

**Ministère de la Santé
Programme National de Lutte contre le SIDA/MST/TUB
République de Côte d'Ivoire**

HIV/AIDS DRUG ACCESS INITIATIVE

Preliminary report

Covering the period August 1998-March 2000

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May 2000

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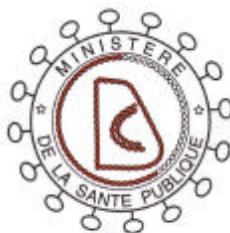
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Introduction

In industrialized countries, use of effective antiretroviral (ARV) therapy has significantly reduced morbidity and mortality among HIV-infected persons. However, due to its high cost and complexity, very few patients have benefited from ARV therapy in developing countries, though the vast majority of the world's HIV-infected persons reside in those countries. In response to this inequity, UNAIDS and the Ministry of Health (MOH) of Côte d'Ivoire launched "The UNAIDS/MOH HIV Drug Access Initiative" which aims at providing ARV therapy and other AIDS-related therapies at reduced cost to HIV/AIDS patients in four developing countries: Chile, Vietnam, Uganda, and Côte d'Ivoire.

In Côte d'Ivoire, this initiative started in August 1998. As part of this initiative, UNAIDS has negotiated reduced costs for most ARV drugs through discussions with pharmaceutical companies. The cost of a month's supply for two-drug therapy (combination of two nucleoside reverse transcriptase inhibitors) is approximately US\$ 180. However, since this cost remains too high for most persons, the initiative designed a program to provide ARV drugs at a subsidized price (ranging from 50% to 95%) for persons who meet certain socioeconomic conditions. These subsidies are supported by a special "Solidarity Fund" that was established by the Ivorian government with US\$ 1 million in 1998. It is hoped that this fund will be replenished by donations from corporations, donor agencies, as well as special taxes. Eligibility for these subsidies is determined based on socioeconomic and demographic data obtained by the medical staff at the time of the patient first visit or eligibility screening and is then reviewed by a National Committee.

As of March 31, 2000, six treatment centers were providing ARV therapy through the UNAIDS Initiative in Abidjan, the largest city in Côte d'Ivoire :

- Department of Infectious and Tropical Diseases, University Hospital (CHU) of Treichville;
- Department of Pediatrics, CHU Yopougon;
- Outpatient TB Clinic of Adjamé;
- Military Hospital, Abobo;
- USAC Outpatient Clinic for HIV patients, CHU Treichville;
- Montagnier Foundation Clinic for HIV patients (CIRBA), Treichville.

Patients are referred to these centers for information regarding the initiative, for evaluation, and for prescription of ARV therapy and monitoring. The physicians at these centers determine which patients should receive treatment and which drugs are to be prescribed. Criteria used to make these decisions include the patient clinical status, biologic parameters, and ability of patient to pay for drugs (with or without national subsidies). Biologic eligibility criteria were established by an expert committee serving as a national advisory board, and include a CD4 count <500 cells/ μ L or a CD4 count \geq 500 cells/ μ L with a HIV-1 plasma virus load >10,000 copies/ml.

A complete evaluation of this program should include four components:

- 1) the decision-making process and impact on the health system;
- 2) the impact of increased access to ARV therapies, drugs for opportunistic infections, palliative care, and other medications for HIV-infected patients;
- 3) the impact on the activities and work load of health personnel, and;
- 4) the impact on the perception of HIV in the general population.

Many indicators exist to measure the potential impact of increased access to drugs and care for HIV-infected patients, for example the number of patients who receive therapy, the response to therapy, the reduction in morbidity and mortality, the ability to sustain the costs of care and the ability to adhere to complicated medication regimens for an extended period of time. For the purposes of this evaluation, Projet RETRO-CI has provided technical and logistical assistance to the Ivorian MOH and is the centralized location for data entry and laboratory testing.

Objectives - Program evaluation

1. To describe sociodemographic and health-status characteristics of all patients evaluated for eligibility to participate in the UNAIDS/MOH HIV Drug Access Initiative.
2. To identify reasons why some patients who present for eligibility evaluation do not receive ARV therapy.
3. To assess biologic outcomes of patients for whom ARVs are prescribed:
 - 3.1 To describe the types of therapies prescribed
 - 3.2 To evaluate viral and immunologic response to ARV
 - 3.3 To describe the clinical response to ARV
 - 3.4 To assess survival of patients receiving therapy
4. To estimate the laboratory costs incurred by Projet RETRO-CI in supporting this initiative

Procedures - Methods

The MOH of Côte d'Ivoire requested the support of RETRO-CI for the implementation and evaluation of the UNAIDS/MOH Drug Access Initiative. To establish the implementation of the program, standard data collection forms were developed and used since August 1998 to collect information on the following: demographic characteristics, socioeconomic status, previous medications taken, therapy currently prescribed, clinical information, status of follow-up and the results of pertinent laboratory results. All the data collected are sent along with biologic samples to Projet RETRO-CI for data entry and laboratory testing. Persons accessing the UNAIDS/MOH Drug Access initiative

follow a three-stage process: eligibility screening, initiation of therapy, and follow-up to monitor and evaluate the response to therapy.

1. Eligibility screening

A social worker in each of the accredited centers collects sociodemographic information upon presentation of each patient. Then, a physician assesses the patient's past medical history including prior and current ARV drug use, and a physical exam is performed. To determine biologic eligibility, a blood sample is then drawn. The specimen is sent to Projet RETRO-CI laboratory for serum chemistry, hematology, CD4 count and viral load. CD4 count was performed by flow cytometry (Facsan, Becton Dickinson, Aalst-Erembodegem, Belgium). HIV-1 RNA viral load was quantified in the plasma by reverse transcriptase PCR (RT-PCR) Amplicor HIV-1 Monitor Assay, version 1.5 (Roche Diagnostics Systems, Branchburg, NJ). This assay accurately quantifies HIV-1 subtype A/G recombinant viruses which are the predominant subtypes in Côte d'Ivoire. The limit of viral detection was 200 copies/ml.

Upon request of the physician, Projet RETRO-CI submits a standardized anonymous summary report to the national committee for application and deliberation regarding the subsidy.

2. Initiation of therapy

If the patient meets the sociodemographic and biologic eligibility criteria and the committee has agreed to allocate a subsidy, the physician initiates ARV therapy. If the patient experiences an acute medical problem preventing him/her from initiating ARV therapy, the patient is seen in follow-up for treatment and reassessment of the problem. In such a case, patient will initiate therapy only if the medical problem is cleared.

3. Follow-up

Following the initiation of therapy, a patient is seen regularly at 1 month, and then every three months by his/her physician at the accredited center to assess response to therapy. Blood samples are drawn and sent to Projet RETRO-CI's laboratory for serum chemistry, hematology, CD4 counts and other immunological markers, and viral load testing. The clinician may modify the ARV regimen according to these results, if necessary.

