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Setting up an HIV/ART Programme in Rwanda

An MSF case study of the first two years at Kimironko health centre in Kigali

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Stockholm 2006

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Introduction

This is a report of an antiretroviral treatment (ART) programme within Médécins Sans Frontières-Belgique (MSF-B) at a health centre in the outskirts of Kigali. It gives a practical example of how to plan and perform a successful and sustainable ART programme with pre-existing resources in a low-income setting.

HIV is today the single disease that causes most morbidity and mortality in Southern Africa.[1] More than 40 million people are infected with HIV worldwide, of which 25 million (60%) live in sub-Saharan Africa, a region harbouring 10% of the world's population. This should be compared to 1.6 million (4 %) in the USA, Western and Central Europe together. In 2005, an estimated 3.2 million people in sub-Saharan Africa became newly infected, while 2.4 million adults and children died of AIDS.[2] According to WHO about 4.7 million of the HIV-infected people in southern Africa need treatment. In June 2005 still only about 11% of these received treatment, compared to about 3% in December 2003 when the WHO 3 by 5 initiative was launched.[3]

With the advent of HAART (highly active antiretroviral therapy) in 1994, using triple therapy (three drugs) to treat HIV, there exists a means of haltering this epidemic, allowing people and countries literally to get back on their feet and live a decent life. There are many obstacles on the road to ART for everyone who needs it in low-income countries; lack of economical resources, lack of political stability and infrastructure to organize the treatment, and most of all lack of trained personnel to distribute the medicines and provide a proper medical follow-up. The example of Brazil, where the government provided free ARV's for everyone in need[4], showed that it was possible and definitely cost benefit. It is important to bear in mind, though, that even if Brazil is among the low-income countries of the world, they have an HIV prevalence of about 10 times less than that of Rwanda and many other sub-Saharan African countries, and an economy that is about 10 times stronger.

Purpose

Using a state health centre as an example, the first aim of this report is to describe a model for ART in a poor urban setting where local nurses and social assistants were trained to run a sustainable ART programme only with the initiation and supervision of a medical doctor from MSF. Secondly, the patient cohort is described in terms of adherence to treatment, loss to follow up, mortality and CD4-gains.

Rwanda

Rwanda is a small country of 26 000 km² in the mountainous area of the Great Lakes – bordering the Democratic Republic of Congo, Uganda, Tanzania and Burundi. The climate is moderately tropical due to the high altitude, where the capital Kigali with 800 000 inhabitants is situated on 1500 meters over sea-level. In 2004 Rwanda had approximately 8,5 million inhabitants and one of the fastest growing populations in the world with an annual population growth of 2,8 % per year. It has been considered as one of the poorest countries in the world, and in 2000 the national poverty rate was 60% (i.e., the percentage of the population living below the national

poverty line).[5] In 2003 the foreign debt was mounting to 1200 million Euros, representing 80% of the GDP, but in 2005 Rwanda was among the countries granted debt relieves by the World Bank and this figure is now down to 12%.[6]

The "under 5-mortality rate" in 2003 was 203 per 1000 children.[7] One million children – 12 % of the total population – were orphans, cared for by impoverished families or community networks.[6] The Rwandese official statistics for HIV-prevalence among pregnant women in Kigali in 2003 was 13.5%, but reliable statistics for the countryside was not available due to lack of HIV testing facilities. According to WHO the estimated HIV prevalence in the population aged 15-49 years in 2003 was only 5,1% with 230 000 (range: 150 000-350 000) in need of treatment.[8] When this MSF-B ART programme was about to start in 2003, the estimated number of HIV positive persons in Kigali was around 110 000 and there were only two NGO's (IMPACT and Luxemburg Development) providing ART to about 1200 of them. The estimated number of HIV-positive persons in the Kimironko catchment area was about 10 000, assuming a population in need of ART around 3000.

Background and description of the MSF HIV programme in Kimironko

MSF-B is a NGO (non governmental organization) that has been working in Rwanda since 1991 and at Kimironko health centre since 2002. In 2003 MSF-B also started a parallel HIV programme in Kinyinya health centre in the outskirts of Kigali, which will not be further described in this report.

Kimironko health centre

Kimironko is an urban state run health centre functioning since many years. The catchment area covers a population of about 75 000 people in an area of about 25 km². This information is important considering the accessibility of treatment for the patients. Most people in the catchment area lived close enough to easily access the health centre, either by foot or by affordable bus-tickets.

In 2003, Kimironko health centre served the entire population in the catchment area as follows;

- out-patient department (OPD) divided on two rooms; one for non-HIV and one for HIV patients
- four wards for hospitalization (TB-ward, maternity ward, male and female ward) with a total of 26 beds
- family planning programme
- antenatal care including a governmental PMTCT programme (Prevent Mother To Child Transmission) giving a single dose of nevirapine to the mother at the beginning of labour and to the baby within 72 hours after delivery
- +/- 50 deliveries per month
- national vaccination programme
- service for tuberculosis treatment according to the national programme with directly observed therapy short course (DOTS)
- general laboratory with the capacity to perform Giemsa stain on thick blood film for malaria, Ziehl-Neelsen stain on sputum for acid fast bacilli (to diagnose tuberculosis), microscopy on urine and faeces for parasites and for white and red blood cells. The laboratory assistants also had the training to perform India Ink staining on cerebrospinal fluid to diagnose cryptococcal meningitis, which was used when a medical doctor was put in place to perform lumbar punctures

- VCT (Voluntary Counselling and Testing) was performed in an additional laboratory for HIV-testing that had been constructed by MSF-B in 2002 offering HIV testing to all pregnant women and TB patients (at no cost) as well as to volunteers (at a cost of 200 FRw = 0.30 Euro). The tests used were "Rapid Tests"; Determine, UniGOLD and Capillus, enabling to confirm true positive results and rule out false positive ones.
- small distribution pharmacy

The staff consisted of 1 medical assistant, 2 nurses "A1" (3 years of training) and 10 nurses "A2" (2 years of training), 6 aid-nurses, 3 counsellors, 1 laboratory technician, 1 nutritionist, 1 educationalist, 4 cleaners and 3 night guards. According to Rwandese policy due to the lack of medical doctors in the country there was no doctor. All the staff, in every different position, got an incentive from MSF-B consisting of a salary increment ranging from 25 000 Rwandese francs (~35 Euro) for the head nurse or laboratory technician in charge, to 15 000 RFr (~21 Euro) for ordinary nurses and counsellors, 10 000 RFr (~14 Euro) for aid nurses and 7000 RFr (~10 Euro) for cleaners and guards. This should be compared to an ordinary nurse's salary of about 12 000 RFr (~17 Euro) per month. The idea was to encourage a holistic care for the HIV patients as well as awareness among the staff to detect HIV symptoms in yet not diagnosed patients, always taking into account the possibility of HIV. The nurses and counsellors specifically trained and responsible for the ART programme later got the higher increments.

