

ANTIRETROVIRAL DRUG ACCESSIBILITY TO HIV/AIDS PATIENTS IN BAMAKO, MALI (West Africa)



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DEDICATION

To my beloved husband Hammadoun Aly Sango who missed my company for a long time. I express my gratefulness with grateful thanks for your patience during my absence, your support and help

To my lovely and wonderful children who missed me for a long time

- *Ma Cherie* Agna Sangho
- *Mon Petit* Hambarké Sangho
- *Mon Petit Petit* Demba Sangho

In loving memory of my mother may your soul rest in peace Amen!

To my father for your love, support and blessings

This thesis is dedicated to all of you.

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ABSTRACT OF THESIS

ANTIRETROVIRAL DRUG ACCESSIBILITY TO HIV/AIDS PATIENTS IN BAMAKO, MALI (West Africa)

Background

The republic of Mali is a landlocked country located in West Africa. The national HIV infection prevalence rate was 1.7% in 2001 and still below 2% in 2004. In Mali, ARV drugs are free of charge for HIV/AIDS patients. By the end of 2005 there were 6 000 HIV-infected patients receiving ART out of 22 000 in need (32% coverage). By 2006, it was 37% of coverage. Do these patients under ART have regular access to ARV?

Objective The main objective of the study was to assess patients' perception of difficulties in access to ARV drugs for patients on ART

Methods: A quantitative cross-sectional study was conducted among HIV/AIDS patients and dispensers at the three ARV sites in Bamako, the capital city of Mali. Data were collected with questionnaire by using a face-to-face interview with 210 patients under ART at least one month and 16 dispensers.

Findings

Our findings showed that ARV was perceived accessible in patients and dispensers opinions even though dependant variables. But some main difficulties have been cited related to the lack of money for transportation fee, long waiting time, stigma etc.

138 patients (66%) were female. The mean age for patients was 35.17 ± 9.23 years. 183 patients (87%) were residing in Bamako. 169 patients (80%) had low or no income.

During this study, we estimated the median distance to reach the ARV site to be 9km, the median cost of transportation 500 Francs CFA (≈ 1 US dollar), the mean time to reach ARV site was 100.64 ± 225.80 minutes, the mean waiting time to get ARV at the treatment site (medical prescription plus ARV dispensing) was 3.80 ± 2.65 hours. 166 patients (79%) used public transportation to reach ARV sites.

The advices given by dispensers and received by patients were not consistent. The findings showed existence of differences between the three ARV sites and also between genders in some variables.

Conclusion: Generally, ARV was accessible to the majority of HIV/AIDS patients but some difficulties still existed. However another study would enable the possibility of finding out patients who still have no access to ARV.

Sangho Fanta

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ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CESAC	Center for listening and counselling for HIV-infected patients
CHC	Community Health Centers,
DPM	Direction of Pharmacy and Medicines
EDS III	Health and Demographic Survey
ESTHER	Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau
FMPOS	Faculty of Medicine Pharmacy and Odonto-Stomatology
GDP	Gross Domestic Product
HAART	Highly Active Antiretroviral Therapy
HCNLS	National High Council for AIDS control
HGT	Hospital Gabriel Touré
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HPG	Hospital of Point G
IDU	Injecting Drug Users
IMAARV	Malian Antiretroviral Drug Access Initiative
INN	International Non-proprietary Name
Km	Kilometer
Min	Minute
MoH	Ministry of Health
NDP	National Drug Policy
NEDL	National Essential Drugs List
NGO	Non Governmental Organisation
NLQ	National Laboratory of Quality
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NOK	Norwegian currency
NRTI	Nucleoside/Nucleotide Reverse Transcriptase Inhibitors
PI	Protease Inhibitors
PLWHA	People living with HIV/AIDS
PMTCT	Prevention of Mother to Child Transmission
PPM	Government central medical depot
SOLTHIS	Solidarité Thérapeutique et Initiatives contre le SIDA
SSA	Sub-Sahara Africa
TB	Tuberculosis
UNAIDS	United Nations Joint Programme on AIDS
UNICEF	United Nations Children's Fund
WHO	World Health Organisation

CHAPTER 1: INTRODUCTION

1.1 Background of Mali

The Republic of Mali is a landlocked country located in West Africa with an area of about 1,241,000 km² and 13.518 million inhabitants (1). The capital city is Bamako. The country is divided into eight administrative regions namely Kayes, Koulikoro, Sikasso, Ségou, Mopti, Tombouctou, Gao and Kidal. People are divided into many different ethnic and linguistic groups. Mali being a former French colony has French as official language. However, around 80% of the population speak Bambara (language of Bambara ethnic group).

1.1.1 Main health indicators and health system

- The life expectancy at birth was 48.3 years in 2004
- The child mortality rate under 5 years was 21.9% in 2004 (2)
- The adult mortality rate 15-60 years old was 47.5% for female and 40.9% for male (1)
- The national Human Immunodeficiency Virus (HIV) infection prevalence rate was 1.7% in 2001 (3) and still below 2% in 2004 (4).

The health sector policy is based on community self-financing (user fee and cost-recovery).

The health system is organized into public and private sectors. The public sector is organized into four levels which are:

- The first level is made of the Community Health Centers (CHC) that is in French Centre de Santé Communautaire (CSCOM) 674 by June 2004 (5) and 729 by June 2005 (6)
- The second level corresponds to the first referral made of the District Health Centers (DHC). There were about 58 DHC as at June 2004 (5)
- The third level is made of regional hospitals in each of the 8 regions of Mali
- The fourth level national hospitals

In Mali, there are many health institutions and nursing schools where health workers are trained such as the Faculty of Medicine Pharmacy and Odonto-Stomatology (FMPOS) - Faculté de Médecine, de Pharmacie et d'Odonto-Stomatologie. In addition, Mali has a national laboratory for drug, food and water quality control - National Laboratory of Quality (NLQ) or Laboratoire National de la Santé: LNS.

There are also various disease control programs which target: Malaria, Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS), Tuberculosis (TB), Shistosomiasis etc.