The following procedures have been implemented to facilitate the transfer of forms and specimens between the six participating centers and Projet RETRO-CI. Each patient entering the initiative has a personal identification number. Data from the questionnaires are entered into one database; names and personal identifiers are entered into a separate database; access to this latter database is strictly limited to two persons.

Thereafter, any additional questionnaires and specimens collected will be identified by the personal identification number and not by any other personal identifier. Each time that a questionnaire is administered, taken to Projet RETRO-CI, and entered into the database, a copy is sent to the attending physician for the patient's hospital record.

The staging process used in this Initiative distinguishes three different populations:

- 1) patients who want to access this initiative,
- 2) patients who return after the eligibility screening to find out the result of their request, and
- 3) patients who have been successful in obtaining ARV therapy.

In order to evaluate this program, information from patients belonging to these three different populations was collected since August 1998. All this information has been centralized at Projet RETRO-CI and monthly reports have been generated. These reports are discussed during regular meetings with representatives of the different centers involved in this evaluation.

Results

1. Description of sociodemographic and health status characteristics of all patients evaluated for eligibility to participate in the UNAIDS/MOH Drug Access Initiative.

1.1 – Socio demographic characteristics

1.1.1 Number of patients accessing the eligibility screening

As of March 31, 2000, 2144 patients presented to the accredited centers for eligibility screening. The number of patients attending the accredited centers for the first time since the beginning of the initiative is summarized in Fig 1. This number includes patients who were already on ARV therapy prior to the UNAIDS/MOH initiative but who joined the initiative because of drug price reduction; 270 drug-experienced patients joined the Initiative of whom 222 were taking ARV therapy at the time of this evaluation. An average of 113 new patients presented to the clinics each month. However, in December 1998, a relatively small number of patients attended the clinics. In contrast, the number of attendees exceeded 150 both in April and May 1999.

1.1.2 Clinics accessed and basic demographics

Men have been marginally in excess among those accessing the initiative. Most have been Ivorian citizens residing in Abidjan (see table1).

Fig 1: Number of patients attending the eligibility screening in the UNAIDS/MOH Drug Access Initiative in Côte d'Ivoire, as of March 2000

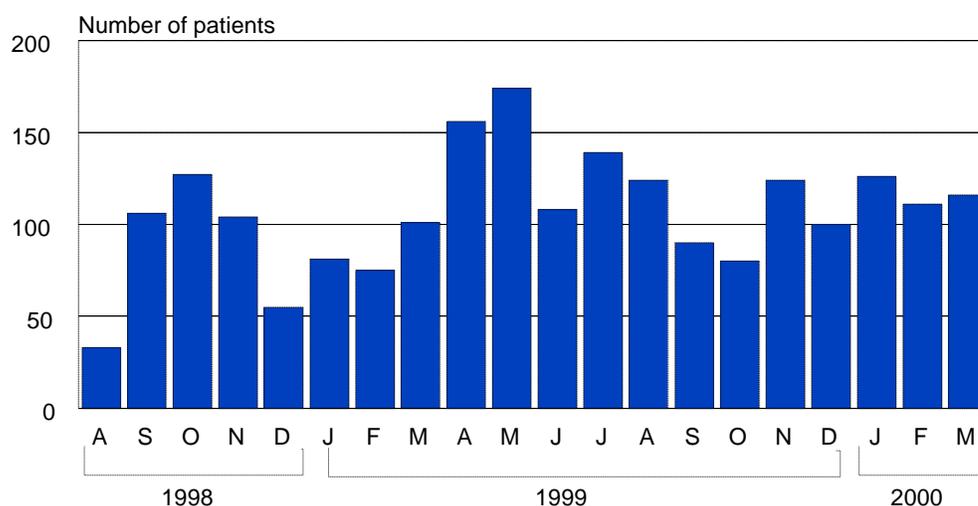


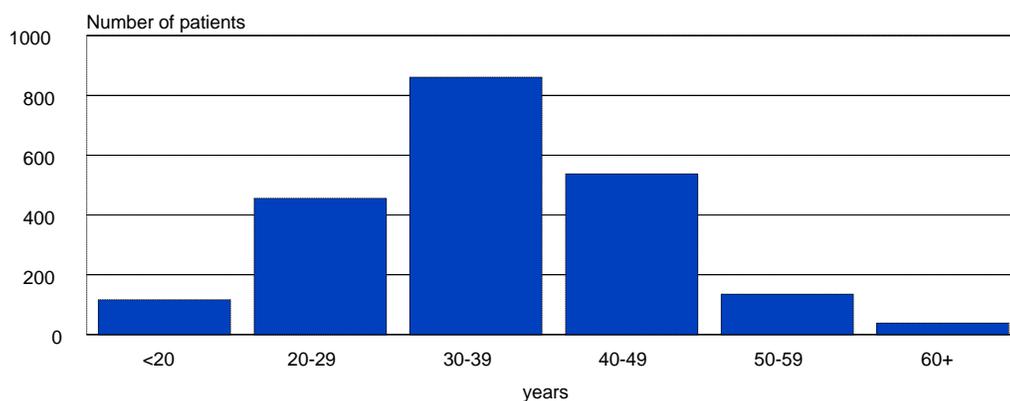
Table 1. Number of patients (N=2144) by center and their characteristics

Characteristics	N	Percent
Female	1038	(48)
Clinics		
TB clinic Adjame	807	(37)
Infectious Diseases Department	585	(27)
USAC clinic	379	(18)
CIRBA clinic	183	(9)
Military Hospital	99	(5)
Pediatrics (Yopougon)	91	(4)
Ivoirian citizenship	1883	(87)
Residing in Abidjan	1638	(76)

1.1.3 Age

Overall distribution by age group is shown in Fig 2: the majority of patients have been between 20 and 49 years old. Of those 20 years of age or older, the mean age was 36 years (range 20-83). The percent of patients under 20 years of age is approximately 5%: and among them, 20% were less than 5 years old. Of those under 20 years of age, the mean age was 7 (range 1 month-19).

