD4 <15%

During the time of my mission, MSF changed from Triomune 40 to Triomune 30 in all patients, so as to reduce side effects. It also introduced Kaletra. The MOH made these changes almost at the same time as us. The person who was the head of the HIV unit was very responsive. In general, when we wanted to make a protocol change, we discussed it with them and then we made it. And a few months later it was implemented at the national level. MSF was always some months in advance in bringing about the change but it was always motivated by the emergence of new drugs or new WHO protocols.

At the end of my mission the first-line treatment remained the same but we were beginning to discuss changing it.

Dr Sylvie Goossens, MSF Malawi HIV programme Medical Coordinator, from September 2005 to July 2007 (in French).

In October 2007, a month after my arrival, Arnaud Jeannin (Deputy Desk Manager) said to me: "It would be good to do a test or a little research to start the implementation of Tenofovir and stop this damned D4T." That was in 2007, Tenofovir was already around, but the cost of it was much less affordable than D4T. So, this attempt at initiating a new protocol was not one taken at ministry level. Internally, I don't know if there was any "resistance", but there must have been, [because] even if it is an approved drug, it needed to go through a kind of trial, as this would have been a new protocol. It was quite complicated. There were a lot of lab tests required. But Arnaud has worked hard on it in spite of it all and I think he was right.**Michaël Le Paih, MSF France Malawi HIV/AIDS Programme Head of mission, from September 2007 to July 2009 (in French)**

When the Global Fund began to have money and distribute drugs, when antiretrovirals were strongly in the ascendant, national programs set themselves to develop their management plans. However, national programs in terms of training and supply have a lot of inertia. Training staff in a new regimen takes huge energy on their part. Even if there are molecules such as Tenofovir © which are much better than D4T (this has been recognised for years now), making governments take action and to get rid of D4T to implement Tenofovir © which has less side effects, that takes a long time. Without taking into account that it is a bit more expensive and cost is a component that governments look at too. If the drug is more expensive, with the same sum of money they will treat fewer patients. So this represents a huge inertia that needs to be shifted. And us within this, as we are very embedded in national programs, we are embedded in this inertia. Governments are not going to say: "There is a new molecule, try it in Chiradzulu, and we'll do something else in the rest of the country." They believe that the staff with whom we work, they are MoH staff who must implement MOH protocols. They authorise us for certain pilot tests if they have a strong rationale and fall within clinical research.
Dr Szumilin, MSF France medical department Aids advisor, from 1998 (in French)

In the hospital, different drugs protocols were used by MSF and MoH staff. Therefore in October 2009, with the intention of improving the collaboration and integration of MSF and MoH staff, it was decided to harmonise general protocols such as for malaria, or the use of painkillers as well as protocols for treatment of opportunistic infection, TB and with ARVs in the hospital and in health centres.

In 2010 the WHO changed its first-line recommendation to a Tenofovir©- based therapeutic regimen. However the Malawi authorities introduced this regimen only for certain groups such as pregnant women and TB patients. A full implementation of Tenofovir in the first-line regimen was not possible due to lack of finances.

In 2011 MSF's proposal to introduce first-line Tenofovir throughout the Chiradzulu programme was again refused by the Malawian authorities.

MAP for Malawi, October 2009

During the next few years, MSF needs to determine those areas where we can harmonise our ART protocol to be more in line with those of the MoH. This should be strategically divided into:

1. *Those areas where MSF is willing to consider changing its protocol*
2. *Those areas where MSF is NOT willing to consider changing its protocol. Note : MSF will need to take responsibility for the drug supply for the district on these particular regimen*

These two categories can be dealt with differently.

- *For the first, this will be a gradual process with clear guidance from coordination on the steps to take to implement these changes*

- *For the second category MSF will need to be involved at the central level with advocacy toward the MoH and donors to change the national protocol and operational research supporting these protocols.*

The new medical focal point will need to begin this process as soon as possible with a detailed review of MSF's current protocol, where it differs from MoH and where we can already start to make changes. This will also be the blueprint for planning the integration of protocols over the 3-5 years and for developing our approach toward the government and donors on the various regimens that we may not agree with.

- **Nutrition assistance**

March 2006 onwards, nutritional support was delivered to patients that were severely malnourished and preventatively to patients that were considered at risk of developing malnutrition. They would receive some Ready-to-Use Therapeutic Food (RUTF) that was locally produced.

This distribution were criticised and eventually transferred to MoH and their partners (UNICEF) for lack of proven effect (over HAART) on the health of the patient. It was however maintained for children.

We started in March 2006. We used an enriched paste with milk produced by a local manufacturer, validated by Nutriset. We also had the quality validated by the MSF centre in Bordeaux. We never had a problem of supply or quality with this local producer. It was the equivalent of Plumpy'nut ©, except that it was in pots rather than sachets, so the viable duration for consumption was shorter. We gave it to all children born to HIV-positive mothers and in the early weaning phase, all HIV-positive pregnant women, all patients hospitalised with opportunistic infection, all TB patients, all patients who were losing weight, all patients who had a BMI well below normal. Basically, we gave it to almost everyone ... But in fact the dosages were different. Those who were really malnourished received the equivalent of three pots per day and the other received only one pot. So there was a curative arm and a preventive arm. The preventive arm was heavily criticised and was dropped. But we kept this enriched paste for the malnourished patients.
We tried to measure the impact with the epidemiologist who was there at the time. We did a type of analysis to the extent that we could. But unfortunately as usual the records were not always properly completed, some had even been lost. The desk found that the study this had not been done according to the conventions and that its results would therefore not be meaningful. The actual results were a little rough. So, this analysis was never taken into account. But we still had a lot of contact with the College of Medicine in Blantyre who also had an HIV service and had established a real study with a real protocol to see the impact of nutrition on HIV patients and the progression of the disease. But there was nothing of note in these studies to suggest that improved nourishment of patients, preventively, could slow the progression of the disease, and ensure that the viral load was more stable for longer.
Dr Sylvie Goossens, MSF Malawi HIV programme Medical Coordinator, from September 2005 to July 2007 (in French).