With the creation of the National High Council for AIDS control (HCNLS in French Haut Conseil National de Lutte contre le SIDA), the program of HIV/AIDS was dissolved and replaced by a unit called Cellule Sectorielle de Lutte contre le SIDA under the responsibility of the Ministry of Health (MoH).

1.1.2 Health expenditures

Mali is one of the poorest countries in the world, with a Gross Domestic Product (GDP) of 1 000 US dollars. The health expenditure approximated 6.6% of the GDP in 2004. The total health expenditure per capita was 54 US dollars in 2004 (1).

1.1.3 National Drug Policy

The National Drug Policy (NDP) or Politique Pharmaceutique Nationale (PPN) was adopted in June 1998. The main goal of the pharmaceutical policy is to make good quality essential drugs accessible geographically, physically and financially to the population (7).

The drug policy is also based on the concept of essential drugs with emphasis on promotion of generic drugs under International Non-proprietary Name (INN) -Denomination Commune Internationale (DCI). (8).

The NDP is based on essential drugs selected through the National Essential Drugs List (NEDL) -Liste Nationale des Médicaments Essentiels (LNME) which is revised every two years. The last known revision took place in February 2006.

It is necessary to indicate that essential medicines are those that satisfy the priority health care needs of the population (9)

In 1995, after the devaluation of Francs CFA (local currency in Mali), there was a health initiative under the Implementation of Procurement and Distribution Scheme (IPDS) -Schema Directeur d'Approvisionnement et de Distribution des Médicaments Essentiels (SDADME).

Under the scheme, all public health facilities received the first stock of medicines based on costs at unit level: regional hospital, district warehouse or drug outlet. Appropriate cost – recovery plan was required to permit and maintain regular supply. Funds collected from the drugs sold at health services are used to buy and replenish sold drugs.

In the process, it was observed that collaboration between public and private sector would improve availability of drugs.

The Direction of Pharmacy and Medicines (DPM) - Direction de la Pharmacie et du Médicament (DPM) established in September 2000 is responsible for coordination of different activities in the pharmaceutical sector.

The supply pipeline in Mali is 12 months (from central level to drug outlet).

Procurement of essential drugs for the public sector is done by the government's central medical depot, Pharmacie Populaire du Mali (PPM). Drugs are bought through competitive tenders and based on established annual procurement scheme. Most of the tender processes are done under INN. However, the main source of drug supply for all public health facilities is the PPM. In the case of shortage at PPM or/and regional warehouse public, health units can order drugs from the private wholesalers and their regional unit.