Fig 2: Age group distribution among patients accessing the UNAIDS/MOH Drug Access Initiative in Côte d'Ivoire, August 1998- March 2000 (N=2144)



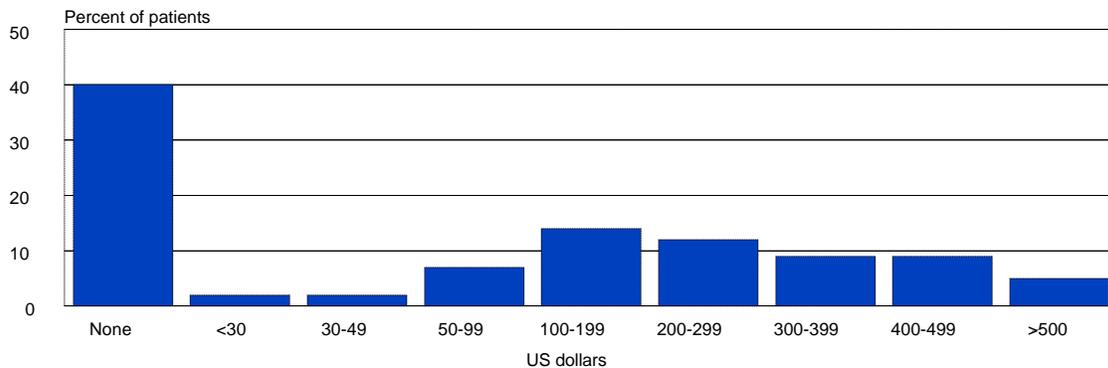
1.1.4 Economic and professional characteristics

There are a number of characteristics that may indirectly indicate economic status of patients, such as the household daily food expenditure. Approximately 55% of patients spend between 2 and 5 US dollars daily for the food of the entire household.

The chart below represents the distribution of salary or monthly income of patients presenting for eligibility screening. Of these patients, 40% have no income and approximately 45% have an income between 50 and 400 US dollars.

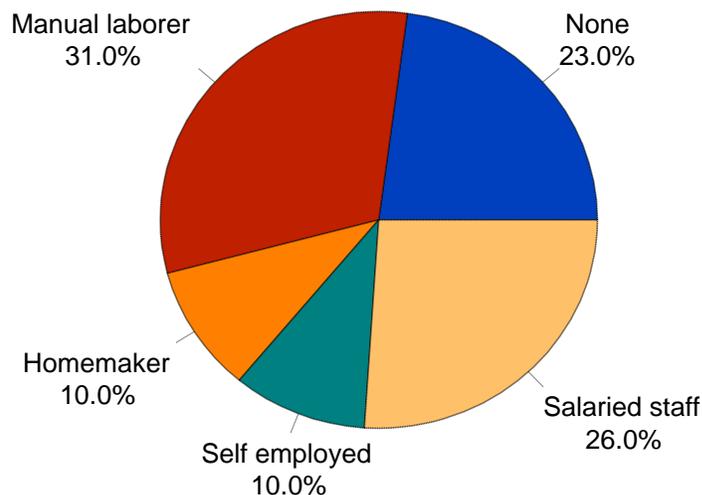
Approximately 35% of patients were the financial providers for more than 4 adult persons and at least 3 children in their household.

Fig 4: Monthly income of patients presenting for eligibility screening in the Initiative - Côte d'Ivoire



A high percentage of patients had no professional activity. Approximately 31% of patients accessing the Initiative have been manual laborers, 26% salaried staff and 10% self employed (Fig 5).

Fig 5: Professional activity of patients accessing the Initiative as of March 31, 2000 - Côte d'Ivoire



1.2. Health status

1.2.1 Medical characteristics

Table 2 below shows the HIV serostatus, CD4 counts, and clinical status of patients accessing the UNAIDS/MOH Drug Access Initiative. Of all patients attending the eligibility screening, 90% were infected with HIV-1, more than 50% had a CD4 count of less than 200/ μ l, 55% met the 1993 CDC expanded AIDS case definition, and 35% were taking chemoprophylaxis for opportunistic infections, principally cotrimoxazole.

Table 2. Medical characteristics of patients presenting for eligibility screening in the Initiative - Côte d'Ivoire (N=2144)

Characteristics	N	Percent
HIV status		
HIV-1	1930	(90)
HIV-2	55	(3)
HIV-D	116	(5)
CD4 count (F1)		
0 – 199	1192	(55)
200 – 499	636	(30)
>500	314	(15)
CDC AIDS case definition	1178	(55)
OI prophylactic regimen	752	(35)

As shown in Table 3, few patients attending the eligibility screening had abnormal biochemistry values using the ACTG (AIDS Clinical Trial Group) classification scheme and a national evaluation scheme established by the School of Pharmacy of University of Côte d'Ivoire. Very few abnormal values (grade 3 and 4) were recorded in the eligibility screening specimen of the three different categories of patients. Among ARV-naïve patients, drug-experienced patients receiving ARV, and drug-experienced patients not currently taking ARV, the prevalence of severe anemia was 8%, 3% and 5% respectively. Regarding the other biochemical parameters, fewer than 3% of patients in any group had abnormal values.

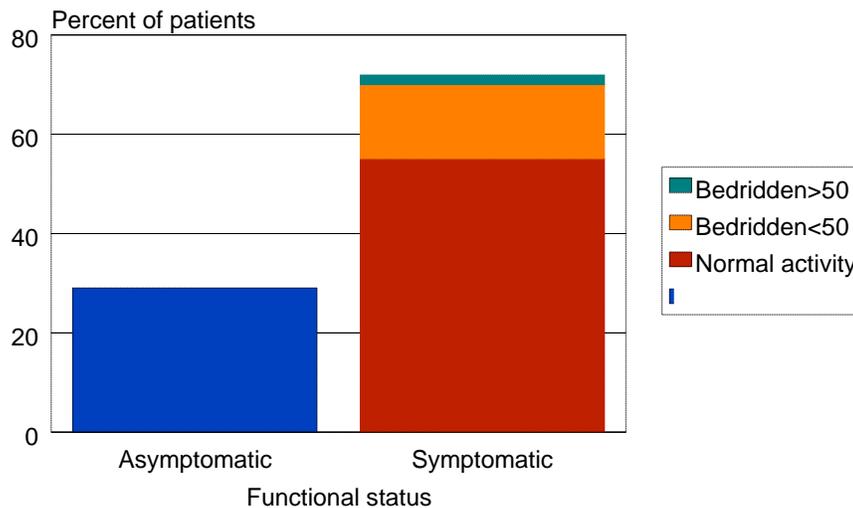
Table 3. Percentage of abnormal values in eligibility screening specimens of patients presenting for the Initiative

ACTG classification (grade 3 and/or 4)	ARV-naïve (n=1874)	Drug-experienced receiving ARV (n=222)	Drug-experienced not taking ARV (n=48)
Hemoglobin	8	3	5
Neutrophils	0	0	0
Platelets	1	1	0
Urea	0.5	0	2
Serum creatinine	1.5	0	3
SGOT	2	2	1
SGPT	0	0	0
Alkaline phosphatase	1	1	0
Amylase	0	0	0
Glycemia	0	0	0

1.2.2 Functional status

The major presenting symptoms were wasting, cough and fever. Figure 6 below shows the functional status of patients at the time of eligibility screening.

Fig 6: Functional status of patients presenting for eligibility screening in the Initiative - Côte d'Ivoire



Although 72% were symptomatic, the majority had a normal activity.