Notes taken by the Head of Mission on the visit by Rony Brauman (ex MSF president and CRASH member) to MSF's Chiradzulu programme, August 2008
Nutrition, we (CZ & others) are going too far on searching whatever results on efficacy. We should stick to provide food for patient within criteria but not going further than monitoring simply the use of PPN.

From 2008, tracers were in charge of distributing this nutritional support. New nutritional protocols were established to cover only patients with clinical criteria such as severe malnutrition or PMTCT weaning period.
Since 2010, the RUTF part of the nutrition programme has been covered by UNICEF in several pre-qualified health centres.

- **Support to the hospital**

Needing a referral health structure, MSF had been maintaining its support to Chiradzulu Hospital in internal medicine and TB services for HIV/AIDS-related health care.
But the implementation of that support remained very difficult and unsatisfying. One of the main difficulties was the organisation of task-sharing between MSF and MoH staff, because of the lack of motivation and absenteeism amongst the MoH staff. As a result, for years MSF had been working in substitution of the MoH. Faced with medical and administrative difficulties, MSF teams regularly questioned the rationale for their own presence in the hospital.

There were wards that were managed by the MOH and others which were managed by a mixture of MSF and MOH staff. So there were MSF clinical officers and MOH clinical officers. Initially, the MSF staff was only supposed to see the HIV patients and the MOH staff the other patients, but this proved unworkable. After much discussion we decided that the MSF staff would see all patients, sharing the tasks with their MOH colleagues. But even if in theory each time there was supposed to be an MSF and an MOH clinical officer there, in practice the MSF doctor always found himself on his own, because the MOH staffer was still in training, on leave, ill, or just absent.
Dr Sylvie Goossens, MSF Malawi HIV programme Medical Coordinator, from September 2005 to July 2007 (in French)

In September 2006, MSF introduced incentives for some of the hospital MoH staff in order to motivate them. For a while this yielded some positive results but only in terms of attendance. The quality of nursing care did not improve to the standard expected.
In 2008-2009 GTZ (annex 9) carried out a study on the impact of incentives in Chiradzulu district health structures. It showed that incentives had almost no impact on staff attendance and motivation.

In October 2009, MSF decided to plan a progressive reduction in incentives over the following three to five years.

In the meantime, the efforts of the MoH to train and deploy more and more staff in the health structures were proving fruitful. The number of COs increased from four to more than 20. But these staff was hardly ever present as there was always an MSF medic around ready to take care of the patients.

In 2010, acknowledging this problem, MSF decided to stop replacing its own staff. Step by step each vacant position had to be filled by MoH staff.
At the same time the MoH District Manager asked MSF to provide the MoH clinical officer with some technical support to improve management of the hospital (i.e. organising the rosters). An expatriate physician was assigned as medical advisor along with an expatriate nurse to work with the staff on day-to-day management in the wards.

Shinpei Shibata, MD, IPD referent doctor (TB ward/Boma clinic/paediatric ward) MSF F Chiradzulu 1/10/09 –29/06/10 Handover/End of mission report
You most likely will face human resource problems at TB ward. My understanding of "ensuring a good quality of care for patients" was not only to do my best to make MOH CO available with help from deputy DHO (Mr. Kandaya), but also to help patients directly when there is no MOH CO available. Therefore, I rounded on patients at TB ward often. I fully understand that it could perpetuate the human resource problems by a MSF staff constantly providing care at TB ward when MOH is not willing to provide COs there consistently. However, I just could not simply leave patients unattended for days when they need medical cares. There have been suggestions from the medical focal point and field Co that I should leave the ward alone. However, doing so would have been against my

ethical belief as a doctor and against my understanding of what humanitarian organisations like MSF would chose to do in a situation like this. I did what I believe was right for me. It is up to you and the current medical focal point to decide what would be the best for people in Malawi.

In the hospital, I was working in the wards for MSF. It was the same work as the MOH staff work. But our colleagues from MOH when they would see that we were working from morning until afternoon then they were just making themselves comfortable because they would know that even if they didn't work the patients were not dying: they were in good hands, in MSF hands. **Charly Masiku, MSF France Malawi HIV/AIDS Programme Clinical officer, from 2007 to 2010 then Deputy Medical Coordinator (in English)**

Another problem lay in the hospital's HIV/AIDS testing. Many inpatients, while they were obviously suffering from HIV/AIDS infections, were not put under HAART because they had not been tested. It was particularly crucial for the TB patients whose probability of co-infection was high. So it was introduced that they would be given all the information and counselling they needed to voluntarily test, while not forcing them to be tested.