Procurement scheme in Mali

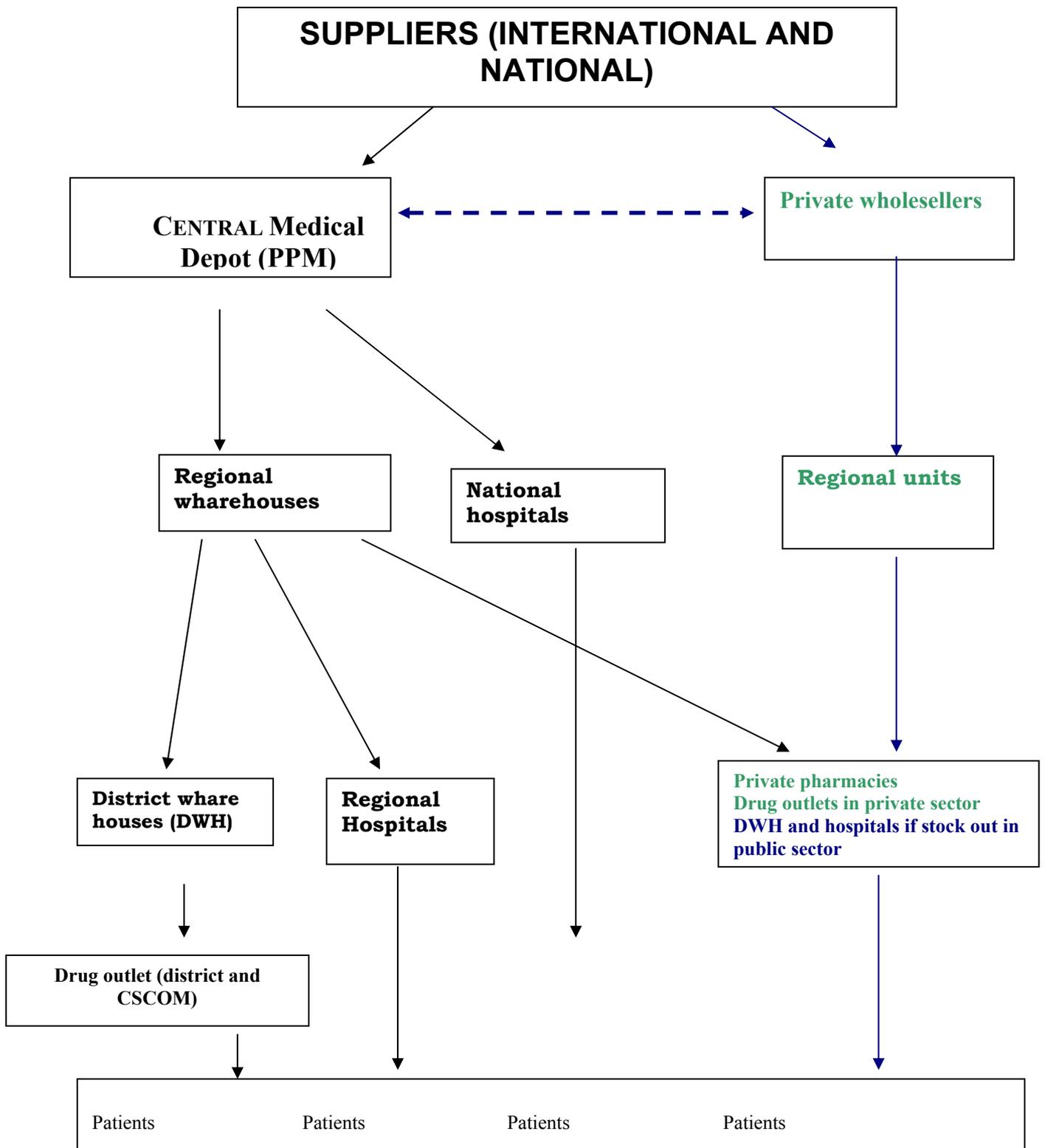


Figure 1: Procurement scheme in Mali

1.1.4 Antiretroviral (ARV) drug supply in Mali

ARV drugs supply Chart

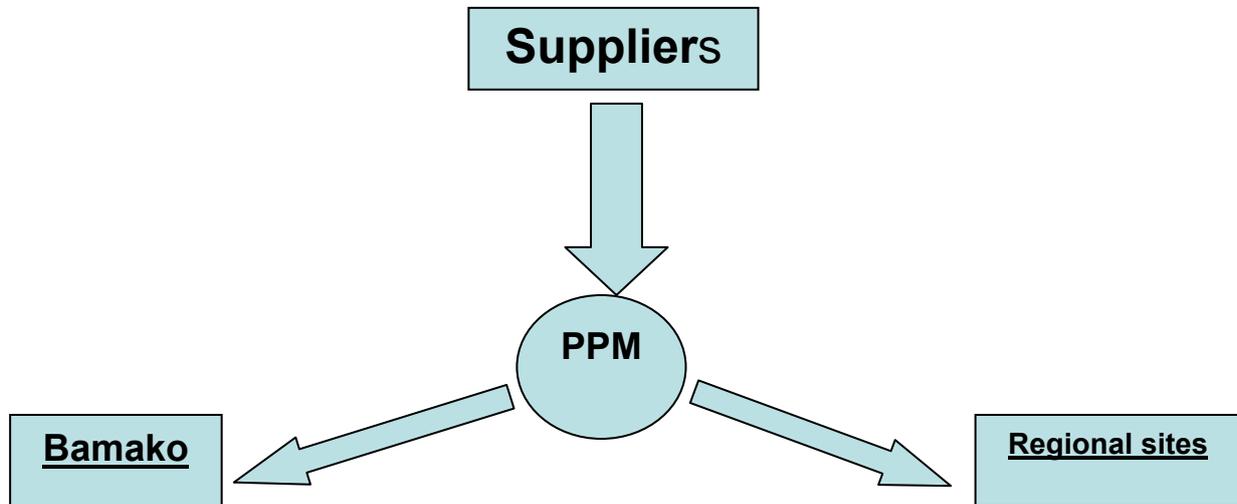


Figure 2: ARV supply scheme in Mali

At the time of data collection ARVs were only available through public sector, at national and regional levels.

The technical services involved in the management of ARV drugs are:

- HCNLS which coordinates all activities in the fight against HIV/AIDS in Mali.
- The financial service of the Ministry of Health, Direction Administrative et Financier (DAF), is responsible for buying the ARV drugs.
- The DPM is in charge of drug order processing for the Ministry of Health.
- The PPM is specifically responsible for ARV procurements: order, storage and distribution, to the treatment sites (ARV sites) based on regular scheme.
- ARV sites: the sites managers are pharmacists who estimate the needs of drugs based on the number of patients and treatment regimes (treatment type). They do the dispensing and also give advices to patients.

In addition to the above structures, there are two other committees involved in the ARVs program: a therapeutic committee which is responsible for the choice of the treatment regimes (first and second lines) and another committee - Committee for ARV Drugs and Lab Tests Management, which is responsible for monitoring of the ARV drugs.

It is to be noted that Mali does not produce ARV drugs; therefore, procurement of ARV drugs is based on importation.

1. Quantification of ARV drugs

Each treatment site makes an expression of needs or requisition for ARV drugs to cover one year. The quantification of needs is done by the pharmacist and the prescriber (skilled medical doctor) based on:

- Treatment guidelines (protocols)
- Monthly inclusion of new AIDS patients
- Last drugs consummation (monthly or annually)

The DPM thereafter compiles various decentralized quantifications from each treatment site. The general requisition or needs of ARV drugs is transmitted to the financial service of the MoH which commands PPM of ordering the drugs.

2. Financing

The purchase of ARV drugs is dependent on funds availability. For example in 2004, only 1/3 of the drugs needed were bought by the PPM. But, nowadays the supply is becoming regular. The main fundings are from the national budget, Global Fund, World Bank, United Nations Children's Fund (UNICEF), Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau (ESTHER), Solidarité Thérapeutique et Initiatives contre le SIDA (SOLTHIS) etc. The latter organisations, ESTHER and SOLTHIS, are French Non Governmental Organisation (NGO).

3. Procurement

In Mali, drugs for AIDS are supplied by the PPM.

After the needs are estimated by the sites, an extra quantity of drugs that accounts for about 3 - 4 months supply is added to the general order. At the moment, the private sector is not enrolled in the ARV drugs procurement and distribution.

Upon reception at central level, the stock is placed under quarantine for laboratory test (quality control). In Mali, however the NLQ is not well equipped to performing all the necessary tests for drug quality control.

4. Distribution

ARV drugs are initially stored by PPM and gradually distributed according to the needs of the different treatment sites based on their monthly request. These ARV drugs are distributed based on drugs availability at central storage.

In many instances, a treatment site can utilize its means of transportation in collection of supplies or allocated drugs so as to avoid long distribution delay which could lead to shortage. In a case of shortfall in distributed supplies, a treatment site is permitted to make a return journey to collect outstanding allocations whenever it is available.

5. Dispensing

The ARV sites are the only structures approved for dispensing drugs to patients. The dispensing is done under the responsibility of pharmacists who are also the site managers.