The AIDS project
Initially, support was given by MSF-B to the health centre in terms of renovating and constructing buildings, giving financial incentives to the state employed personnel and sponsoring the care and medications for the HIV positive patients. An expatriate medical doctor and a registered nurse employed by MSF-B started the "AIDS project" in 2002 where they provided some supervision for the health care centre and started giving training sessions for the nurses in diagnostic skills and treatment of opportunistic infections due to HIV.

The persons tested HIV positive in the VCT were offered a booklet for free with the MSF-B stamp granting them access to free health care and medication at Kimironko at the expenses of MSF-B. In their first consultation, a patient file was made by the nurse. Here, the stage according to the WHO clinical staging system *(Appendix A)* was evaluated and every patient in WHO stage II-IV received co-trimoxazole prophylaxis at a dose of 2 tablets of 480 mg every day. This regimen is considered easier to follow than the one predominantly used in Europe with 2 tablets 3 days weekly and the aim is firstly to protect against the opportunistic infections Pneumocystis Jirovecii pneumonia and toxoplasmosis but also to give protection against many ordinary bacterial infections such as salmonellosis, pneumococcal disease etc. Stage I patients were requested to come on three-monthly consultations, and stage II-IV patients should come every month to collect the co-trimoxazole tablets and have a clinical check-up.

Complementary branches in the AIDS project working out-side the health centre were formed by Rwandese MSF-staff. First the IEC-team (Information, Education and Counselling) composed of a teacher and a nurse, who addressed the need for prevention of HIV in the community around Kimironko, working primarily with commercial sex workers, youth groups in schools and people attending bars.

Secondly, three home based care-nurses (HBC) formed a team reaching out to AIDS-patients in need of terminal care in their homes. Finally, an administrator and a social assistant established contact with local organizations for people living with HIV/AIDS (PLWA) in the neighbourhood, in order to offer economical and administrative help from MSF-B.

Patient characteristics
In this report the first 300 patients who began ART in our programme will be included. The inclusion period runs from Oct 7th 2003 until Oct 19th 2004 and the follow-up period continues until Oct 2005. 300 patients divided on 168 women, 77 men, 23 girls and 32 boys who began ART during this period. The women were between 22 and 63 years old (mean 37,5), the men between 18 and 58 years old (mean 40,8) and the children between 3 and 15 years old. The patients were all Rwandese, speaking Kinya-rwanda, the local language. Roughly about 10% of them also spoke some French. Most of them did not have any formal education and were unemployed without any formal salary, but lived by small commerce. The MSF policy has always been to reach out to a country's poorest population lacking other means to attain health care. Therefore, in the beginning of the programme, the economical situation for the patients eligible for ART was evaluated on a home visit by the social assistant to assure that the patient did not have an income exceeding 50 000 Rwandese francs (~ 70 Euro) /month *(Table 1).*

Preparing for ART
When the part of the programme that will be described in this report started in September 2003, the aim was to begin anti-retroviral treatment (ART) for the HIV-patients in need in the cohort of about 1000 HIV patients attending Kimironko health clinic. It was not clear though, how many of the files that represented active patients and how many that were deceased or lost to follow-up. During the study period, new patients were included in the AIDS project through our and other VCT centres, and in January 2005 the number of HIV patients had increased to about 3000.

Training of staff
Initially, there was only one nurse in charge of all the HIV consultations. She handled the files and referrals to the laboratory as well as the medical assessment and prescription of medication after test-results etc. It was a huge task, and it was obvious that it was already getting out of hand in volume for one person.
In order to start ART as soon as possible to relieve the queue of sick HIV patients demanding a lot of care for opportunistic infections, a team that could make a concentrated effort needed to be trained. Firstly, in close collaboration with the head nurse of the health centre and the MSF supervisory nurse we chose 3 nurses and 3 social assistants to form an "ART team". They were chosen considering personal interest and background training. As the ex-patriate medical doctor in Kimironko I started by holding a two day training for the team in which the first part consisted of basic knowledge of HIV and WHO clinical staging system, mechanisms of ART, medical follow up by evaluating CD4 count etc. The second part of the training in which the ex-patriate nurse assisted included "Tools for patient counselling and education before starting ART", as this was considered a vital concept in order to obtain adherence and treatment success. The idea of this ART team was to be multivalent with nurses able to rotate between consultations for opportunistic infections including co-trimoxazole prophylaxis, ART initiating and follow up, and

ART counselling. Gradually, as the ART programme was scaled up, new nurses and social assistants were included in the team, receiving the same training.

The consecutive step was to start general trainings in HIV medicine for all the nurses employed in Kimironko (and Kinyinya) health centres including HIV pathogenesis, WHO staging, co-trimoxazole prophylaxis and treatment of opportunistic infections. These trainings were held by the medical doctors (my French colleague working in the other MSF-B programme in Kinyinya and my-self) as two-day' courses, repeated until all the nurses had attended. By obtaining a broad awareness of HIV medicine, the nurses could professionally counsel the population attending the health centres and direct them to HIV-testing on clinical suspicion. The trainings also served as a base for recruitment of new nurses to the ART-team.

The selection process
A flow chart **(A-F)** on how to be included in the ART programme was constructed. The nurses used a questionnaire on every routine HIV consultation in order to find suitable candidates for ART.

A) Fulfilling the first three *social* **selection criteria**

1. Residing in the Kimironko catchment area since at least 6 months
2. Adherence to follow-up consultations and co-trimoxazole prophylaxis in Kimironko health centre for at least 3 months.

   These first two criteria could be excluded in the case of pregnant women needing to start ART urgently (see comments below).

3. Having revealed his or hers HIV-status to at least one person willing to act as a "companion" (=preferably someone from the family or a close friend who could attend the counselling with the patient and offer support in every day life in adhering to the ARV treatment).

B) If the patients fulfilling these three social criteria also were in WHO stage II-IV, they were given an appointment for **CD4 testing** – to see if the fourth *medical* **selection criteria** was fulfilled;

4. CD4-count < 200 / microlitre

C) The patients thus fulfilling all four selection criteria were given the first of three **ART counsellings** by a specially trained social assistant from the ART-team. The detailed contents of the topics in this counselling, are listed in *Appendix B.*

D) If no major constraints were found by the social assistant in the counselling, the patient was anonymously presented by the medical doctor to a **"Selection committee"** where those considered most in need were selected to get access to the MSF ART-programme.

E) The patients selected by the committee then attended yet **two ART counsellings** *(Appendix B)* before starting ART.

F) The patient and his/hers "companion" then came for an **individual consultation to initiate ART** (see "Initiating ART").

Comments and explications on the flow chart;

The selection criteria and committee **(A,B,D)**

The first and vital step was that the nurse on her routine HIV consultation was well trained and had time to identify the patients in need of ART. This proved to be a considerable obstacle since due to time constraint and a high work load the routine consultations where the patients came for their monthly co-trimoxazole prescription or even on extra consultation due to acute illness could be very swift. In average, each of the three consulting nurses in the multivalent ART-team made 20-40 consultations per day. Also, the tradition for patients to actively raise their plaints was not at all as strong as in European health systems. So, we designed a questionnaire with the four selection criteria, and encouraged the nurses to complete this form for every patient and put it in their files even if they did not yet fulfil all the criteria. The idea was to re-evaluate this at every consultation and thus enlighten the patient on the possibility of receiving ART if and when they fulfilled the criteria. One example could be to encourage the patient to actively finding a companion by revealing his/hers HIV status, an important step towards reducing stigma.