When I arrived, there was no systematic testing of the hospital patients. There was only voluntary testing. There were big discussions about this within the counselling team. Some said it was essential to test everyone, that it could save their life, etc. But the majority of us were against it. You should never test someone against their will, in case they are not psychologically ready to accept the diagnosis. In the end we found a compromise, a somewhat intermediate solution: all inpatients would be routinely seen by a counsellor, but not so as to be tested. It was just a matter of speaking to the patient, informing them, in a one-to-one. Normally, the rule was that patients should go back to their hospital room and then return voluntarily if they wanted to be tested. Even if they gave their agreement, they were not to get tested right away. We had to avoid them feeling obliged to accept only because they were impressed by the authority of the white coat. It had to be truly voluntary, taking that step forward independently. But at least everyone benefited from a real counselling session, not just a chat ... This was implemented for all the internal medicine departments, but obviously more intensively for TB patients. At first, when the TB patients were not routinely tested for HIV, there were no doubt many who were infected who did not know, and who were treated with the eight month protocol.
Dr Sylvie Goossens, MSF Malawi HIV programme Medical Coordinator, from September 2005 to July 2007 (in French).

From 2007 the number of hospital admissions significantly increased, partly due to the use of MSF mobile team cars for referral. But the mortality rate remained between 15 and 20% because many patients hospitalised were HIV-positives in an advanced stage but were not aware of their status and therefore had not started treatment in time.

- <u>Enhancing biological diagnosis and follow-up tools</u>

While they were disregarded at the beginning of the program, laboratory tests, like measuring CD4 and viral load, came back as important tools.

This comeback was also facilitated by progress within the industry. As early as 2003 a CD4 count machine, the Partec flow cytometer, which had been recently released, was tested in the Chiradzulu laboratory. After some preliminary difficulties it appeared to be very reliable. Overall it was able to test CD4 counts daily for many more patients than the original manual method.

Operations Meeting February 25, 2003: Chris Brasher

The machine we have now can perform about 30 CD4 tests per day, [which] is insufficient given the increasing number of patients. We have started to include patients without counting their CD4 and find that the clinical criteria are more stringent than the biological criteria. We recently ordered a machine put on the market by a German company that is supposed to be able to perform 400 tests a day. It is transportable and particularly suited to the field.

In the meantime, the teams had started to see many more patients suffering from side-effects, and began to ask for more laboratory equipment.

At the beginning of my mission, in 2005, we only checked CD4 occasionally, when there was a problem. Regular CD4 monitoring for all patients was put in place and laboratory activities doubled or tripled as a result. Control of CD4 became a regular activity and mobile teams returned daily with samples for laboratory analysis. This wasn't the case at all at the beginning when we only had one machine. There were three by the time I left. And then we started to implement monitoring of viral loads, but not in our laboratory, and just for patients suspected of failure. Samples were sent from Chiradzulu to validated labs in Blantyre which did the viral load tests.
Dr Sylvie Goossens, MSF Malawi HIV programme Medical Coordinator, from September 2005 to July 2007 (in French).

Allowing for earlier detection of any potential treatment failure, these laboratory tools also contributed to lighten the burden of scaling-up. In effect patients detected with a very low viral load would be integrated to the Six Month Appointment's system while the team's efforts would be concentrated on patients with treatment failure also detected by the tests.

However these tools still came with management constraints as the blood samples needed to be collected and transported quickly to the laboratory. Thus the development of simplified laboratory monitoring of patients was proving to be more and more necessary.

In 2005 Helen Lee, a researcher from Cambridge University proposed a partnership with MSF to develop a viral load rapid test, called SAMBA (Simple AMplification Based Assay). After various episodes, MSF decided to collaborate with the Cambridge team by allowing them to make clinical tests in the Malawi program. In late 2011 the system was developed and the MSF team was waiting for authorisation from the Malawian health authorities to start using it regularly in its program.

Transmissions, MSF Weekly Newsletter on Operations n°173 29 June 2011

The feasibility study in actual field conditions for SAMBA (Simple Based Amplification Assay), which took place in March in Chiradzulu, has produced its first results. This test, developed by a research unit in Cambridge, is a semi-quantitative and rapid viral load test, able to be used in laboratories that are not very specialised. The first results are very encouraging as they reveal a 98% correlation with the reference test ("Gold Standard"). This week, MSF and the Cambridge research unit have also obtained permission from the President of Uganda to continue the clinical trial in Arua; the idea here is to repeat the experience but this time with a single blood sample taken from the fingertip and drawn up by capillary action. This marks a further step towards simplification of care: no longer does it require a nurse to take blood.

At the end of this second trial, if it proves conclusive, a third trial should be conducted again in Malawi. This would consist of a test that is not semi-quantitative but qualitative (detection threshold of 1000

copies of the virus), i.e. the presence or absence of infection. If this trial has positive results it will facilitate the early diagnosis of infection in infants.