1.1.5 Treatment guideline in Mali

The treatment is mostly based on:

- 2 Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTI) + 1 Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) which are expected to cover 80% of the needs of new patients
- 2 NRTI + 1 Protease Inhibitors (PI)

First line treatment

Stavudine (D4T) + Lamivudine (3TC) + Nevirapine (NVP)

Alternative regimes

Zidovudine (ZDV) + Lamivudine (3TC) + Efavirenz (EFZ)

Zidovudine (ZDV) + Lamivudine (3TC) + Nevirapine (NVP)

Stavudine (D4T) + Lamivudine (3TC) + Efavirenz (EFZ)

Particular case of TB

Stavudine (D4T) + Lamivudine (3TC) + Efavirenz (EFZ)

Second line treatment

Abacavir (ABC) + Didanosine GR* (DDI) + Indinavir/Ritonavir (IDV/r)

*GR = gastro-resistant

All these ARV drugs except Ritonavir can be stored at room temperature, which is 15 – 25 degrees Centigrade, up to 30 in some climatic zones.

1.1.6 Mali's response to the HIV epidemic

The Malian Antiretroviral Drug Access Initiative - Initiative Malienne d'Accès aux Antiretroviraux (IMAARV) was launched in 2001.

During this period, ARV drugs were subsidized and only available at the three treatment sites, all located in Bamako:

- Two national hospitals: Hospital Gabriel Touré (HGT) and Hospital of Point G (HPG)
- One NGO: Center for Listening and Counselling for HIV-infected patients - Centre d'Ecoute, de Soins, d'Animation et de Conseil (CESAC)

It was not until 2005, that the government of Mali declared ARV drugs free of charge for every patient in need under Decree No 05 – 147/P-RM of 31/3/2005. The free ARV drugs were facilitated by the Global Fund and partners such as ESTHER (Bamako, Kayes and Sikasso), SOLTHIS (Ségou) and the creation of the High Council for AIDS Control for Funds Mobilisation.

From being subsidized in 2001, ARV drugs were made free of charge in 2005 for every AIDS patient in need. The ARV prescriber's guideline was that a beneficiary tests HIV positive and also meet biological criteria stipulated under the overall national guideline. In April 2006, there were 14 ARV sites and 60 Prevention of Mother to Child Transmission (PMTCT): Prevention de la Transmission Mère-Enfant (PTME) sites in Mali.

In addition to the existing centers, there are related projects. The treatment is based on tri-therapy and is delivered through 14 ARV sites, all located in urban centers.

Free ARV drugs encourage people to undergo screening for their HIV status because of the treatment opportunity and availability. A good antiretroviral therapy (ART) requires an efficient ARV drug procurement scheme and a regular availability. However, making drug available at ARV sites through a well organized procurement scheme does not necessary make drug accessible to HIV/AIDS patients. **Therefore accessibility to ARV drugs is a crucial component for the success of ART.**

1.2 Literature review

1.2.1 Antiretroviral Drugs

ARV inhibits the replication of HIV. There are four main groups of anti-HIV drugs. Each of these groups attacks HIV in different ways.

- NRTI
- NNRTI
- PI
- Fusion or Entry Inhibitors (10).

Of these 4 groups of drugs, only the fusion inhibitors are not used in Mali.

ART is the main type of treatment for HIV/AIDS. Though it is not a cure, but it can prevent people from becoming ill for many years. Thus ART seeks to improve HIV patients' quality of life.

The term Highly Active Antiretroviral Therapy (HAART) is used to describe a combination of three or more anti-HIV drugs. The treatment consists of drugs that have to be taken every day for the rest of the patient's life (11)

Access to antiretroviral therapy is essential for survival of people living with HIV/AIDS (12).

1.2.2 Accessibility of treatment

Access to drugs depends on four key points: rational selection, affordable prices, sustainable finances and reliable health systems. A barrier to access to treatment is anything that prevents patients from getting the treatment they need (13).

There are different types of barriers to access to HIV/AIDS-related treatment:

- Financial barriers – such as the cost of drugs and the need to prioritize other general supplies, such as food;
- Organizational barriers – such as poor administration of treatment services and lack of skilled staff;
- Physical barriers – such as treatment facilities being distant and transport not being available; and
- Social barriers – such as stigma being associated with a HIV treatment and patients concern on issues of confidentiality.

Access may also be measured by distance, time, costs, or social and cultural factors (14).

1.2.3 Antiretroviral drugs accessibility to HIV/AIDS patients

1.2.3.1 Overview of the HIV/AIDS epidemic

AIDS was first recognized in 1981, and since then more than 25 million people have died from it. AIDS is the leading cause of death worldwide, closely followed by TB and malaria (15).

In 2005, 40.3 million adults and children were living with HIV. Among those, 25.8 million lived in Sub-Sahara Africa (SSA). More than 77% of the 3.1 millions annual deaths due to AIDS occur in SSA countries (4).

HIV spreads through high risk groups such as men who have sex with men and Intravenous Drug Users (IDU) in developed countries.

For the developing countries, it is usually through heterosexual contact, transmission from mother to child during pregnancy and delivery, and contaminated blood in medical area (15).

1.2.3.2 Condition and status of access

Despite the burden caused by the AIDS epidemic, access to ART is still very low.

In June 2005 for example, only 1 million received ART (15% coverage) out of 6.5 million (0-49 years old) who were in need in low and middle-income countries under “3 by 5” initiative (means treated 3 million patients in need at the end of 2005) (4).

According to the report of the World Health Organisation (WHO) and the United Nations Joint Programme on AIDS (UNAIDS), 1.3 million people were receiving treatment at the end of December 2005 (16).

In Mali, 6 000 HIV-infected patients received ART in December 2005 out of 22 000 (0-49 years old) in need (32% coverage). The average monthly inclusion is 349 patients which represents those eligible for treatment (medical criteria) (16). The recent report from April 2007 indicated a ART coverage of 37% (17).

1.2.3.3 Barriers to ARV accessibility

1) Cost of ARV

Cost of ARV drugs is observed to be one of the most important barriers that contribute to its inaccessibility.

a) ARV not free

In Burkina-Faso, Nguyen et al. (2003) demonstrated that the cost of drugs has been and remains the main barrier to increased access and adherence to treatment.