1.2.3 Clinical signs and symptoms

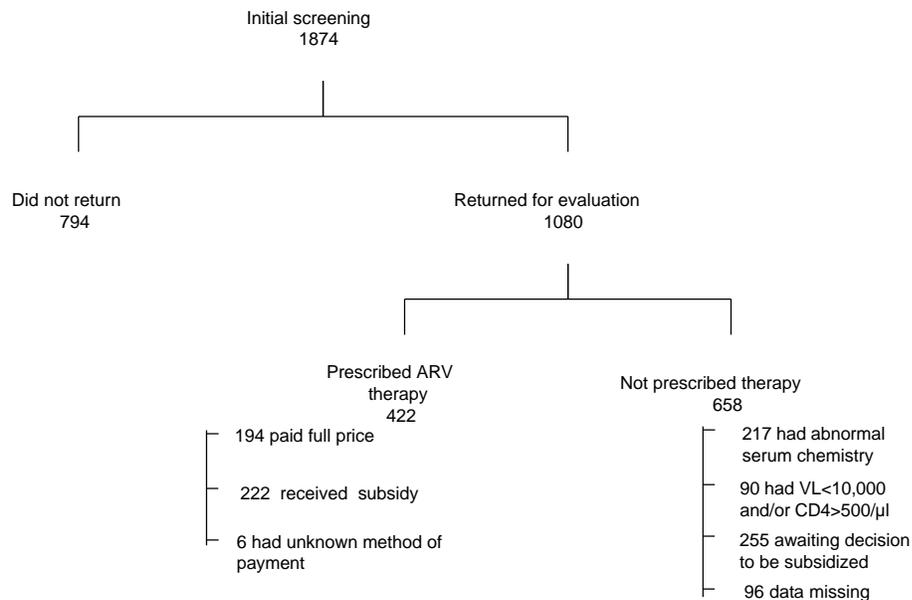
Upon physical examination, the most frequent clinical findings were the following:

Leucoplakia	208 (10%)
Cachexia	227 (10%)
Polyadenopathy	461 (21%)
Dermatitis	496 (23%)
Candidiasis	971 (45%)

2- Assessment of non-prescription and prescription of ARV therapy

The second objective of this program evaluation is to identify reasons why some patients who presented for the eligibility evaluation did not receive ARV therapy. On Figure 7 is a flow chart with the status of naïve patients with or without follow-up and prescription of therapy.

Fig 7: ARV-naïve patients accessing the UNAIDS/MOH Drug Access Initiative - Cote d'Ivoire, August 1998-March 2000



In this flow chart, 1874 naïve patients underwent the eligibility screening. Of these, 794 (40%) did not return to the clinics to obtain the results of the screening. An evaluation of the reasons for non-return to the clinics is planned for later this year. Patients will be contacted either by their care provider or social worker to document the reasons for non-return to the clinics.

Of the 1874 ARV-naïve patients presenting for initial screening, 1080 (60%) returned to the clinics for further evaluation. Of these, 422 received ARV therapy and 658 did not. At the initial screening, an additional 270 ARV drug- experienced patients have also presented. Of them, 48 had a history of ARV therapy but were not currently taking ARV drugs. These patients are not represented in Figure 7.

The reasons for non-prescription of ARV therapy among naïve patients who returned for further evaluation after initial screening have been the following:

Decision for subsidy pending	255 (39%)
Abnormal serum chemistry	217 (33%)
Serum chemistry to be rechecked	136 (21%)
Data missing	96 (14.%)
Viral load $<4 \log_{10}$ copies and/or $CD4 > 500/\mu l$	90 (14%)

The pending decision for subsidy accounts for the most important reason of non-prescription. As of March 31, 2000, 255 patients were still waiting to receive a decision on their application for subsidy. Of those, 86% have been awaiting the decision for more than 2 months (Figure 8).

Subsidy in the UNAIDS/MOH Drug Access Initiative is allocated by a National Committee and ranges from 50% to 95%. The table below compares characteristics of patients paying full price for their ARV drugs and those who obtained their drugs at a subsidized price.

Table 4: Characteristics of patients by subsidy category at initiation of therapy in the Initiative (n=649)

Characteristics	Paid full price	50% subsidy	75% subsidy	95% subsidy
Income $< \$ 200$	72	75	80	83
CDC AIDS case definition	62	52	54	50
CD4 count $< 200/\mu l$ (baseline)	71	73	57	62
Viral load $> 10,000$ copies/ml	52	72	70	69

Patients who paid the full price were marginally less likely to have an income below US \$200 compared with patients who received subsidies.

3. Follow-up of patients for whom ARVs are prescribed

As of March 31, 2000, 649 patients have been prescribed therapy through the UNAIDS Drug Access Initiative. Of these, 422 were ARV-naïve at the time of initial screening.

Based on an average enrollment rate of 32 patients per month, it is expected that 1152 patients would have started ARV therapy by August 2001.

3.1 Description of therapies prescribed

3.1.1 Medication classes of antiretroviral therapy available

Reverse transcriptase inhibitors (RTI)

–Nucleoside RTI (NRTI)

–Non Nucleoside RTI (NNRTI)

Protease inhibitors (PI)

Other adjuvants

–Hydroxyurea (HU)

3.1.2 Definitions

For the purpose of this evaluation, the following definitions will be used. Note that the following definitions are widely used and serve as the reference for antiretroviral therapy.

1- Highly Active Antiretroviral Therapy (HAART)

The intent of this type of therapy is to provide maximal suppression of plasma viral load.

It includes:

- 2 NRTI+ NNRTI or
- 2 NRTI+ PI or
- 3 NRTI (if includes Abacavir)

2- 2NRTI usually referred to as “dual therapy”

The intent of this type of therapy is to suppress plasma viral load though the suppression may not be maximal. It includes:

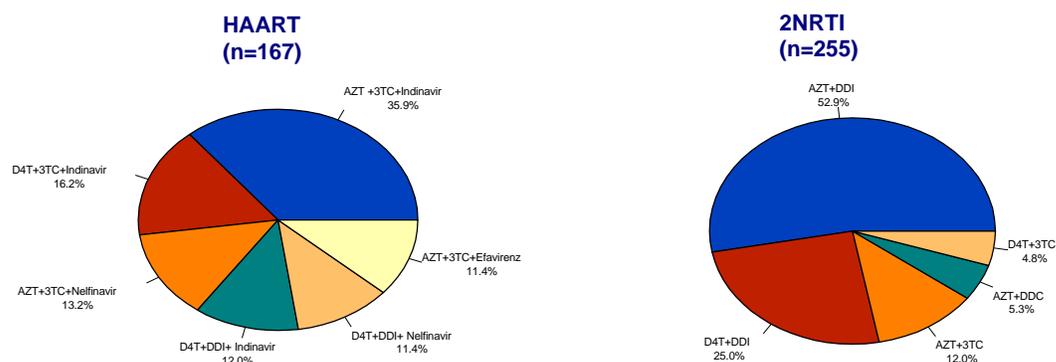
- 2 NRTI+/- HU

3.1.3 Regimen prescribed

Figure 10 below is a pie charts presenting the regimen prescribed among naïve patients.