We met Helen Lee late 2005. She asked MSF for €2 million in funding for research and development of SAMBA. But MSF and in particular CAME and Epicentre were too much demanding in terms of patents being gratis, so she managed to find the money by herself. In 2007, the MSFF President, asked the medical department if anyone was willing to follow up on this "Franco-Cambridge proposal" and we agreed. It involved "lending" our fields for clinical trials.
First, Helen circulated a questionnaire within the MSF movement to determine expectations regarding the nature of a semi-quantitative test that was constrained by field conditions. (...) Semi-quantitative means that it does not indicate the number of copies of virus in the patient's blood but whether the number of copies is below or above a certain threshold. After several meetings and expert advice, we said that we could work with 1000 copies as the benchmark. Which means that if a patient shows less than 1000 copies, OK; but if the result is more than 1000 copies, it's not clear whether that means 1500 or 100,000. So usually we would re-give that patient the short speech on adherence, then some time later we would redo the SAMBA test and see if the result was still above 1000. If this was the case, we would put him or her on second line treatment. (...)
Helen soon established a system for amplification of the virus and its semi-quantitative measurement, these being the two final stages of testing. But her main problem remained for a long time the first step which consisted of extracting the virus from the patient's plasma before putting it in a simple machine to amplify and measure. It took time. I do not put pressure on her because I knew it took time. And she eventually found the solution.
From extraction to measurement requires two hours in all. She has automated many steps. This still requires a certain amount of electricity though. The first SAMBA test under field conditions was carried out in our program in Malawi with Daniel our Ugandan laboratory technician who is now a SAMBA specialist. He went to Cambridge twice, to be trained. The first clinical trials began in Malawi in February 2011. Cambridge left the machine there for us and now we would like to have government approval to use it. But for that Helen still has to present the results, which are excellent, to the Ministry of Health. Of course she will also publish them. With publication and peer recognition, the validation process to registering the machine will move more quickly.
Dr Elisabeth Szumilin, MSF France medical department Aids advisor, from 1998 (in French)

We knew that eventually, for patient monitoring, the king of all tests would be viral load. CD4 cells are very interesting because they give a sense of the immune system, but an indirect and delayed sense of the infection. The test - which is not perfect in fact - but which gives a direct idea of the infection's intensity at a given point, is viral load. So we were pretty happy to be able to imagine having a system for measuring viral load able to be used at health centre level, working with just a car battery and a lightweight device the size of one to two shoe boxes, which could performs the few tests required every day for ten dollars or so each... This greatly reduced the cost of investing in laboratories, which requires air-conditioned rooms, heavy machinery, maintenance costs.
Dr Jean-Hervé Bradol, MSF France President from 2000 to 2008 (in French)

In a very long-term perspective, simplified diagnostic tests were seen as a tool which would help to build patient capacity to manage their own health. Thus by lightening the medical staff's burden, it would allow them to take charge of more patients.

In AIDS patients the issue is getting good results through to the end while waiting for a very powerful therapeutic or preventive tool. But we are not there yet and in the meantime we must think about managing patients for the duration. Patients today have become very observant over the past ten years. They are all people who have seen their wives, their cousin, their boyfriend, their girlfriend, die of the disease, so they take their pills because their reality motivates them. But gradually much of that incentive will be lost, so we'll have to help patients take ownership of their disease and this will be done through simple tests. In Malawi, there are plans to put the rapid viral load test into health centres. There are also patients and health systems that do not want consultations happening every month. Half of these consultations are unnecessary. The economics of health has become a real concern. Change is heading in this way and it makes decentralisation possible, to take the most sophisticated

techniques for care close to the patient, whether that is the medical institution closest to the patient's home, or as good as in the home. If you want to get the patients to be observant over many years, the team must transfer responsibility for treatment to the patients, which requires monitoring tools to catch up. When we trust the patient, we are nonetheless more comfortable if now and then we can do a viral load test to see if our confidence is not misplaced. And we really need to give this trust, otherwise we will not be able to absorb this mass of patients, especially in some homes where the disease is very present. We need this type of tools. They exist in developed countries, but with a more sophisticated design, so you can't transfer the technology. We did it a bit with the machines for CD4, but it's hellish on a daily basis.
Dr Jean-Hervé Bradol, MSF France President from 2000 to 2008 (in French)

TOWARDS INTEGRATION WITH THE MOH

From 2004, with the start of the Global Fund's ARV funding in Malawi, MSF was no longer the only organisation implementing an HAART programme in Malawi. But in 2007 the team was still thinking that for the health authorities of Malawi the MSF Chiradzulu program remained a model for their own national plan.

MSF has been a model for the government. The MOH was always moving ahead in the same direction as us, just a few months behind. I think our work really served as a guide, really helped them to move forward. Every time we innovated in some way, they voiced a few doubts and once they saw that it worked on our side, the launched it at national level. In all the meetings, they always did a historical recap of what MSF had done.
Dr Sylvie Goossens, MSF Malawi HIV programme Medical Coordinator, from September 2005 to July 2007 (in French).

For the period 2006-2007, Malawi's national program, coordinated by the National Aids Commission (NAC), had a 77 million dollar budget. In June 2006 treatment had been initiated in almost 60,000 patients in the public heath structures of Malawi, 61% of them women and 6% children. However the detection of HIV-TB co–infection was still weak (15% compared to 71% in MSF structures). Low also was the number of patients put on PMTCT treatment (1%). In Oct 2006, VCT was being conducted in the 11 public health structures of the district but only half of the people diagnosed with HIV would come to be treated.

In 2008, 221 structures in Malawi were distributing ARVs for free. A total of 141,470 patients were on HAART treatment, representing 50% of the number of eligible patients.

In January 2008, based on this positive evolution, the MSF Malawi desk started planning to handover the MSF program to MoH between 2010 and 2011. In early 2009 the decentralisation and task-shifting process was completed in the Boma clinic and in Chiradzulu district's ten health centres where the full range of services for HIV/AIDS patients was available: testing and counselling (done by MoH HSAs), ARV initiation and dispensing, counselling, health education, PMTCT One Stop Service, Early Infant Diagnosis (DBS), SMA, nutritional support for the malnourished (children to adults), CD4 testing, viral load and TB testing (though still done outside the health centre) and tracing.