The selection criteria and committee were subject to Rwandese governmental instructions and not put in place by the initiative of MSF-B. In a situation with such a huge gap between need and access most low-income countries have implemented some method of rationing ART in order to provide a fair distribution.[9] Our selection committee was composed of the medical doctor in charge of the medical district of Muhima, the head nurse of Kimironko, a representative from MSF-B and a representative from each of the three local organizations working with PLWA (people living with HIV/AIDS) that MSF-B collaborated with in the area. In practice, no-one who fulfilled the social and medical criteria and had been evaluated by the nurse and the social assistant in counselling was turned down by the selection committee, but their role became more to prioritize in the beginning of the programme when capacity was limited and the queue was long. Initially it was agreed upon to prioritize children, pregnant women and single parents with responsibility for children. In 2005, when the programme had been running for >18 months, the situation in Kigali had somewhat changed for the better concerning access to ART, and the Rwandese Government approved to omit the committee. Then the selection process continued based only on the patient fulfilling the criteria and attending ART counselling.

Pregnant women **(A)**

In treating pregnant women with full ART it is possible to substantially reduce the transmission from mother to child during delivery compared to in untreated women and compared to in women receiving only a single dose of nevirapine in the PMTCT-programmes[10]. With this knowledge, pregnant women already in the HIV programme were prioritized to receive ART as soon as possible, but we also tried to actively find and include the women tested positive in the VCT offered to all pregnant women. The counsellors in the VCT were nurses and counsellors employed in the health clinic, who had had a governmental training in HIV counselling and then as time went by had participated in our training of all the staff in HIV medicine. Finding a pregnant woman being HIV positive, they immediately transferred her to a key nurse in the ART team with "A1" training for mid-wives. She gave the first counselling, modified to the needs of the pregnant woman who thus recently had received her test results.

These women could be included and started on ART without fulfilling the first two selection criteria as it is of such great importance to take the opportunity to start ART

in time before delivery to reduce the transmission to the child. So, if the psychological and social situation admitted, the pregnant women got an appointment for CD4 testing as soon as possible, bypassing the normal queue and adherence criteria. Sometimes there were problems such as a woman or her husband not willing to accept the information, denial or shock that made it difficult to start treatment. But when possible, and if the CD4 count was below 350, ART was initiated as soon as possible after the first trimester. The reason for not giving ART including nevirapine to all pregnant women is that the risk of nevirapine associated hepatic and serious rash toxicity is more frequent in women than in men and especially in women with an elevated CD4 count. Actually, according to WHO guidelines, the limit is CD4<250, but we didn't see any adverse effects in our few pregnant women with higher CD4 count treated with Triviro®/Triomune® containing nevirapine *(see "The ARV treatment regimens"*).

If a woman already on ART falls pregnant, there is no contra-indication to continue treatment during the first trimester, with the exception of efavirens, Stocrin®, that has been shown to be teratogenic in the first trimester in animal trials.[10] Having the choice when to start ART in a non-treated woman, it is considered optimal to wait until the second trimester if the woman doesn't need treatment urgently. It was rarely an issue, though, that the women were found "too early" in their pregnancy, since they often came quite late for antenatal care. Even so, in the eligible cases we always tried to initiate ART no matter how late, considering that the quick effect of triple therapy reducing viral load still gave a better protection for the child than a single-dose of nevirapine.

Another important issue, that will not be further discussed or investigated in our cohort, is that studies have shown a risk to develop a resistance mutation to nevirapine after receiving a single-dose[11]. This is due to the long half-life of the molecule allowing for mutations to arise when the concentration of the drug is falling in the blood. It might thus be impossible to use nevirapine, the cheap back-bone of triple therapy in low-income countries, in treating women who have received a single-dose nevirapine in a PMTCT programme when they later need ART. Ongoing studies have still to evaluate the clinical importance of this. Thus, the aim should always be to give full ART in stead of only a single-dose nevirapine to pregnant women with CD4 < 350.

ART counselling **(C,E)**
Counselling is a very important phase before initiating ART, empowering the patient to understand and control his/her disease. This encourages good adherence, which is vital in order not to develop resistance. Probably the counselling pre-ART is the best possibility we have when the patients are focused on receiving therapy since they are feeling ill. In a low income setting the patients are also painfully aware of the dangers with HIV, seeing their families and friends dying of AIDS. A good counselling is possible to achieve with small means, as in the case of Kimironko where the counsellors had the above named training and then used posters with pictures to educate the patients. These posters were developed in collaboration with the MSF IEC-team, drawn by a local Rwandese artist and elaborated after feed-back from patients, counsellors and nurses.

The third counselling was performed as a home visit in order for the social assistant firstly to evaluate the credibility of the patient – that he/she actually had a home in the

Kimironko catchment area as stated and that the family was aware of him/her being HIV positive and in need of starting ART. Then, practical advice was given on how and where to store the medications in the house to keep them out of reach for children, animals etc. Finally, this home visit served as a means of being able to trace the patient if he/she wouldn't show up for medical appointments in the future. In practise, this rarely became necessary, because mostly the system with the companion as a contact person worked well enough.

Initiating ART

ART groups

The patients began their treatment in "ART groups". This meant that a group of 5 persons per week came together on the same day to start treatment and then on their regular check-ups, even though the consultations were individual. The size of the groups increased successively as the programme was scaled up, to about 15 patients per group. This group system served several functions; by coming regularly on the same day for ART check up the patients in a group got to know each other while waiting, having the possibility to exchange experiences and worries. They also exerted a control function on each other to adhere to treatment and not to miss their appointments. Later, with the help of the MSF IEC-team, the ART groups formed larger support groups where they met together with a animator from MSF. These support groups offered a more formal meeting point to discuss stigma, side effects, difficulties with adherence and other every day-issues of ART. Some groups even transformed into a forum for starting micro finance projects together to find jobs, as well as daring to contact politicians to demand better conditions for HIV positive persons in society.

The first ART consultation

On the day of initiating ART, the patient and his/her companion thus came for distribution of the first tablets in an individual consultation with a nurse from the ART-team. Two nurses worked in adjacent rooms, and the patients in the group sat outside waiting for their turn. The consultation comprised of a check-up that the patient and his/her companion had understood the essentials of the counselling as well as a brief control of their medical status. If everything was in order, the ARV tablets were given to the patient to swallow in front of the nurse (DOT principle) and the tablets for the evening given in a sachet. One important task in this consultation was to exclude active tuberculosis or other treatable opportunistic infections before starting ART. Ideally, this should have been done already in the ordinary consultations, but due to the time constraints described above, even strong symptoms of i.e. tuberculosis could have been overlooked. Another issue was to emphasize the two most important and dangerous side effects that could arise after starting nevirapine; namely a rash as a sign of an allergic reaction or yellow eyes and stomach pain as a sign of hepatitis. In any of these cases, the patients and their companions were instructed to contact the health care centre immediately.