3.1.4 Characteristics of patients receiving ARV therapy

Fig 10: ARV regimens prescribed for naive patients (n=422)



Naïve and drug-experienced patients beginning therapy under the initiative were compared regarding sociodemographic and clinical characteristics (see Table 5). Naïve patients were more likely to have a monthly income of less than US\$ 200, lower CD4 counts at baseline, and were less likely to be on prophylaxis for opportunistic infection than drug-experienced patients.

Table 5. Comparison among characteristics of naïve and drug-experienced patients

Characteristics	Naïve (n=422)	Drug-experienced (n=222)
Mean age (years)	34	35
Female	41%	45%
Monthly income <US\$ 200	68%	42%
Secondary education or lower	72%	69%
Median viral load at baseline (log ₁₀ copies/ml)	5.5	4.3
Median CD4 count at baseline (cells/μl)	89	192
Met CDC AIDS case definition	69%	33%
Taking OI prophylaxis	33%	45%

3.2 Evaluation of virological and immunological response to ARV therapy.

Patients enrolled in the UNAIDS Drug Access Initiative have been followed over time and evaluated biologically every 3 months. Patients have undergone biochemistry evaluation, CD4 count and viral load testing. Response for ARV-naïve patients will be the major focus in this chapter.

The assessment of virological and immunological response to ARV therapy response will be presented in the following fashion:

Therapy information was categorized as 2NRTIs, HAART and other. The analysis was conducted in two ways. Firstly, the response to therapy was assessed in an as-treated analysis and then in an intent to treat analysis. The latter is presented in the appendices 3 and 5. For both analyses, estimated response to antiretroviral therapy at selected times (days) after initiation of treatment was computed using the scatter plot smoother in S-PLUS software called “super smoother”. This method was used to be able to assess response to therapy among patients who did not adhere to follow-up visits. This method uses regression splines to fit a continuous curve to the data by piecing together local fits to different portions of the data. The super smoother uses a cross-validation method to choose the span of data used for each fit. Laboratory measurements are assumed to be independent.

3.2.1. ARV-naïve patients

3.2.1.1. As treated

This type of analysis is based on the effective time patients have contributed to a specific type of therapy. Therefore, this analysis takes into account any change from one type of therapy to another.

Fig 13: Changes from baseline in viral load among ARV-naïve patients (n=422)
(As treated)

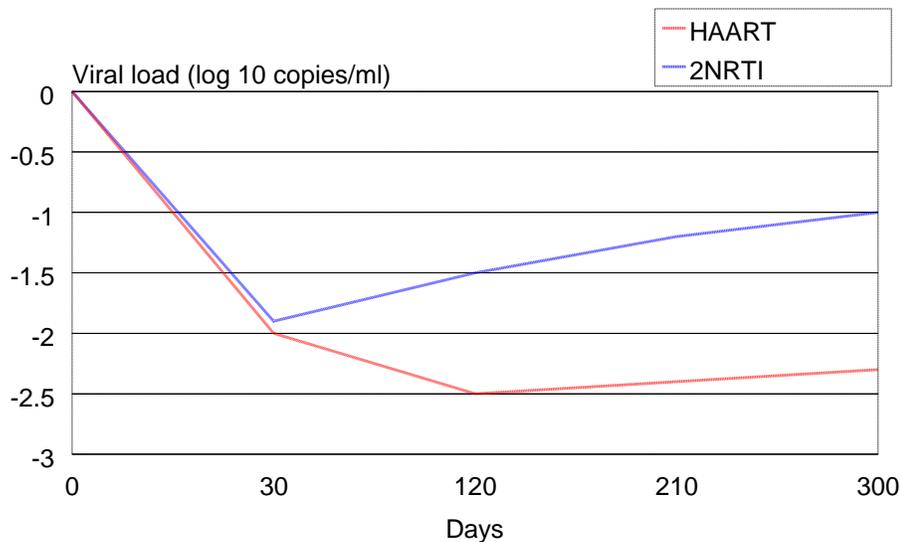


Fig 14: Percent of ARV-naive patients with undetectable viral load (n=422)
(As treated)

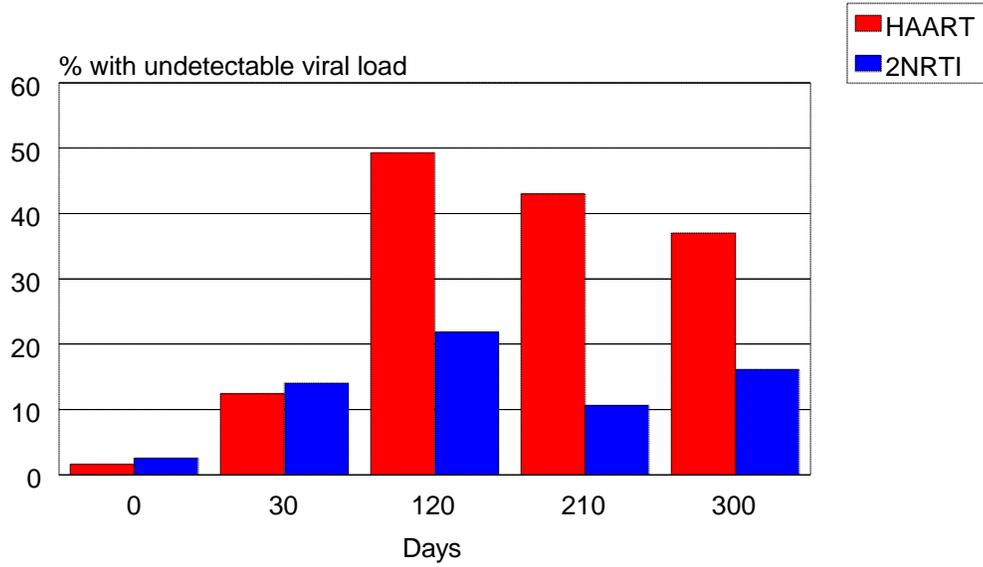
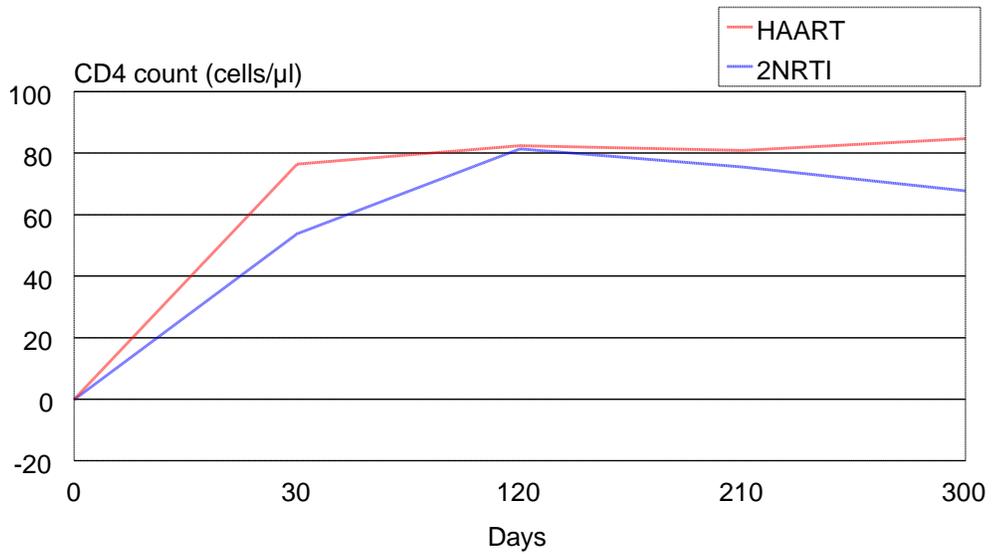