Desk Presentation to Executive Management Team of MSFF Chiradzulu AIDS program – 21 January 2008
Timeline 2008-2011
2008 - Completion of the decentralised model
2009 - Consolidation of access to care (Module 4) and access to medication (HSA)

2010 - Evolution of the handover of simple versus complicated cases / Evaluation Phase
2011 – Handover to the MoH, closure of MSF programme

However in 2009 it became obvious that the MoH was not able to cope with the increasing number of patients, that a handover process would take years, and that a clear strategy of capacity-building at MoH level was necessary.

Over 2009 and 2010, MSF efforts were supposed to be dedicated to stabilise the project with a focus on integration of MSF activities into the government system. The main objectives were to complete the training courses on complicated cases and ensure staff attendance in the health centres. But in 2010, the MSF team had to implement a massive vaccination campaign in response to a measles epidemic outbreak and this plan was not completed.

MSF France Annual Activity report Malawi 2009-2010

It also became necessary to find ways to do more in terms of simplifying care and treatment. In an effort to understand how best to approach this kind of simplification while still maintaining the objectives of improving patient retention and outcomes, it was vital to have a firm understanding of the cohort in Chiradzulu; who is being served, what constraints do they face in accessing care and remaining on treatment and what support do they have in their communities?
(...)
The areas of the program where special attention was focused during this time included the finalization of providing the complete package of services in all the MoH district level health facilities, training of staff on these services, and improving and maintaining quality care through supervision and close collaboration with the MoH.

In 2009, MSF also moved its headquarters from Blantyre to Lilongwe in an effort to be more involved in central level programming discussions, to be an active participant in coordination meetings, and to facilitate a closer technical relationship between MSF and the MoH on a variety of levels.

With a cohort of active patients reaching 23,136 by the end of 2009, the focus of the project for 2010 was on longer term objectives such as rationalization of services, deeper involvement of communities in patient care and follow-up, as well as a simplification of treatment as recommended by the World Health Organization. By the end of 2010, the number of people being actively followed in the program totalled 26,851.

Important work was also done with the Ministry of Health in Chiradzulu to align services in a more integrated matter, such as nutrition, treatment guidelines and data collection, and to work on problem solving together in key areas, most notably drug accountability and staff presence in the health facilities.

During these two years, MSF continued to support the MoH HIV activities in 9 peripheral health facilities: Mauwa, Bilal, Chitera, Mbulumbuzi, Namadzi, Namitambo, Ndunde, Nkalo and Milepa. At the central level, this on-going support includes the HIV Boma clinic located within the district hospital, and the in-patient wards that have an important burden due to HIV (TB ward, male and female wards). MSF also responded to acute needs that the MoH face, such as during outbreaks and other emergencies.

In the meantime in 2009, the MSF coordination office was moved from Blantyre to Lilongwe, the political and administrative capital of Malawi, with the objective of facilitating MSF's efforts to get into discussions and policy-making processes at national level.

- **Global Fund stock-out**

At the same time, the Malawi health system appeared to be more and more fractured. In 2009 and 2010 there were several stock-outs of drugs due to delays in disbursements from the Global Fund, to management issues in the supply chain, and to problems in the interaction between the MoH and procurement agencies.

Therefore MSF committed to ensuring continuity of treatment for its patients in Chiradzulu. It was decided to provide buffer stocks while developing an appropriate advocacy strategy alongside.

Annual plan 2010, MSF France HIV Care and treatment program Chiradzulu, Malawi

The most pressing issue is the problem of ARV supply. As we know, in 2009 GF was 5 months delayed in releasing its funds for the purchase of ARVs. This means that the order that was supposed to arrive in Malawi in July 2009 is still incomplete. However, only a small amount of first line drugs are still pending. The problem we are facing now is the next order and the next round of funds to be released by GF. Already they are late, and we know that a delay of a minimum of 4 months is expected from the time the funds are released up to the moment the ARVs will arrive in country. This means in the best- case scenario we can expect the next 6 months order to arrive in Malawi in April 2010.

Much of our current stock will run out in January. In other districts, they expect stock outages in December. While we know that some regions of the country experienced outages of first line drugs for the first time since the national HIV program was launched in 2004, it is not clear how many facilities are still turning their patients away. An emergency order to 3 months supply of ARVs has been placed with Paris to be delivered as soon as possible to Chiradzulu, and a second 2 month buffer stock has been order and should be maintained in the logistics warehouse in Bordeaux until needed. This way, if any drugs are close to expiration, we can share them with other projects in Uganda or Kenya.

On a practical, operational level, the only two districts in the southern portion of the country (and potentially the entire country) that have access to ARVs from implementing partners are Thyolo with MSF Belgium and Chiradzulu with MSF France. This means, come the end of the year, in those health centres that border neighbouring districts, we can expect to see an increase in the number of patients coming from those regions experiencing ruptures in their stocks. All of the medical staff have been briefed, as well as the health educators to give the health talks in the waiting areas, to stress to the patients coming to the HIV clinic that no matter where their village of origin, we will treat them. What need to be avoided are people who are already on ARV pretending to be new patients in order to access the medication. As initiation in Chiradzulu is based on CD4 count, any "new" patients would not be given any ARVs until they had a rapid test, and the results of their CD4 test back. This could mean interrupted treatment and an increased risk of developing resistance to their treatment regimen. We will monitor these numbers in order to plan for any significant increase in drug consumption.