Monitoring and follow-up

Initially, a lot of focus was put on the DOT principle (Directly Observed Therapy – used by WHO in many low income countries´ tuberculosis programmes), and the schedule comprised of daily DOT-visits with the ART nurse from Mon – Fri during two weeks. The idea of this was to assure good adherence as well as a safe supervision of side effects. In the beginning, this served as a good way for the nurses to get into the routines of the treatment schedule, to be confronted with the patient's

problems and complaints and getting used to handling them. After a while, when the programme started running smoothly, experience showed that the patients understood the importance of adherence as intended in the pre-ART counselling, making such frequent visits unnecessary. So, the schedule was adjusted little by little, gradually spacing out the frequency of appointments. In January 2005 the routine was to begin treatment on a Tuesday, come back on Friday the same week and then receive tablets for one, two and then four weeks at a time. As the number of ART groups increased, several groups could start the same week, on different days.

MSF have a special statistical programme called FUSHIA, used by all MSF HIV programmes worldwide, and a trained secretary was employed to consecutively enter the data for the ART patients from the handwritten patient files to the computerized FUSHIA. An adjusted form of this data-base, allowing analyses of treatment adherence and outcomes, has been used to make the tables in this report.

Laboratory monitoring
All ART patients had a base-line laboratory investigation at treatment start composed of Hb, WBC, differential count and plt, ALAT and creatinine. These tests were performed in MSF's own laboratory in Kinyinya and tests could be transported there from Kimironko daily. To monitor initiation of nevirapine, ALAT was repeated week 2, 4 and 8, and thereafter every 6 months. Haematology was repeated once a month for patients on zidovudine and every 6 months for other patients.
CD4 count calculated with a FAXScount was performed in the state Treatment and Research on AIDS Centre (TRAC) laboratory in Kigali. MSF could send a limited number of tests for analyses once a week to a cost of initially about 10 Euro. Thanks to resources from the Global Fund, the price was reduced to 2 Euro in 2004. All patients had CD4 count before initiation of ART and the goal was to monitor CD4 count every 6 months on treatment. Reasons for deviations from this rule are discussed below in *"Results with comments after the first 2 years of ART"*.

The ARV treatment regimens
The first line treatment in our programme was Triomune®/Triviro® *(see Appendix C)*. This tablet is composed of two nucleotide reverse transcriptase inhibitors (NRTI's); lamivudine (3TC) and stavudine (d4T) and one non-nucleotide reverse transcriptase inhibitor (NNRTI); nevirapine (NVP). During the nevirapine introduction is important to gradually increase the dose during two weeks, which was done by giving one tablet of Coviro 30/40® (150 mg lamivudine and 30/40 mg stavudine) plus one tablet of Nevipan® (200 mg nevirapine) in the morning and then Coviro® alone in the evening during 2 weeks. After this the full dose of Triomune/Triviro30/40® (150 mg lamivudine, 30/40 mg stavudine, 200 mg nevirapine) one tablet twice a day could be started.

Alternative regimens were Coviro® twice a day in combination with Stoccrin® 600 mg once daily (efavirenz, the other NNRTI) or Avocomb® (300 mg zidovudine plus 150 mg lamivudine) in combination with either nevirapine or efavirenz. For side effects and reasons for different therapy, see *"Type of ART"* below.

A second line treatment was provided in 2004 consisting of the NRTI's Videx EC® (400 mg didanosine, ddI) and Ziagen® (300 mg abacavir, ABC) plus the protease inhibitor Kaletra® (133 mg lopinavir boostered by 33 mg ritonavir).

Results after the first 2 years of ART

In November 2005, I got the opportunity to return to Kimironko to collect data from the patient files and the FUSHIA data base concerning treatment outcomes. I have verified and selected data, and the results are presented in three tables.

Table 1. Patient characteristics at initiation of ART at Kimironko Health Centre (Oct 2003-Oct 2005)

	Numbers	**%**
Gender all (male/female)	109 / 191	37% / 63%
Children < 15 y (boys/girls)	32 boys/23 girls	58% / 42%
Gender adults (men/women)	77 / 168	
Mean age adults (male/female)	40,8 /37,5 y	
Socioeconomic status		
unemployed	190	63%
public sector (10-40 Euro/m)	9	3%
private sector (40-80 Euro/m)	2	1%
other job	42	14%
student	37	12%
not applicable (children)	20	7%
Marital status (for comments see text)		
single	17	7%
married/cohabitating	116	49%
widow	84	35%
divorced	23	9%
WHO stage at ART start (only for adults)		
I	4	1%
II	41	17%
III	162	66%
IV	38	16%
Mean CD4 count at treatment start (N=230)	116	
Men	99	
Non-pregnant women	117	
Pregnant women (N=9)	247	
CD4 % at treatment start for children (boys/girls)	11% / 12%	
Adults with CD4<50 at treatment start	59	26%
Adults with CD4<200 at treatment start	189	82%
Previous ART yes	5	2%
no	295	98%
Type of ART		
1=TC3-D4T-NEV,	282	93,7%
2=TC3-D4T-EFV,	6	2,0%
3=TC3-AZT-NEV,	4	1,3%
4=TC3-AZT-EFV,	8	2,6%

Comments to Table 1;

Gender

Women are in majority, 63% of all ages, probably reflecting the fact that stigma due to HIV and reluctance of visiting health care facilities is greater among men than among women in Rwanda.

Socioeconomic status

is divided into five groups; unemployed (the majority of our patients), working in the public sector (10-40 Euro/month), private sector (40-80 Euro/month), other job (including small commerce as well as commercial sex workers), student (including all children going to school) and "not applicable" for the youngest children.

Marital status

Sometimes "commercial sex worker" (in French "femme libre", literally meaning "free woman") was put in the patient file for women who from time to time sold sex when they needed money, without being fulltime prostitutes. Under *"Marital status"* these women (at a number of 5) have not been included, nor have the children, thus the percentage refers to the remaining group of 240 patients.

WHO stage at ART start

Staging according to the WHO clinical staging system *(Appendix A)* was performed on every adult patient on their very first consultation after having tested HIV positive. For children the CDC staging system was used, but due to a difficult way of estimating the stage, giving extremely vague bases for data it has been omitted in this report. Even for adults the staging might not be completely reliable due to several factors. Firstly, in the beginning of the MSF AIDS project in 2002 when the first 1000 patient files were made, the nurses had a very poor education on the staging system. Secondly, many of the diagnoses indicating for example stage 4 (AIDS defining) disease were not possible to confirm in the Rwandese health care system (such as toxoplasmosis of the brain, cryptosporidium diarrhoea, CMV retinitis etc) and might thus have been missed. On the other hand, for example a patient presenting with oral candidosis (stage 3) who answered in the affirmative to the question whether they had pain on swallowing was immediately considered having oesophageal candidosis (stage 4) without the possibility to confirm this by a gastroscopy. The WHO stage marked in the patient files is included in this report after all, since it at least gives an idea of the situation. It is also interesting to note in the patient data base used to make the tables that the correlation between WHO stage and CD4 count was sometimes very low.