Fig 16: Changes from baseline in CD4 count among ARV-naive patients (n= 422)
(As treated)

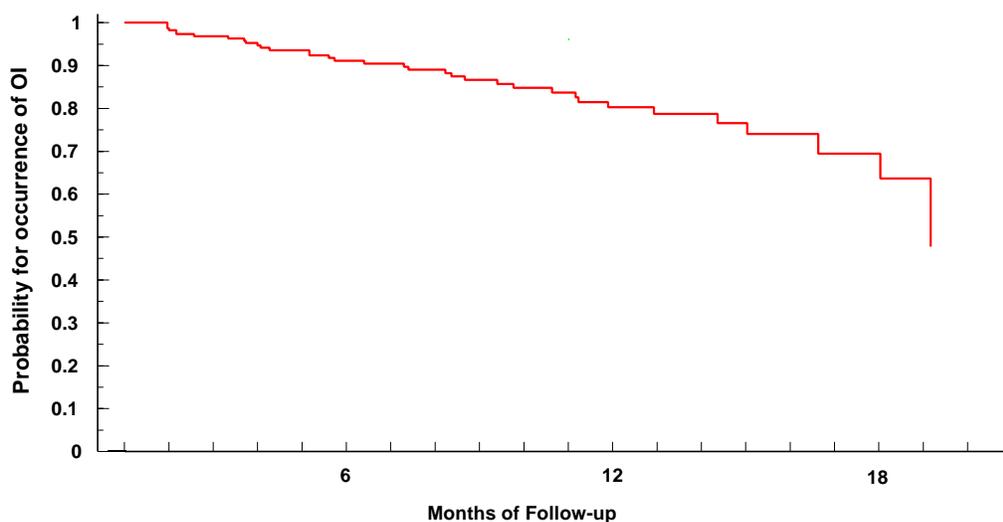


3.3 Clinical response to ARV therapy

3.3.1 Occurrence of opportunistic infections (OI)

In general, patients accessing the UNAIDS/MOH Drug Access Initiative were at an advanced stage of HIV infection upon accessing ARV therapy. This analysis presents the occurrence of opportunistic infections over time after initiating therapy. Figure 17 shows the time interval between initiation of therapy to the time patients present with the first symptom of the category B of the 1993 CDC expanded AIDS case definition. However, there are a number of limitations to this approach since it was neither possible to determine whether these patients had a previous history of AIDS nor to document it. Therefore, patients with an AIDS indicator disease at initiation of therapy were excluded and the clinical status used was based on the clinical examination on the day of initiation of therapy. At 6 months, 11% of patients had experienced at least one episode of opportunistic infection and this number increased to 18% at 1 year. This analysis did not reveal any difference in the different therapy groups. However, due to the limited number drug-experienced patients it was not possible to conduct this analysis by history of ARV therapy.

Fig 17: Time from initiation of therapy to the occurrence of the first opportunistic infection among patients without OI at initiation of therapy (n=254)



3.3.2 Tolerance of ARV

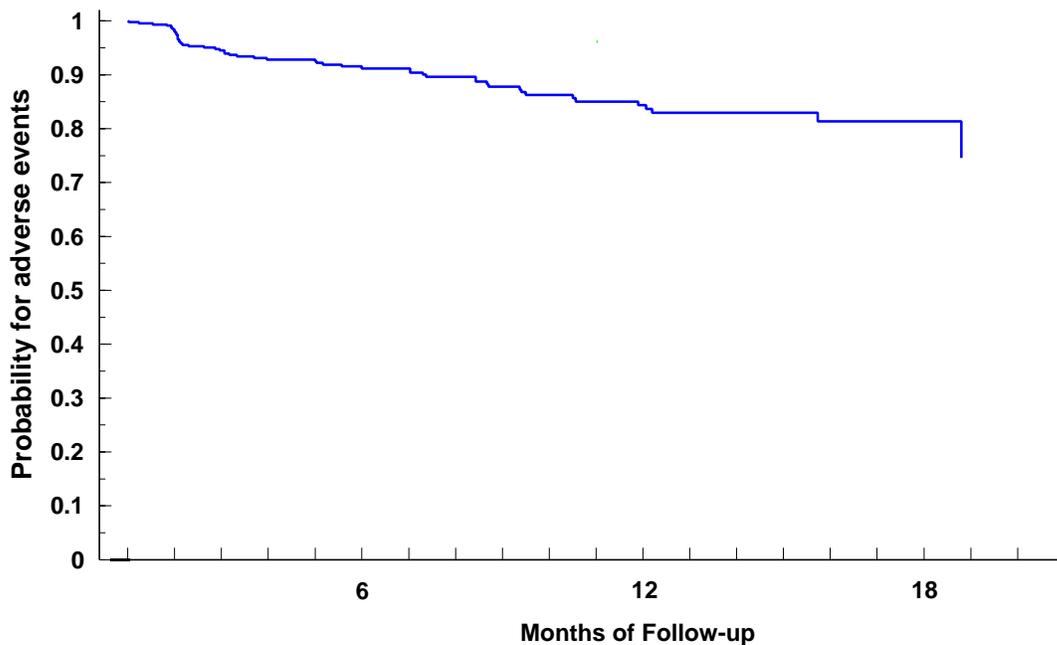
At the eligibility screening, patients had a serum sample drawn for serum chemistry. The biochemistry evaluation is also performed on each patient at each follow-up visit. This chapter refers to adverse events for patients on ARV therapy. The severity grading is presented in the table below. At initiation of therapy, very few patients had abnormal biochemistry results as shown in the following table.