We will also work with the Ministry of Health and the HIV Unit to draw up and distribute to all ARV sites in the country instructions to follow for the various treatment regimens in case of stock outages so that patients are not just turned away as happened with the last supply rupture.

At the end of 2010 the Global Fund rejected the Malawi proposal for Funding Round 10. The proposal was considered to be too ambitious and there were concerns about Malawi being able to implement it.

Annual plan 2010, MSF France HIV Care and treatment program Chiradzulu, Malawi

Malawi's main donor for HIV and TB is Global Fund. In terms of ARVs, Global Fund is the exclusive donor. This year, the national programs of malaria, TB and HIV were all presented separately. The applications for TB and malaria were submitted through the round system (round 9 to be exact). The malaria application was approved while TB was not. In part, the reasons behind this denial include some issues Global Fund has with the bookkeeping system of the Ministry of Treasury, as well as the fact that there is not National TB Director. Apparently this cannot be appealed. This cut from GF as well as a 40% cut in the national budget for tuberculosis leaves Malawi's national TB program with $2 million for the entire year of 2010. This is incredibly disappointing as the national tuberculosis lab in

Lilongwe has finally become operational meaning it is possible to detect drug sensitivity and multi-drug resistant tuberculosis in country rather than shipping samples to South Africa. Without funding, the fate of this program along with the national drug sensitivity survey that was planned, are up in the air.

The HIV grant application was submitted through the new National Strategy Application (NSA) which Global Fund (GF) considers to be a learning wave. The idea is that this application should function as an extension of the National Action Framework of each country, and the gaps in funding identified are then requested to GF. The request for Malawi was for $375 million over a 3 years period. Malawi, along with Kenya was both unsuccessful. While there is the opportunity to appeal within 28 days of the official decision, the prospects for being a successful appeal look dismal as they are allowed to only "demonstrate factual and obvious errors" that were made by the technical review panel. One of the main arguments against the Malawian application was that it was not "innovative enough". It is difficult that the only donor for ARVs would refuse funding for his huge national program which has been able to put over 250,000 people on treatment in under 6 years in a country with one of the worst patient to medical staff ratios in the world. It also puts in question the ethical obligations of GF and other donors that have made extensive promises for funding HIV programs, including the one in Malawi. If this NSA appeal is unsuccessful, the only option for Malawi is to try with round 10 which is planned for May 2010. This is worrisome as this leave a large portion of the operation costs for 2010 unfunded.

- **New WHO guidelines**

In the meantime, in late 2009, WHO had come up with new protocol recommendations relevant to management of HIV/AIDS patients.
As a result, in 2011 an important part of the MSF team's efforts was dedicated to the training for initiation of these new protocols. Several positions held by expatriates that had been suppressed due to decentralisation were temporarily re-opened to supervise the training of staff in the new protocols and modify the set-up. By October 2011, 300 staff (50% MSF and 50% MOH) had been trained in the new treatment protocols.

As a result of the threshold for HAART initiation being shifted from a CD4 under 250 to CD4 under 350, the MSF ART cohort increased by 20%.

Concerns were raised regarding the MoH programme capacity to implement the new WHO guidelines, considering the Global Fund's refusal to fund Malawi within Round 10 and the withdrawal of funding by the UK Department for International Development (DFID). Eventually, these new protocols were partially introduced in the Malawi national plan and reserved for specific groups of patients such as pregnant women and those co-infected with TB.

Malawi 2011 "fiche projet"

Public Health Context
In November 2009, the World Health Organization (WHO) has released their new HIV treatment recommendations calling for earlier treatment and new treatment regimes. Only some months later, Malawi had to submit both a request to the Global Fund (GF) to reprogram rolling continuation channel (RCC) funding and a proposal to GF for a grant in Round 10 (RD). Implementation of the new guidelines was to be funded in the first instance from reprogrammed RCC funds, with RD 10 funding coming in later to support.
Basically, a massive roll out of the new WHO guidelines was proposed with a raise of the CD4 count threshold from 250 to 350, an introduction of TDF based therapy for adults and new regimens for children and with an implementation of lifelong antiretroviral therapy (ART) for HIV infected pregnant women (so called option B+). The proposal was also including new approaches such as male circumcision and introduction of the so-called family care clinics. This proposal was requesting for one of the most important grants of this round –more than 560 million US $ for a five year period. In December 2010, Global fund rejected the proposal as too ambitious, doubting the country's capacity to implement all new interventions and approaches as proposed. The lacking strategy for the transition to the new guidelines, concerns regarding human resources capacity and major flaws in the budget

are also mentioned among the reasons for the refuse. After the RD10 rejection Malawi received the official request from GF to submit a formal proposal for the reprogramming of RCC grant – including revised work plan and budget. While in December health authorities were still evaluating the possibility to maintain the implementation of the new guidelines (to be financed principally with the RCC grants) it is now evident that the available funds are not sufficient to finance this option? At the time of writing different strategies are under discussion but RCC funds are assured at least until 2013.
Changes in funding levels and major problems in coordination between the main donors, UNICEF as the procurement agency, and the various government offices had caused severe problems in the drug supply in the whole country and directly affecting MSF projects in 2009. Stock outs were also occurring in 2010 but to a minor extent and the health authorities, acknowledging more easily the gaps, have been more active even though the deep routing problems in drug management, storage and dispatch in the country have not been addressed.