In Botswana, Weiser et al. (2003) established that the cost was the most significant treatment barrier to ART adherence.

In Malawi, van Oosterhout et al. (2005) stated that the most important reasons for non-adherence were shortage of drugs in the hospital pharmacy and personal financial constraints.

In Rwanda, Fisher et al. (2006) found that 24% of patients who interrupted treatment have done so because of financial problems.

The conclusion of these four studies is that ARV should be either subsidized or made free of charge to patients in order to increase treatment access (18-21).

b) ARV subsidization: Taverne’s study 2003 showed that subsidizing ART is not enough to favour better access as shown by the experience of some countries (Ivory Coast, Senegal, and Mali) (22).

In Ivory Coast, while the awareness about existing drug program limited access to ART (23), the fee paid by the patient also represents major obstacle for proper medical management. Therefore, free access should be implemented in Africa countries (22).

It is expected that free access should provide rational treatment to patients and reduce the demand for ARV drug on the informal market that can reduce the risk of resistance due to misuse or inappropriate use. (24).

2) Free access to ARV

The question may arise as to the accessibility level to ARV drugs after the removal of cost for HIV/AIDS patients. Theoretically, free access should necessarily improve accessibility to ARV drugs. But in practice, certain barriers may still exist.

a) Demographic characteristics: age and sex

A study carried out in British Columbia, Canada among IDU showed that ART drugs were accessible for female and young people. Female IDU are twice less likely to receive ART than male. Young IDUs were however less aware of ART benefits, and less likely to seek care (25). The investigators did not explore barriers for female to access ART and the IDUs constitute a specific group of patients.

b) Time and cost of transport

The limitation of ARV access was shown to be related to cost of transportation by Benjaber et al. From a study on antiretroviral treatment compliance carried out in Morocco there was considerable distance between patient settlements and treatment sites. (26).

c) Difficulty in picking up medication

An evaluation of ART in a Rio de Janeiro public clinic showed that 23.7% (14/59) of AIDS patients lacked medication for more than a month. Among those 78% did not manage to pick up their medication but the investigators did not report the reason which could include stigma, waiting time etc. (27).

d) Lack of adequate health care delivery system

The issue of confidentiality is crucially important in view of widespread AIDS related stigma and discrimination (28). In Mali, the lack of adequate facilities for dispensing presents serious challenge to protect patients' confidentiality. In this case, some patients would prefer to get their medication outside the working days, usually on Saturdays (29).

1.3 Rationale of the study

The problems related to ARV drugs accessibility for HIV/AIDS patients are of geographical, economical and socio-cultural type. An irregular access to antiretroviral drugs could lead to drug resistance and increased morbidity and mortality of these patients (18;26;27;30).

HIV/AIDS patients are subject to stigma and discrimination. However, HAART transforms AIDS from a debilitating and fatal disease to a chronic and manageable one (31).

Investigators from Uganda concluded that stigma could be reduced if ARV drugs are integrated in the general drug supply scheme (32).

Some settings are not accessible during rainy season (33) which could disturb drug availability and accessibility. When patients do not pick up their medication, the drugs could expire, causing wastage of the scarce resources in poor setting.

From the light of these studies, one could say that accessibility to ARV is a prerequisite for treatment use, compliance or adherence. ARV drugs for a treatment can be available locally but at the same time are not accessible (13). Few studies were done for ARV drugs accessibility. **However, to our knowledge no study has explored ARV drugs accessibility in a poor, non-ARV drug-producing setting, where these drugs are made free.**

In Mali, ART program is going to be expanded, the present study will explore the difficulties that ART patients encounter when getting their ARV drugs in order to make efficient, the expansion of ARV sites.

CHAPTER 2: AIM AND OBJECTIVES

2.1 Aim

Numerous barriers can limit access of HIV/AIDS patient to ARV drugs: location of ARV dispensing sites, cost of transportation, long waiting time, stigma and discrimination, trust in health system and ARV drugs, insufficiency of qualified personnel for dispensing, manner of ARV dispensing etc.

Our study will focus on geographical and financial accessibility, quality of dispensing and opinions of HIV/AIDS patients and dispensers, on ARV drugs accessibility.

In the light of these public health major challenges, this study is undertaken with a view to provide some recommendations that will improve and facilitate ARV access to HIV/AIDS patients.

The findings will identify and illustrate difficulties to ARV drugs accessibility which can be related to patient and/or to a country's health system.

2.2 Research question

What are the difficulties which limit ARV drug accessibility for HIV/AIDS patient?

2.3 Objective

2.3.1 General objective

To identify and assess difficulties to ARV drugs accessibility for HIV/AIDS patients

2.3.2 Specific objectives

1. To describe the socio-demographic variables (sex, age, profession, income etc)
2. To determine the average distance for patient to reach treatment site
3. To determine the mean time spent by patients, to reach ARV sites
4. To determine the mean waiting time to get ARV drugs
5. To determine the means and cost of transportation
6. To identify other problems associated with access to ARV drugs
7. To determine the quality of dispensing in terms of confidentiality and advices
8. To describe patient and dispenser's opinion on ARV drugs accessibility