Type of ART

In 2000 when the production of generic ARV combination tablets (Fixed Drug Combination, FDC) was started by Brazilian and Indian pharmaceutical companies (*Ranbaxy and Cipla)* the possibilities for large scale treatment in low income settings increased substantially. Since then, the prize of ART has fallen from about 10 000 to 140 Euro per patient per year[12]. MSF took the decision to use Triomune®/Triviro® as first line treatment in their ART projects. It has been shown to be an effective and practical combination[13] even though it necessitates a dose increase of nevirapine from 200 mg OD during the first two weeks to 200 mg BID from then on. This is required in order to induce liver enzymes for its own metabolism and reduce the risk of side effects such as a severe rash developing into a Steven Johnson syndrome, or a likewise life-threatening hepatotoxicity. In spite of these possible side effects,

nevirapine is still the backbone of most triple therapies in low income countries, being a cheap and powerful drug, almost comparable to the protease inhibitors in efficacy. The protease inhibitors which would be safer and even more potent drugs are mostly too expensive and demanding too elaborate laboratory monitoring for low income countries. The vast majority (93,7%) of our patients were treated with Triomune®/Triviro® as one of the aims of the project was to find a treatment regimen as cheap and easy as possible so that the patients could stay with their initial therapy.

Mean CD4 count at treatment start

For treatment follow-up absolute CD4 count (cells/microlitre blood) was used for adults and CD4 percentage (absolute CD4 count divided by total lymphocyte count) for children up to 15 years of age. This ratio is a more correct way of comparing in growing children as the total number of lymphocytes increases with age. The internationally accepted limit when to initiate ART is at a CD4 count below 200 in adults and 15% in children. Severe immune deficiency is classified as CD4 count of 50 in adults and 5% in children. Initially 82% of the adults in our cohort had CD4<200 and 26% CD4<50. "Mean CD4 count at treatment start" is measured for only 230 out of 245 adults. The patients thus lacking initial CD4 count are firstly those included in the programme after starting ART elsewhere, and who did not know their initial CD4 count. Secondly, even in our own programme, CD4 count was initially not measured for stage 4 patients before treatment start, since according to WHO guide-lines stage 4 patients can start treatment regardless of CD4 count. They were thus presented to the selection committee on clinical grounds. Later we realized that this made it impossible to judge treatment success in terms of CD4 increase, so from about April 2004 patients in all WHO stages had a CD4 count before initiating ART.

As noted previously (*see "Pregnant women"*) pregnant women could start ART at a higher CD4 count, why they are presented as a separate group.

Table 2. Treatment outcome measured as gain in CD4 as compared to at treatment start at Kimironko Health Centre Oct 2003-Oct 2005

	Mean CD4 count absolute (% gain as compared to tx start)			
Patient group	**6-9 months**	**12-15 months**	**18-21 months**	**24 months**
All adults	233 (+100%) N=207	279 (+20%) N=194	316 (+13%) N=96	251 (-21%) N=17
Men	211 (+113%) N=62	268 (+27%) N=63	277 (+4%) N=33	244 (-12%) N=6
Non pregnant women	230 (+97%) N=136	273 (+19%) N=125	337 (+23%) N=62	255 (-24%) N=11
Pregnant women	390 (+58%) N=9	539 (+38%) N=6	273 N=1	
Children - boys	24%	28%	24%	
- girls	26%	27%	26%	
CD4<50 at start	149 (+548%) N=43	219 (+47%) N=45	269 (+23%) N=27	247 (-8%) N=7
CD4≥50 at start	255 (+72%) N=151	301 (+17%) N=139	335 (+12%) N=58	252 (-24%) N=9

Comments to Table 2;

Treatment outcome measured as gain in CD4 count as compared to at treatment start
Our aim was to check CD4 count every 6 months, but this proved difficult for several reasons. Lack of accessibility of the patient or lack of staff as discussed below (*see "Conclusions"*) were some reasons, another that MSF had a narrow quotient of allowed number of CD4 analyses per week in the TRAC laboratory. Often there was not space for all the patients to have their CD4 count tests run on the exact week. Therefore, the mean CD4 results are presented in three months' intervals ("6-9 months" or "12-14 months"), since this was the time span in reality.

After 6 months the mean gain in CD4 count for all adults was 100%, and for those with CD4<50 at treatment start the mean gain was 548% compared to 72% for those with CD4>50 at treatment start. This trend continued over time, showing that it is worth while and even more cost benefit to treat the most sick with ART. After 12 months, the increase in CD4 was less in all groups, which is the normal pattern[14], mounting to 20% in average. After 24 months the mean CD4 count seems to diminish instead of as earlier increase, and the mean gain is negative. This is explained by the small number of patients who were treated for 24 months and the choice of using mean and not median CD4 count. Since the patients started ART gradually during the inclusion period of 12 months, and the follow up period continued yet another 12 months, it's only for the very first patients starting ART in Oct 2003 (N=16) that we have results of CD4 count at 24 months in Oct 2005. These patients were among those with the lowest CD4 count at treatment start in the cohort, since at the program start the first patients had waited for a long time. As time went by, we caught up with the queue, and the patients starting later had a comparatively higher CD4 count. When examining the individual CD4 counts in these 17 patients (6 men and 11 women) one sees that 11 of them clearly increased their CD4 count as compared to at treatment start, 4 of them stayed on more or less the same level while 2 had a mean CD4 count loss. Two of the patients who had a static CD4 count had had treatment interruptions (one due to a suspected lactic acidosis and the other due to lack of money when paying for her ART personally previous to being included in the MSF programme). The third patient had switched therapy from d4T to AZT due to paresthesies but without treatment interruption and the forth had no special remarks in her file. All of them had come perfectly for ART the appointments. One of the two patients with declining CD4 count at 24 months had had a major abdominal surgery the previous year, when she had to make a short treatment interruption, and she had also switched therapy from d4T to AZT and from NVP to EFV. The other had no remarks in her file, and had come perfectly for her appointments. She was a rescapée from the genocide, though, with frequent and severe attacks of headache, if this could be a possible explanation for non-adherence. The rest of the patients have not been scrutinized like this, but this was done as an example.

Table 3. Adverse treatment outcomes among ART patients at Kimironko Health Centre Oct 2003-Oct 2005

Adverse outcomes		Number	%
Mortality		24	8%
Side effects			
	Anaemia/neutropenia on AZT	9	3%
	Neuropathy on d4T	38	13%
	Lipoatrophy on d4T	3	1%
	Hepatitis/allergy on NVP	13	4%
	Psychiatric side effects on EFV	1	0,3%
	Susp lactic acidosis on NNRTI	3	1%
Treatment interruption; reason	Lost to follow-up	1	0,3%
	Moved from area	2	0,6%
	Side effects	8	2%
	- hepatitis on NVP	5	
	- lactic acidosis	3	
	Intercurrent medical conditions (TB, lymphoma, operations, psychiatric troubles)	7	2%
	Low adherence	1	0,3%

Comments to Table 3:
The *mortality rate* of 8% is low, considering the patients having advanced HIV disease and poor nutritional status when starting treatment.