The recent evolution risks to jeopardise the up to now relatively successful scale - up process in Malawi. In the second semester of 2010, there were approximately 225,000 people alive and on treatment with 396 sites across the country providing ART. But only 58% of those estimated to be in need of ARVS are on treatment, and only 34% of HIV positive pregnant women are in the country where people can be initiated on 2nd line alternatives. Only 52 facilities in Malawi have CD4 machines and generally many are not in working order. As a result, approximately 70% of patients are initiated on ARVs with staging only. [...]

Review activities 2010- Decentralisation
Preparing the implementation of the new recommendations some reorganisation of the project structures was necessary. Lack of collaboration in- between the different parts of the project and a lack of a global vision of the project was identified a major problem. A 6-months plan identifying and sharing the objectives of the different teams is elaborated by national and international field team and evaluated regularly. Thus, a more transversal approach of organisation, information sharing and evaluation of activities has been introduced –aiming for a better coordination and support between the different departments and to avoid duplication.

The shortages in ARV supply also pushed more patients from other districts to seek treatment in Chiradzulu where MSF continued to ensure ARV supply for its programme. MSF came to realise that the programme thus had de facto coverage beyond the Chiradzulu district population, extending to the population of South Malawi, and that its objectives had to be readapted while considering this reality.

MSF Chiradzulu HIV AIDS Program Activity report 2009-2010

On average, 55% of patients of the sample are coming from outside Chiradzulu district, and 39% of these patients have a health centre closer to their home that dispenses ARVs.

As for why people come to Chiradzulu for their HIV care, the main reasons given were shorter wait time, followed by better clinic hours (see Table 3). 42% of patients surveyed cited staff behaviour and drug availability as their reasons for coming to the district.

Table 1: Reasons for coming to Chiradzulu for patients with a closer health centre.

Waiting time is shorter	*74%*
Clinic hours are better	*71%*
Staff was not nice at closer health centre	*42%*
Clinic ran out of drugs	*42%*
Other	*41%*
Avoid stigma	*36%*
ARVs were not available in closer health centre when starting HAART	*25%*

For the 41% who responded "other", these main reasons include because they know MSF gives better care (N=16, 21%), good availability of CD4 results (n=4, 5%), they are escorting someone else (n=3, 4%), stigma from family (N=2, 3%), and referred by clinicians (N=2, 3%).

There are a significant proportion of patients (36%) that feel enough stress from stigma that they are willing to travel to another district for their care and treatment. This indicates that much work is still needed throughout the country at the community level on issues of stigma and HIV.

Most of these issues are not likely to be remedied any time soon, as they are linked directly to issues of limited resources, staffing shortages, supply chain management and the financial health and stability of the national program. It does indicate on the one hand that we would expect a slight increase of patients in Chiradzulu if there is another drug outage. It also suggests that as the MoH program expands with more ARV facilities and more staff, there may be a reduction in patients coming from outside of the district.

MSF Malawi "Fiche projet" 2011

Review activities 2010-Decentralization
At the end of 2010, MSF supports the HIV care and treatment program in 11 out- patient facilities including the OPD of the district hospital. We are currently following over 26,000 patients who are HIV+ with close to 18,000 active and on HAART. Per months, an average of 500 new patients was enrolled in the cohort and about 340 started on HAART.
The cohort in Chiradzulu is quite diverse and with the intention to better understand its dynamics, we conducted an exit survey in the 5 health centres that border other districts. It turned out that in these 5 locations there is an average of 50% of the patients coming from other districts. Most of them come to Chiradzulu because it is closer than the health facilities in their own district. A more detailed analysis and mapping is planned but anyway, the future operational planning has to consider that the project is de facto not only covering one district.

In 2012 integration of MSF and MoH staff remains a challenge. There are still persistent problems to sort out such as the lack of qualified MoH staff willing to work in rural areas and in health centres because of the low salary and various socio-economic reasons such as the difficulties of transportation and/or poor housing.

The number of consultations done by the nurses or medical assistants slightly increased from 2009 to 2010 (43.3% to 46%). However so far in the health centres, most of the consultations remain done by MSF staff.

Annual plan 2010, MSF France HIV Care and treatment program Chiradzulu, Malawi

Human resources will continue to be a major hurdle for MSF for a long time to come. Today, the MoH roster for the district is only 50% filled meaning that MSF continues to provide the staff to fill this other half of the medical staffing needs. A few very simple policies will be implemented in order to facilitate a gradual process of integrating MoH staff. First, we will not replace any MSF medical staff that quit or are fired. We have also created a very slow schedule for new MoH staff requests that have been discussed with the District Health Officer (DHO) for the coming 12 months. While this will in no way come close to solving the problem, until there are more students graduating in the medical field, the reality is that there is no solution. However, we must remain steadfast in the pressure that we apply to the DHO in filling as many posts as possible.