Table 6: Adverse events for patients on ARV therapy

Biochemistry	% with grade 3 or 4
Hemoglobin	4
Neutrophils	0
Platelets	1
Urea	0
Serum creatinine	0
SGOT	1
SGPT	0
Alkaline Phosphatase	1
Amylase	0
Glycemia	0

A Kaplan-Meier analysis was conducted to assess the time from the initiation of ARV therapy to the occurrence of the first adverse event (grade 3 or 4). Patients were censored at last visit or loss to follow up, and the analysis was restricted to persons with follow-up, laboratory values (more than 1 record per patient), excluding patients with adverse events at baseline. Approximately 18% of patients had an adverse event within 12 months.

Fig 19: Time from initiation of therapy to the occurrence of the first adverse event using ACTG classification scheme (n=454)



3.3.3 Adherence

Adherence to therapy in the UNAIDS Drug Access Initiative will be evaluated later this year.

3.3.4 Sustainability of therapy

Status of patients receiving therapy was determined as of March 31, 2000 and patients were classified into three major groups:

Patients active on ARV therapy:

patients who had an initial visit or a follow up visit in the 120 days prior to March 31, 2000, were considered active on ARV therapy.

Patients known to have died:

deaths are usually reported by a family member or next-of kin

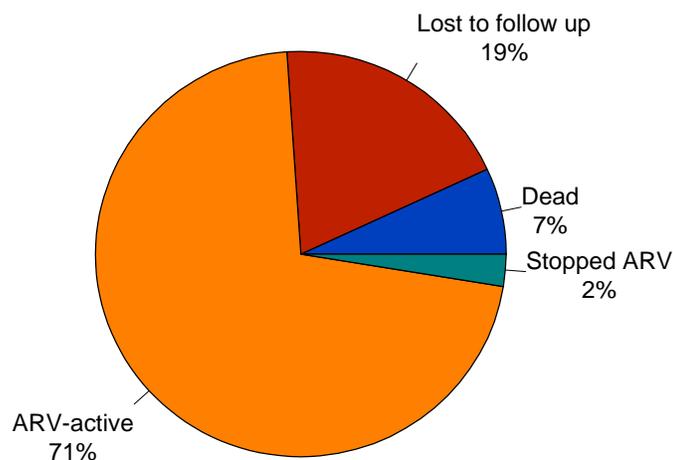
Patients considered lost to follow-up :

if they did not have any visit in the 120 days prior to March 31, 2000.

The results among the 649 patients who were receiving therapy through the Drug Access Initiative are presented in the Figure 20 below. Patients who are known to be alive and who stopped ARV therapy as of last visit represent 2%. This number does not include patients who stopped and then resumed ARV therapy.

The probability of a patient staying in care, who is active taking ARV therapy was calculated by considering the patients who are known to have stopped ARV therapy or those who are lost to follow-up. This probability is 74% at 6 months and 62% at 12 months. Patients who had died were considered to have been actively on ARV therapy until their last visit and therefore were censored in this analysis.

Fig 20: Status of patients enrolled and receiving ARV therapy in the UNAIDS Drug Access Initiative as of March 31, 2000- Côte d'Ivoire



3.3.6 Causes of death

As of March 31, 2000, 44 patients were known to have died. There has been no possibility to document the causes of death. The deaths were usually reported by a family member or ascertained by a social worker when trying to invite patients who are late for their follow-up visit to return to the clinic. Therefore, there is possibility that the number of deaths reported may have been underestimated.

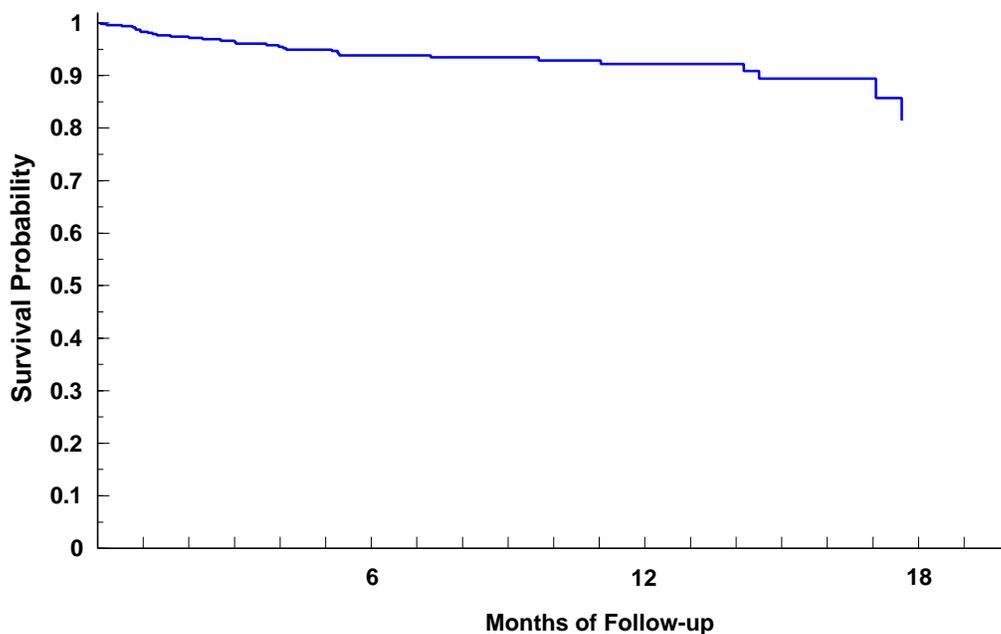
3.4 Survival

Analysis of survival was conducted and results were divided into two major components. The first analysis considers only patients known to have died. The outcome event in this type of analysis was the death. All the other categories of patients including those who stopped ARV therapy or were lost to follow-up during this period were considered to be alive up to the last visit.

3.4.1 Overall survival

The overall survival has been 93% at 6 months, 90% at 12 months, and 86% at 18 months. This effect is however not likely to reflect the reality because deaths are passively reported to the care providers by the family members.