The number of reported *side effects* is low, only 67 events in 56 patients. This is probably partly due to that patients in this setting did not always report side effects as in Europe, having a greater motivation of coping with therapy since the option in their eyes was death. The health care system was also so overloaded that there was seldom time or routines for thorough questioning or for giving the patient time to express his problems. So, one should be aware that possibly there was a higher degree of e.g. neuropathies to stavudine than reported in the patient files, but the figures also implies that few of the side effects were severe enough needing the intervention of a medical doctor.

Only in 8 patients did a side effect lead to *treatment interruption*. With the dose increase schedule for nevirapine and a close monitoring of ASAT we did not have more than 5 patients put off nevirapine treatment due to hepatotoxicity. Transitory increase in ASAT due to enzyme induction in the liver when starting nevirapine is common and should not lead to change of therapy or be conferred with clinical hepatitis. It is known that patients with high CD4 count are more prone to react to nevirapine[15] and maybe this is why our patients with severe immunodeficiency were spared from negative reactions to a large extent. The cases of lactic acidosis are only on clinical suspicion, as confirmation with lactate testing could not be performed in Rwanda. Some patients had treatment interruptions due to intercurrent medical conditions, unrelated to ART. For example, two women had to do emergent abdominal surgery, why they could not swallow tablets for some days, and in one case a patient had psychiatric problems unrelated to ART that made it impossible for her to adhere to treatment.

Many patients got tuberculosis, but only very seldom did we have to interrupt their ART due to this. The principle was to try to find symptoms of tuberculosis before starting ART in order to give TB-treatment first. It is almost always more urgent to treat an opportunistic infection, after which the CD4 count normally rises a bit, than to treat the HIV, unless the CD4 count is < 50. It is important to avoid starting TB-treatment and ART at the same time, due to the difficulties of discerning the cause of side effects such as hepatotoxicity or severe rash that could be due both to rifampicin and to nevirapine/efavirens.

The adherence rate is high, and as of November 2005 only 4 patients in the entire cohort of 900 patients were *lost to follow up*. In the cohort of the first 300 patients presented here, there was 1 patient lost to follow up for unknown reason and another 2 who moved from the area without organized follow-up from us.

Conclusions

After the successful introduction of HAART in the western world around 1995, HIV has become a treatable disease in these countries. High costs of ART and lack of organized health care systems in low income countries have thus far prevented the development of a similar treatment success in the countries were the bulk of the HIV patients live and the need of treatment is greatest. Another difficulty has been reluctance from the western world to sponsor and facilitate treatment programmes in African countries, presumably based on the apprehension that people in countries with poorly developed schooling systems are less able to understand the basic mechanisms of ART and the need for adherence. This report wants to give an example showing that it is feasible to run a successful ART-programme even with low resources in terms of staff, and that people affected by HIV in a low income country definitely are as able, if not more, as people with schooling in the western world, to understand and follow instructions on how to manage their medication. Partly this might be due to the harsh knowledge gained in low income countries where lack of treatment has forced people seeing their families, friends and neighbours die from AIDS. Thus, most patients are very eager to receive ART and definitely understand the need of adherence as this is often literally their only chance of surviving. In contrast, in the western world, with almost unlimited resources, the patients often think that there is always a “second chance” if they mismanage their first line treatment. Having expressed this personal reflection after working with HIV-infected patients in both Sweden and Rwanda, some of the difficulties we encountered will be mentioned, with recommendations on how to cope with them.

Preparations and planning

Training of staff before starting ART is vital. The crude availability of ARV drugs is still only a matter of economy; they can be purchased or donated. But ART is much more than mere medication, and the major problem in many low income countries is the lack of trained staff due to un-sufficient schooling and to “brain drain” where doctors and nurses find better paid jobs abroad. So, in order both to provide trained staff and to raise the status and salaries for health care personnel, it is important with good education and incentives in terms of salary to enable people to stay in their profession. Our staff that had to deal with HIV patients was very receptive and motivated to learn about diagnostics and treatment, and I really felt their engagement for the patients to help when they got more knowledge. The lectures were not complicated but rather focused on giving basic knowledge and easy algorithms to

follow in the direct treatment of patients. The government of Rwanda also organized courses in VCT and ART for health care staff, which of course meant a positive attitude to education.

Lack of accessibility of the patient is a potential problem. When planning an ART programme it is important to restrict the geographical area in order to enable the patients to easily reach their health care centre, considering lack of public transports or lack of money to use them. If something happens that prevents the patient from coming on the exact date, there is usually no system of calling the health centre to get an extra receipt, going to a pharmacy to collect some extra tablets etc. Nor can the health professionals know whether the patient is too ill to come or if he/she just cannot read the date for the appointement. To overcome these problems, we used the system of a companion, as described in the report. In a geographically restricted area as ours it was possible for these companions to alert us in the health centre when the patient fell ill at home or did not adhere to treatment as intended. Also, our social assistants who had been on a home visit during the counselling or at least had collected very thorough information on where the patient lived could go and look for the patient in case of lost to follow up.

Selection and constraints
The selection process differs from European settings. It is considered important in most low income countries and was required by the Rwandese government to assure a fair distribution of ART in a scarce situation. It is important for the health care system to define which groups that should be prioritized and clarify the reasons for this. In our setting, the role of the selection committee was not crucial in practice, since we worked strictly according to selection criteria and the risk of giving personal preferences was negligible. In my opinion, a greater gain with these committee meetings was that they indirectly served to enlighten different parts of society on the importance of ART and reduce stigma – from the head of the medical district to volunteers working with PLWA. A problem could be if a selection committee slows the ART process. In our case, it was not so much waiting for the committee's monthly meetings that slowed the process as other factors; receiving the CD4 result from TRAC *(see "Laboratory monitoring")* took at least one week, and the queue for ART counselling became more and more a "bottle neck" due to lack of counsellors. After the selection committee had approved of the patient there was also a queue for starting treatment, since we could not deal with more than 15 patients per ART group. Nor could we have every day as a "starting day" since we needed space and time for follow-up of the earlier groups. Sometimes the patients didn't come on their appointments to start counselling or treatment, due to factors mentioned above such as illiteracy or lack of transport etc, which forced us to work with a system of giving more patients appointments than we had space for, not to risk slowing the process by working under our capacity. This gave extra work when too many patients actually turned up, having to organize other appointments for them. So, lack of trained counsellors, nurses and localities were the main constraints since we worked in a health care centre where staff was needed for other activities as well.

Even so, I really believe in integrated ART programs, in stead of separate programs put up by some NGO´s only focusing on ART. Firstly they drain the normal health care system of qualified staff and secondly they miss the chance of finding new cases and promoting VCT by having multivalent, HIV educated staff seeing "ordinary"

patients. Lastly, there is also an effect of reducing stigma when HIV patients are mixed with other patients in local health care centres.