Malawi "fiche projet" 2011

REVIEW ACTIVITIES 2010 - DECENTRALIZATION
Organization of the supervision changed from a vertical activity based approach (nursing, SMA, PMTCT) to a health centre based supervision. The objective is to manage our activities in the health centres more globally as HIV clinics and to improve contact and collaboration with the MoH teams. The rotation of MSF staff in all services of the health centre and full integration of HIV care in normal OPD services revealed to be extremely difficult especially in big and very busy health centres. As a first step MSF nurses rotate out of the HIV clinic and into the maternity at the health centres and the MoH nurses who work in the maternity then gets hands on experience in the HIV clinic. This is not a perfect solution but a first step to assure that MoH nurses can apply their knowledge in HIV care and to merge the respective teams. Joint supervisory visits to health centres with MSF and MoH are

regularly scheduled. These visits are important so that the MoH realises problems that come up in the health centres and for MSF to push for solutions.

ACKNOWLEDGING A PARADIGM SHIFT

The option of putting an end to the Chiradzulu HIV/AIDS programme has not been considered, for it is out of the question for MSF to leave 30,000 patients without any possibility to continue their treatment.

Moreover the outcomes of this programme are considered very positive by the international HIV/AIDS care "community".

However, in 2012, after ten years of implementing decentralisation, MSF is questioning the programme's future. A new strategy has to be designed while crucial questions remain to be answered:

- **Considering its poor experience in management of public health programmes how can MSF cope with a patient cohort which is expected to grow from 30,000 to 50,000 in the four years to follow?**
- **How can a serious and sustainable handover of the programme be made to the MoH, while the Malawi economy and as a result its health structures are collapsing?**

To answer these questions, MSF had no choice but to acknowledge that the paradigms of the programme had changed.

- **MSF's management of public health programmes**

MSF needs to let go of some control of the quality of care and strengthen the task-shifting of care to non-medical staff. But at the same time it is critical to remain aware that an HIV/AIDS patient under treatment cannot be completely exempted from medical follow-up.

In order to reduce staff workload and the time spent by the patient in the health centre, it could be considered, in mid-term, to have the SMA for stable patients evolve towards a once-a-year consultation in a health centre, mainly to check CD4 count or viral load but with only six-month drug refill.

At the same time MSF needs to work on a new approach for patient follow-up based on communities such as patient groups or traditional authorities.

By treating more and more patients MSF has most probably been participating in the reduction of HIV/AIDS prevalence in the country. From late 2011 onwards these efforts will be complemented by the implementation of a programme for male circumcision. Indeed, since the publication in PLoS Medicine in 2005 and in The Lancet in 2007 of two key articles describing the impact of circumcision on reducing the transmission of the HIV virus, the desk and medical department have been pushing to introduce this prevention activity in the Chiradzulu programme. However there has been some reluctance within headquarters for several years mainly based on fears that it could lead to a reduction in the use of other preventative means, and thus have a conflicting impact.

In 2010 circumcision activities have been included in the proposal by the Malawi government to the Global Fund, and they remain in the government's plan despite the refusal of funding.
The MSF circumcision project is therefore designed as a pilot project implemented for the government of Malawi, to which it is supposed to be handed over in the short-term while retaining minimal supervision from MSF. It will be initiated in the hospital for men of 15 to 50 years. Then it will be extended to the health centres or even implemented by ambulatory teams.

- Handover to MoH ?

In 2011, after the failure of the three year handover planned in 2008, the process of handover was re-planned over five years.
However the question of the capacity of the MoH to take over remained the same. Therefore, after having claimed for years that the MoH should find the required resources to take over the programme by itself, MSF eventually decided to acknowledge that this ideal would not be fulfilled in decades, and that it was necessary to find other ways to get these resources. It was also acknowledged that with the Malawi economy almost bankrupt there was no expectation of crucial improvement in the health system in the coming years.

MSF is now looking for a model which could ensure long term sustainable sources of funding based for instance on private partnerships such as foundations or private donors.

It has been decided to hand over parts of the programme step by step after having ensured that they will be funded by these private sources.
In early 2012 the handover of the laboratory activities to MoH remains ongoing. So is PMTCT. Counselling activities have been reorganised and reduced.

A new tracing system is being investigated with a reference person in each village in charge of getting in touch with the missing patients.

For the nutritional support the team is trying to have the remaining health centres pre–qualified to be supplied with RUTF by UNICEF.

- Operational research and innovation

Operational research will be strengthened to support these changes and strategies. According to the desk, there is definitely a need to evaluate the impact of MSF's intervention on HIV incidence/prevalence in the district. There was no initial prevalence study done at the beginning of the programme that could be used as a baseline indicator. Therefore this in-depth study needs to consider the impact and acceptance among patients of activities such as circumcision, PMTCT B+, and global access to HIV care after the decentralisation phase.
Other studies should be implemented to explore the clinical issues linked to decentralisation/task-shifting or to cohort ageing.

All along, the MSF F HIV/AIDS program in Malawi has been driven and shaped by various internal and external dynamics whose objectives often contradicted each other.
Once the drug price issue was resolved this program could have been regarded and run as a humanitarian programme, focusing on the treatment of those patients not managed by the health system of their country.

But the scope of the epidemic imposed a permanent necessity to solve the "quality versus quantity" dilemma. Indeed scaling-up has been implemented at a speed that made it more difficult to fulfil the objective of quality of care. Consequently the program had to move from only humanitarian objectives to public health ones and a relevant scope.

External factors such as evolution of the political and economical environment and scientific innovations have always eventually provided the solutions to these dilemmas.
There is no reason why these same factors would not help once again to overcome the barriers that are currently challenging this programme.