CHAPTER 3: METHODOLOGY

3.1 Materials of the present study

3.1.1 Study area

LOCALISATION DES SITES ARV POINT G, Gabriel TOURE, CESAC DANS LE DISTRICT DE BAMAKO

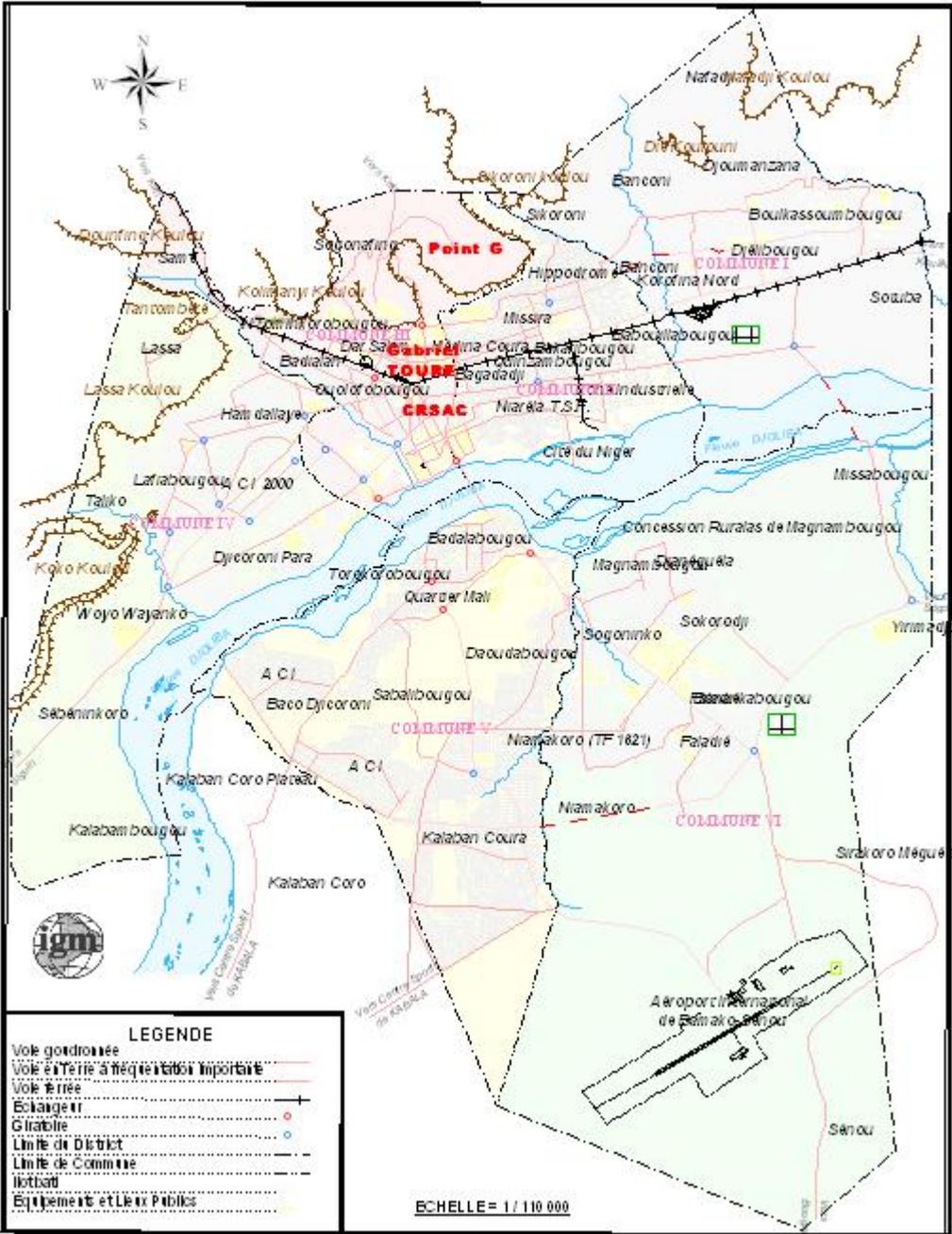


Figure 3: Map of Bamako District with the three ARV sites

The study was conducted in three ARV sites which were providing ART in Bamako, the capital city of Mali. Bamako is situated on the Niger River, in south-west of Mali. In 2006, Bamako's population was 1 690 471. (34). Bamako is divided into 6 communes or municipalities (commune I, II, III, IV, V and VI) and 60 areas ("quartiers"). In December 2004, Bamako had: 50 Community Health Centers based on community responsibility and 6 district clinics. Each commune has a health center under Bamako's two national hospitals. Two out of Mali's three national hospitals are located in Bamako. These are: HGT and HPG both with status of University Hospitals - Centre Hospitalo-Universitaire (CHU). The third is a national hospital for mother and child hospital - Hôpital Mère-Enfant called "Luxembourg". The choice of Bamako is justified by the fact that it was not only the first ARV sites in Mali but retains the experience since 2001. At that time, ARV drugs were subsidized through the Malian Antiretroviral Drug Access Initiative launched in 2001. The three treatment sites which cover approximately 80% of HIV/AIDS patients in Mali (29) are all located in Bamako as follows:

- HGT
- CESAC
- HPG

Each of the three sites has its own organisations of People living with HIV/AIDS (PLWHA) such as:

- "Sabougnouma" at HGT
- AMAS/AFAS at CESAC
- "Yeléen" at HPG

These organisations help a lot in HIV/AIDS patients' support.

The district of Bamako, with 2.5%, had the highest rate of HIV prevalence inside the country followed by the regions of Kayes, Ségou and Koulikoro 1.9% each (3).

In May 2005, 3102 HIV-infected patients received ART in Bamako. The repartition were 750 at HGT, 1445 patients at CESAC and 907 patients for HPG (29). However in July 2006, it was 6343 patients, over the double under ART, 1299 patients at HGT, 3199 at CESAC and 1845 at HPG from which the samples for this study were drawn.

3.1.2 Description of the ARV sites

1) HGT

Hospital Gabriel Touré is the only site which dispenses ARV to the children. The consultation is done in the paediatric unit.

The consultation for adult is done in the unit of gastro-enterology. The site had around 75 patients (adult and children) per day. HGT is located in the second commune of Bamako.

2) CESAC

CESAC is located in Commune III of Bamako. This site is closely situated to the big market of Bamako (Grand marché de Bamako). CESAC specialises on HIV/AIDS treatment. The site receives around 113 patients per day.

3) HPG

Like CESAC, HPG is also located in the third commune in Bamako but on the hill side. The consultation is done at the infectious diseases unit. The dispensing is done for 38 patients per day.

3.1.3 Study population

The specific population from which data are collected is called the study population (35).