Counselling
Thanks to a thorough pre-ART counselling, we believe that we obtained a very high adherence rate. In the cases where patients missed their appointments or gave other impressions of non-adherence, extra counselling was put in as a routine action, preferably by their initial counsellor. Since the ARV drugs were so poorly available, the patients were given only the exact number of tablets needed, in order to prevent every intention of selling tablets on the black market. In practice adherence was measured by asking the patients if they had any tablets left, since that would mean that they had forgotten to take them since they should have only exact the number to last until the next appointment. In reality, adherence to treatment can only be measured as clinical success, that is, increase in CD4 count, which we could present here.

Factors affecting data reliability
In reporting data and doing statistical analyses in a programme like this it is important to emphasize the uncertainty of methods. Firstly, the education of the staff initially was very poor, why the WHO staging and diagnostics e.g. are not reliable. Even further ahead in the programme, the consultations could due to lack of time be too brief to find and note all the symptoms and side effects. Another aspect is the human factor when transferring data from handwritten patient files to a computerized data base, where mistakes could be made giving faults in our data.

Also due to costs and organizational difficulties in getting blood tests on time, the data might not be exact. Concerning e.g. the CD4 count, it is important to clarify that "CD4 count at treatment start" could in reality be several months prior to treatment start, giving a false low increase after 6 months. This occurred especially in the beginning of the programme when the capacity was relatively low and the waiting time long due to many patients in the queue. In these cases, the programme did not have the economical means to repeat the CD4 count in order to have a fresh one, but the patients with a recorded CD4 count below or close to 200 were started on ART when they had completed the selection process. To make up for this delay, we used CD4<300 (instead of <200) to initiate the selection process not to risk that the CD4 count would fall to deep before the patient could start treatment.

Handling side effects and using different treatment regimens
There were very few cases where we had to change therapy due to side effects *(see Table 3)*. The most frequent side effect that our patients encountered was neuropathies due to stavudine (d4T), reported in 37 patient files (12%). Initially we tried to handle this by lowering the dose of stavudine from 40 to 30 mg, adding thiamine as for neuropathies caused by the TB-drug isoniazid, and eventually treating the pain with amitriptyllin tablets. In some cases it was successful and some neuropathies could even be reversed, but mostly it was eventually necessary to switch to the zidovudine containing regimen (Avocomb® plus Nevipan®). No patient had to make a treatment interruption due to this kind of neuropathies, though. When gradually experiencing that in some cases, the neuropathies grew severe and took very long (months) to diminish even after discontinuation of stavudine, we switched therapy more liberally. Unfortunately, when treating with zidovudine in the comparatively high dose (300 mg) in the fixed drug combination of Avocomb® many patients developed anaemia.

In 2004, we got a second line treatment *(see "The ARV treatment regimens")*, containing abacavir (Ziagen®), which could be the solution for patients with both neuropathy and anaemia on previous drugs. Before the arrival of this second line patients often had to go back to stavudine in spite of the neuropathies since the anaemia was more dangerous. In terms of quality of life this was of course a very bad scenario.

Another common scenario was patients on Triomune®/Triviro® needing TB treatment, where the national TB programme included rifampicin. This drug is a strong inducer of liver enzymes involved in the metabolism of e.g. nevirapine and thus reduces the concentration of nevirapine in the blood, allowing for resistant mutations to develop. Our option was to switch nevirapine for efavirenz, the other drug in the NNRTI group, whose metabolism is not as affected as that of nevirapine. Even though concentration of efavirenz may also be reduced by a concomitant rifampicin treatment, we chose not to increase the dose to 800 mg as this could lead to additive toxicity.[13]

A second line treatment is of course important in a serious ART programme. The main target group would be those failing on the first line treatment, but during the first two years of our programme that problem didn't arise. From October 2003 until Jan 2005 we only used the second line drugs in two patients. One was a young woman with suspected lactic acidosis due to NRTI´s, who was put off lamivudine and stavudine and instead treated with the combination of abacavir, nevirapine and Kaletra. The other was a pregnant woman who developed an allergic rash on nevirapine and thus got a triple NRTI-regimen with lamivudine, stavudine and abacavir, since efavirenz that is the normal replacement drug in case of nevirapine intolerance, is teratogenic in the first trimester.

Personal reflection
In the light of the difficulties in setting up an ART programme in a low-income setting with limited resources, it is very encouraging to present our patient's high rate of adherence and CD4 count gain. I hope this example could add to the discussion whether we should focus on prevention or treatment in dealing with the HIV epidemic, strongly arguing that they are interrelated. In my eyes, there is no way of doing effective preventive work without the option of treating those tested HIV positive. In our programme, it became obvious in the example of male partners. Initially, very few men went to VCT, and the HIV cohort was dominated by women. As we wanted to achieve family treatment, focusing on partners and children to come for investigation, we saw very clearly that initially many men were very reluctant to come for testing or ART. Some even hindered their women to come to Kimironko, supposedly due to the bad stigma of HIV. Gradually, as the women on ART got healthier, there were many examples of their men changing opinion and coming for VCT and/or ART. Also on a more general level, the number of persons coming for VCT increased quickly when Kimironko got the reputation of a centre where you could get ART, showing that this raised the reputation of the disease. Obviously, if there is no hope for treatment, why should people go to have a HIV test when it only gives you a proof that you will die? Better then to live and be happy as long as possible? If people don't go for testing, they won't know their HIV status and will thus not be able to protect their partners from getting infected, and the transmission will never be stopped.

There are many models to provide ART, among which this is one that seems to be feasible, thanks to several components. A small geographical area, well trained staff including patient counsellors, a companion emphasising openness about HIV, ART free of charge, starting treatment in groups where patients give spontaneous support to each other are some factors that I believe contributed to our success. It was fantastic to have the opportunity to return to Kimironko to do this follow-up and most of all to meet the patients again and see the individuals and smiles behind these figures.

For the future it would be interesting to investigate whether this treatment success also results in reduced consumption of health care resources, when HIV patients on ART get a strengthened immune system and become healthier. This is of utmost importance in the task of relieving low income countries with a high burden of disease from the vicious spiral of HIV leading to AIDS.