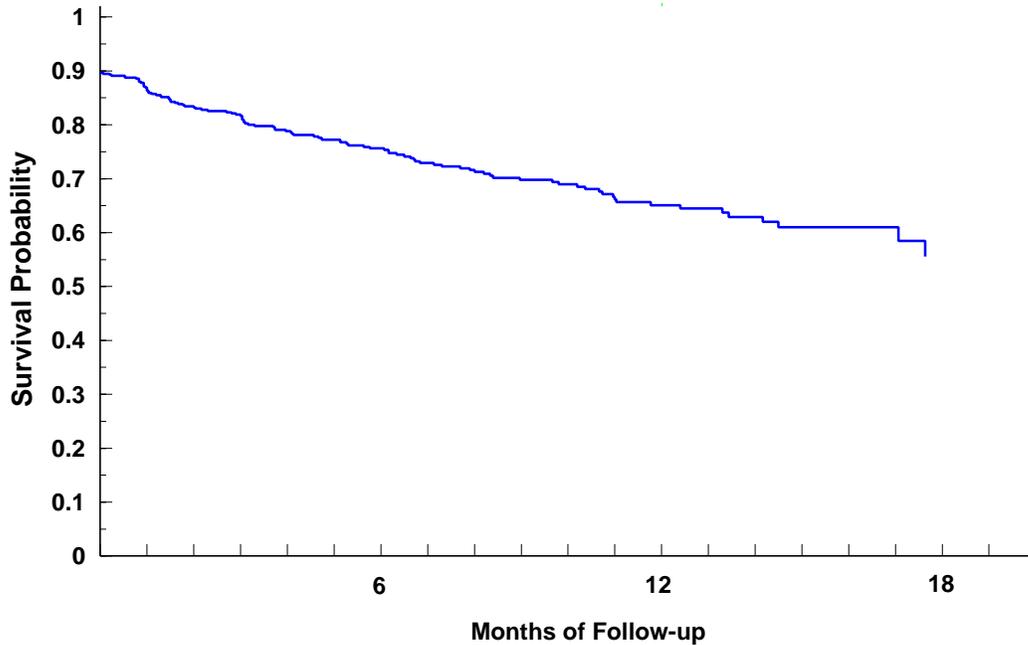
Fig 21: Overall survival among patients receiving therapy (n=649)



3.4.2 Survival and remaining in care

The next survival curve presents a worse case scenario where patients who are lost to follow-up are considered to have died immediately after their last visit. This situation is more likely to depict the reality and to represent persons remaining in care in doctor's practice. In this curve, survival is 75% at 6 months and 64% at 12 months. The 18-month survival is approximately 55%.

Fig 22: Survival and remaining in care- UNAIDS Drug Access Initiative



4. Laboratory cost

Projet RETRO-CI has provided logistic and laboratory technical assistance in support of this initiative at its own expense during the 2-year pilot phase of this evaluation. Results have routinely been forwarded to the treating physician who decides whether to start ARV treatment. As set out in the original protocol, RETRO-CI support of this initiative has been intended for the purpose of evaluation and was not intended to be sustained beyond the period of the evaluation.

At the outset of this Initiative, UNAIDS negotiated reduced prices for certain ARVs through discussions with pharmaceutical companies. The price reductions have come in the form of subsidies from a special solidarity fund that was established by the Ivorian government and seeded with US\$1 million. It has been hoped that this fund would be replenished by donations from corporations, donor agencies, as well as special taxes. Eligibility for these subsidies has been determined based on sociodemographic questionnaire data obtained by a social worker and reviewed by a national committee. However, another large part of the cost of sustaining ARV therapy is the costs of providing laboratory support, and the majority of these costs are the kits or diagnostic reagents themselves. As can be seen in the Table below presenting the costs to Projet RETRO-CI of the various tests that are used in evaluations and in follow-up of each patient, the costs of reagents and diagnostic kits represent the majority of the laboratory costs.

Table 8: Projet RETRO-CI unit laboratory test costs

Test	Cost of test*	Salary	Over-head	Total
CBC	\$3.57	\$0.87	\$2.66	\$7.10
CD4	\$23.10	\$3.48	\$10.65	\$37.23
Multipanel	\$8.48	\$1.39	\$4.26	\$14.13
HIV-Elisa**	\$3.38	\$0.70	\$2.13	\$6.21
HIV-rapid**	\$6.30	\$1.74	\$5.32	\$13.36
Viral load	\$52.50	\$3.31	\$10.14	\$65.95

*reagents and/or kits; also includes disposables (5% of kit cost)

**two tests plus to confirm indeterminants

As set out in the Table 9 below, conservative calculations of the total costs of the evaluations at RETRO-CI from August 1998 through March 2000 exceeded US\$630,000. This represents a cost of almost \$300 for every patient presenting to the Initiative.

Table 9: Projet RETRO-CI costs of ARV Initiative activities (August 1998 – March 2000)

	No. of Naive Patients	No. of Drug-Experienced Patients	Costs
Initial screening	1874	270	\$192,699
Screening evaluation			
Receiving treatment - initial	422		\$ 57,256
Not receiving treatment but returning	658		\$ 19,224
Follow up treatment visits			
Units of 1 mo follow up	342	180	\$ 76,659
Units of 4 mo follow up	329	173	\$ 73,815
Units of 7 mo follow up	300	158	\$ 67,199
Units of 10 mo follow up	295	155	\$ 66,241
Units of 13 mo follow up	206	109	\$ 46,369
Units of 16 mo follow up	145	75	\$ 32,184
All evaluations			\$ 631,646
Cost per patient presenting to Initiative			\$ 295

Whereas UNAIDS has negotiated reduced prices for certain ARVs through discussions with pharmaceutical companies, similar negotiated price reductions for the cost of diagnostic kits and reagents has not yet been achieved. Based on the increasing numbers of patients being followed in this Initiative, consideration should be given to seeking ways of lowering these costs perhaps by working with the major marketers of diagnostic reagents and/or seeking alternative sources of support for future laboratory needs of this Initiative.

Summary

The results of this evaluation can be summarized in three sections related to the initiative procedures and their attendant laboratory costs:

Eligibility screening

- Over 20 months, 2144 patients have presented for the eligibility screening, with an average of 113 patients a month.
- 23% of patients were unemployed and 40% reported having no income.
- 75% were symptomatic: the majority had a normal activity
- 15% had CD4 count above 500 cells/
- Very few laboratory abnormal baseline values are reported

Initiation of therapy

- 42% of patients did not return for evaluation of their screening
- An average of 32 new patients are prescribed ARV therapy a month
- The main reason for non-prescription is the pending decision of the Committee regarding subsidy approval.
- Among naïve patients, 53% started therapy with a subsidy.
- At the time of enrollment in the Initiative, ARV-naïve patients have tended to have a lower CD4 count, have a higher baseline viral load, and have been more likely to meet the 1993 CDC expanded case definition
- Overall 2 NRTI has been the most prescribed type of therapy, although recently HAART seems the preferred choice of regimen.

Follow-up

- After 20 months of therapy the status of follow-up is as follows: 2 % stopped, 7% died, 19% were lost to follow-up and 71% were active on therapy.
- Viral dynamics indicate that HAART has more promising results than 2NRTIs over time; however, so far there is no effect on morbidity, mortality.
- Very few severe adverse events in biochemistry values were reported.

Laboratory Costs

Projet RETRO-CI laboratory costs have been US \$631,646 or almost \$1,000 for each of the 644 patients treated in the Initiative. Most of these costs have been the costs of reagents and diagnostic kits.