The study population consisted of patients under ART (18 – 65 years old) who frequented the three ARV sites in the study period and the dispensers in these sites. The informant was recruited in the ARV sites and interviewed.

3.1.4 Target population

The population from which conclusions are drawn is called the target population (35). The target group for our investigation was HIV/AIDS patients under antiretroviral therapy in the three ARV sites in Bamako and all dispensers.

3.1.5 Inclusion and exclusion criteria

All dispensers in the three sites were included in our study. The criteria for HIV/AIDS patients were the following:

Inclusion criteria: our study included every patient aged 18 to 65 that has been under ART for at least one month. The age group 18 years and above were selected because it consists of people assumed to be responsible for getting their own ARV drugs and they can support their own views.

Exclusion criteria: The following informants were excluded:

- Pregnant women
- Patients below 18 years old
- Patients above 65 years old
- Hospitalized patients
- Informant not willing to participate.

3.1.6 Sampling

The sample procedure was a non-probability sampling (convenience sampling). Convenience sampling was chosen because of some characteristics of our study for example: many dependent variables, scarce data on accessibility and limited resources (time and funds).

The sample selection should have been randomly, being an ideal method for survey (36). In practice however, it was shown that drawing patients from the list of ARV site is extremely difficult especially in effort to interview all of them, because of their lack of regularity at ARV sites during the data collection period. In many of such instances, lack of complete addresses and/or the lack of disclosure about medical condition to their family members or/and community reduced possibility of follow-ups or monitoring.

In all, our sample was 210 HIV/AIDS patients and 16 dispensers located around the three ARV sites. The repartition was done according to the number of patients per site.

Table 1: Patients under ARV by July 2006 and sample size

ARV site	Number of patients HIV/AIDS	Study sample
HGT	1 299	43
CESAC	3 199	106
HPG	1 845	61
Total	6 343	210

Every patient willing to participate after receiving their drugs (who meets our inclusion criteria) was interviewed. All dispensers in the three sites were interviewed. The informed consent of the informant was sought and obtained. We stayed at the ARV sites until the securing of required number of informants needed for inclusion in the study.

3.2 Method of the present study

3.2.1 Study design

A quantitative study using a cross sectional design was used to assess difficulties to free access to ARV drugs by HIV/AIDS patients in Bamako, Republic of Mali.

Many cross-sectional studies are descriptive, and these are called surveys. All information is collected at the same time because subjects are only contacted once (36).

3.2.1.1 Benefits

A cross-sectional study is most useful for description (35;37). Descriptive study involves the description of characteristics of a particular situation, event or case (37). In this circumstance, cross-sectional survey is a suitable design, when little is known of the phenomenon under investigation.

Our study intends to provide the baseline data which can help policy-makers to improve ARV drugs accessibility to HIV/AIDS patients.

Cross-sectional study does not suffer from many disadvantages such as recall bias and loss due to follow-ups as it is usually the case in cohort study. In addition, cross-sectional study is relatively cheap and easy to carry out (36).

3.2.1.2 Drawbacks

- Sample selection

The weakness of most observational studies is that the sample may not be representative of the population investigated. The validity of the extrapolation is therefore crucially dependent on the representativeness of the sample

- Response rate

By using postal questionnaire, the response rate could be low (36).

However in our case a face-to-face interview provided a high response rate. The information was collected at the same time as the informant was contacted. The questionnaire was usually more completely filled than self-administered questionnaire for example. Finally, the cultural context in Mali and the level of illiteracy favoured face-to-face interviews.

The questionnaire assured the confidentiality of the information which is very important in HIV area.

3.2.2 Study period

The fieldwork was conducted in five months, from July to November 2006.

3.2.3 Data collection tool

The research tool (questionnaire) contained both close-ended and open-ended questions.

The closed-ended questions concerned the independent variables while the open-ended questions covered the dependant variables concerning views of informants.

Open-ended question was asked about the opinion of patients and dispensers on ARV drugs accessibility and also patient's satisfaction with manner of drug dispensing.

The questionnaire was constructed in English and translated into French because Mali is a French-speaking country. After the workshop, some improvements were made to the questionnaire.

3.2.4 Variables

The following variables were included in our study:

3.2.4.1 Independent variables

- The socio- economic variables were as follows: sex, age, level of schooling, marital status, profession, patient's income and residence.
- The difficulties variables were the distance covered by patient, the time spent to reach treatment site, the time spent to get ARV drugs, the time spent to get prescription, the means of transportation and the cost of transportation.

3.2.4.2 Dependent variables

- The geographical accessibility was estimated by the distance covered and the time spent
- Financial accessibility
- Opinion of informants about accessibility
- Quality of dispensing
- Patient's satisfaction with dispensing
- Staff coverage for dispensing

3.2.4.3 Operational definitions of variables:

The definitions used in our study were:

Difficulty: anything that can limit an HIV/AIDS patient on antiretroviral therapy to get regular access to antiretroviral drugs.

Dispenser: any person (pharmacist or other personal) who dispenses ARV drugs.

Gender and age

- Gender was Female or Male
- Age the age was recorded in years

Gender and age can influence ARV drugs access according to the literature (25).

Level of schooling means the numbers of years in formal schooling. The level of schooling was categorised as follows:

- No schooling (0 year)
- Primary school (1 – 6 years)
- Junior high school (7 – 9 years)

- Secondary school (10 – 12 years)
- Higher education (>12 years)

The educational background could contribute to increased access to ARV.

Marital status was categorised as single, married, widowed and divorced

In Malian context, marital status could influence financial support for transportation costs. A married woman for example is more likely to get support from her husband.

Profession of the patient was relevant and asked because his/her profession could guide us about his/her income.

Income of patient means how much the patient earns per month. The income provided an insight whether or not the patient could afford to pay the transportation costs. The categorisation of the income level was as follows: no income = 0 Franc CFA, low income from 7 000 to 50 000 Francs CFA, moderate income from 50 005 to 100 000 Francs CFA and high income above 100 000 Francs CFA.