APPENDIX A. WHO staging system for HIV infection in adults and adolescents > 13 years

Clinical Stage I

_ Asymptomatic
_ Persistent generalised lymphadenopathy (PGL)

Performance scale 1:
Asymptomatic, normal activity

Clinical Stage II

_ Weight loss, <10% of body weight
_ Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular cheilosis)
_ Herpes zoster, within the last five years
_ Recurrent upper respiratory tract infections (i.e. bacterial sinusitis)

and/or performance scale 2:
Symptomatic, normal activity

Clinical Stage III

_ Weight loss, >10% of body weight
_ Unexplained chronic diarrhoea, > 1 month
_ Unexplained prolonged fever (intermittent or constant) > 1 month
_ Oral candidiasis (thrush)
_ Oral hairy leukoplakia
_ Pulmonary tuberculosis, within the past year
_ Severe bacterial infections

and/or performance scale 3:
Bedridden, < 50% of the day during the last month

Clinical Stage IV

_ HIV wasting syndrome, as defined by CDC[i]
_ Any disseminated endemic mycosis (i.e. histoplasmosis, coccidioidomycosis)
_ Pneumocystic carinii pneumonia
_ Candidiasis of the oesophagus, trachea
_ Toxoplasmosis of the brain, bronchi or lungs
_ Cryptosporidiosis with diarrhoea, >1 month
_ Atypical mycobacteriosis, disseminated
_ Non-typhoid Salmonella septicaemia
_ Cryptococcosis, extrapulmonary
_ Extra-pulmonary tuberculosis
_ Cytomegalovirus (CMV) disease of organ other than liver, spleen or lymph nodes
- Lymphoma
- Kaposi's sarcoma (KS)
_ HIV encephalopathy, as defined by CDC[ii]
_ Herpes simplex virus (HSV) infection, mucocutaneous >1 month, or visceral any duration
- Progressive multifocal leukoencephalopathy (PML)

and/or performance scale 4:
Bedridden, > 50% of the day during the last month

Source; http://w3.whosea.org/LinkFiles/Training_Materials voluntary-module1-3.pdf

[i] HIV wasting syndrome: Weight loss of > 10% of body weight, plus either unexplained chronic diarrhoea (> 1 month), or chronic weakness and unexplained prolonged fever (> 1 month).

[ii] HIV encephalopathy: Clinical findings of disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection that could explain the findings.

APPENDIX B. Counselling guidelines for the ART programme at Kimronko health centre 2003-2005

COUNSELLING SESSION 1 **Date:_____**

Name + N° patient file:_____

Name of companion:_____

-relation with the patient:_____

Family information (partner and children HIV status + N° patient file):

_____

Socioeconomic status (salary):_____

The first counselling session takes place between the counsellor, the patient and her/his companion (if possible).

The counsellor presents herself, explains her role and the purpose of the counselling, assuring the patient confidentiality. Ask the patient about her/his knowledge on HIV and ART (*very important before starting the counselling !)* and clarify the issues below;

	ASSURE THAT THE « SELECTION CRITERIA » ARE FULFILLED (according to the questionnaire) - note additional information if e.g. the patient lives outside the catchment zone but still have shown to come regularly on appointments - verify if job/income - verify family situation
	Brief definition of **HIV** and AIDS – progress of disease
	Explain what **ART** is
	- Medication that **SUPPRESSES** HIV but that can not cure it
	- Lifelong treatment ~ importance of **ADHERENCE**
	The **RESPONSIBILITY** of the companion and her/his importance
	Ability and understanding of respecting the appointments for ART-follow up (transport facilities to the health centre etc)?
	What are the necessary changes in the patients' every day life to enable a good adherence to the medication?

Give an appointment the Wednesday afternoon succeeding the next Selection committee for the patient to get the decision of the SC and receive the second counselling if selected to start ART …….

COUNSELLING SESSION 2 Date :_____

The second counselling session takes place between the counsellor, the patient and her/his companion (if possible).

Ask what the patient and the companion remember from the first counselling session. Do they have any questions? Then clarify the following issues;

	What are the patients' and the companions' expectations on ART?
	Mode of action of ART, why it is so important to take the medication regularly ; the risk of **developing resistance** ("the virus gets out of the cage")
	Habits to put in place and routines to follow to remember the medication **every day for life at a fixed hour** (on 12 hour intervals) ; **ADHERENCE**
	How to proceed in case of missing a tablet or of experiencing side effects? Who to contact ? **The role of the companion!**
	How to organize ART in case of journeys etc **- come to the health centre in advance!**
	Change of behaviour (openness about ART, importance of condom use in sexual relations etc)

Make an appointment for the third counselling at the patients' home.....

COUNSELLING SESSION 3 Date:_____

The third counselling session takes place between the counsellor, the patient and her/his companion (if possible) at the patients' home, to evaluate her/his socioeconomic status.

	VERIFY the **economic conditions** (that the patient does not have a salary exceeding 50 000 RwF/month). Fill in a form if the patient needs a food supplement and hand it to the MSF social assistant!
	Repeat how to take ART (morning + evening) – ask if the patient has planned what habits to put in place, where to store the medication etc; **ADHERENCE**
	Reinforce the importance of support from the companion and that the other members of the family should be aware of the patients' HIV status and ART
	Importance of not sharing the personal ARV medication with other persons
	Side effects of ART; - IF *vomiting* a tablet within 30 min ; ⇨ TAKE another tablet and go to the health centre the next day to collect an extra tablet - IF severe *cutaneous eruptions* with wounds in the mouth OR *abdominal pain* with vomiting and yellow eyes ⇨ COME straight to the health centre
	Special information for pregnant women and their companions ; The woman should continue ART during labour (and NOT take the single dose nevirapine in the PMTCT program), give the nevirapine dose to the baby, give exclusive breast feeding after birth

During this counselling session, the counsellor should evaluate whether supplementary counselling is needed (if the patient and/or the companion still have a lot of questions or if all the issues have not been clarified).

Make an appointment the following Tuesday morning to start ART and remind the patient to bring some water to drink with the tablet!

.....

APPENDIX C. HAART regimens for adults and children

First line	**Alternative**	**Second line**
d4T/3TC/NVP	AZT/3TC/EFV	ddI/ABC/ lopinavir+ritonavir

Drug dosages

	Adult > 60 kg	Adult < 60 kg	Children
Lamivudine (3TC)	150 mg BID	150 mg BID	4 mg/kg BID
Stavudine (d4T)	40 mg BID	30 mg BID	1 mg/kg BID
Zidovudine (AZT)	300 mg BID	300 mg BID	180-240 mg/m2 BID
Coviro® (d4T/3TC)	40 mg/150 mg BID	30 mg/150 mg BID	see above
Avocomb® (AZT/3TC)	300 mg/150 mg BID	300 mg/150 mg BID	see above
Nevirapine (NVP)	200 mg BID (Initial dose; half dose in OD for 14 days)	200 mg BID (Initial dose; half dose in OD for 14 days)	200 mg/m2 BID (Initial dose; half dose in OD for 14 days)
Efavirenz (EFV)	600 mg QD	600 mg QD	200-400 mg
Didanosine (ddI)	200 mg BID or 400 mg OD	125 mg BID or 250 mg OD	90 mg/m2 BID
Abacavir (ABC)	300 mg BID	300 mg BID	8 mg/kg BID
Lopinavir/Ritonavir	3x133 mg BID	3x133 mg BID	300 mg/m2 BID (of LPV)

Adjusted after"Providing Antiretroviral Therapy at Primary Health Care Clinics in Resource Poor Settings, Preliminary Report: May 2001 – May 2002", Médecins Sans Frontières (MSF) And School of Public Health and Primary Health Care, University of Cape Town

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