Residence: the residence of patient was reported. The report enabled an estimation of distance covered by patient if the patient was not able to give us this figure.

Distance covered by patient means the distance to reach the treatment site.

Time spent to reach treatment site means the time spent by patient to reach the ARV site.

Time spent to get ARV drug means the time spent by patient at the ARV site before receiving ARV drugs.

Time spent to get medical prescription means the time spent by patient at the treatment site before receiving medical prescription.

Waiting time means the time spent at the treatment site to get medical prescription and ARV drugs.

Means of transportation is the type of transportation used by the patient to reach the treatment site. They were categorized as foot, bus, taxi, train, car, bike, motorbike and others.

Cost of transportation: money spent by patient to reach treatment site.

Geographical accessibility: the geographical accessibility was defined according to distance covered or the time spent by the patient to reach the ARV site. We had two sub-variables which were: accessibility by distance and the accessibility by time.

Categorization was done according to the distance or the time as follows:

1) **Accessibility by distance covered.**

The following categorization was used in terms of distance covered by HIV/AIDS patients:

- Very accessible, if the distance covered was ≤ 5 kilometers (km)

- Accessible, if the distance was $>5 - \leq 15$ km
- Less accessible, if the distance covered was $> 15 - \leq 30$ km
- Not accessible, if the distance covered was > 30 km

2) **Accessibility by time spent:**

The following categorization was used in terms of time spent by HIV/AIDS patients:

- Very accessible, if the time spent was ≤ 30 minutes (min)
- Accessible, if the time spent was 31- 60 min
- Less accessible, if the time spent was 61- 180 min
- Not accessible, if the time spent was > 180 min

Financial accessibility: this represents the cost of transportation in percentage of patient income. The financial accessibility was categorised as follows:

- Very accessible, if the cost of transportation represented less than 5% of the patient's income
- Accessible, if the cost of transportation represented 5 – 10% of the patient income
- Not accessible, if the cost of transportation represented more than 10% of the patient income

Opinion about accessibility means self-report opinion about ARV drug accessibility by informant (HIV/AIDS patient and dispenser).

Question was asked whether or not ARV drugs were accessible. The categorization of the positive answers was based on informant's report or response in this manner: very accessible, accessible, less accessible and not accessible.

Quality of dispensing was derived from evaluation of advices given to patients together with considerations of issue of confidentiality. The advices relates to directions given for usage of drugs (example, dosage and administration), side-effects, storage and new appointment. Questions were asked whether or not the informants gave (dispensers) or received (patients) advices. It is considered that confidentiality should be a prerequisite for good dispensing. The quality of dispensing was categorized as poor, acceptable, good and very good based on the advices and management of confidentiality as follows:

- Poor quality of dispensing: any advice without confidentiality
- Acceptable quality of dispensing: confidentiality with one advice
- Good quality of dispensing: confidentiality with two or three advices
- Very good quality of dispensing: confidentiality with more than three advices

The main issue in our study was to find out if the manner of drug dispensing, with emphasis on confidentiality, was a difficulty to access ARV drugs. After data collection, we reviewed the categorisation of the quality of dispensing.

Patient's satisfaction with dispensing was based on the patient self-report on satisfaction with manner of dispensing. The categorization was: satisfied, less satisfied and not satisfied.

Staff coverage for dispensing was based on the comparison between the numbers of HIV/AIDS patients to the number of drug dispensers, which could also explain the waiting time at the ARV sites.

3.2.5 Recruitment and training of research assistant

A male research assistant was recruited and trained for three days. The assistant was a 7th year student of the FMPOS doing his thesis on the nutritional aspect among HIV/AIDS patients. He had already acquired good experience on data collection, which facilitated our communication and collaboration.

3.2.6 Workshop

A workshop was organised with the French questionnaire which enabled us to discover meaningful ways of asking the patients in Bambara some important questions for our research. The workshop included one social anthropologist, one public health personnel, one dispenser from HPG, four representatives of HIV/AIDS patients from the three ARV sites and the two interviewers (main investigator and assistant). After the workshop, some changes were made to the questionnaire.

3.2.7 Pilot test

Prior to data collection, the questionnaire was pre-tested at Koulikoro ARV site, one of the main towns in Mali located 60km from Bamako. This pilot test helped to review the questionnaire and to check if it is understandable and acceptable by informant (HIV/AIDS patients and dispensers). The pre-test was done in September 2006 and concerned 18 informants. The respondents were 17 patients and 1 dispenser.

The choice of Koulikoro was motivated by the fact that it has approximately the same characteristics as Bamako. Bamako was avoided because the information could be spreaded out which could lead to bias. After the pilot test few improvements were made to the questionnaire.

3.2.8 Data collection and handling

Face-to-face interviews were used to collect data, through questionnaires. Data was collected from October to November 2006 at the three ARV sites (HGT, CESAC and HPG).

Both the main researcher and research assistant conducted the interviews. All interviews were done in French for dispensers as well as in Bambara language for the patients, except one patient from Sierra Leona who was interviewed in English.

Since there was limited time, the interviewers (the principal investigator and the assistant) stayed at each treatment site until the number of patients needed had been obtained (43 for HGT, 106 for CESAC and 61 for HPG). The sites were randomly drawn for a working order in the data collection as follows:

- First HGT
- Second CESAC
- Third HPG.

The interview of a patient was carried out at the end of the patient's visit, that is, after collecting medication or sometimes during the waiting time before collection of the drugs at pharmacy level.

The interviews at CESAC and HPG were conducted in private rooms allocated for this purpose such as the counselling room and room for HIV medicines storage. At the HGT, the office of the chief pharmacist was used for the interviews.

All dispensers provided signed written consent whereas the patients provided either verbal consent or signed written consent (option of regular signature or thumb print).

At the commencement of data collection, the main researcher and the research assistant jointly conducted the interviews. Thereafter, the interviewers became familiar with the questions and improved their ability to formulate questions in Bambara language. All the answers were reported in French and checked for conformity. After each interview (before the informant leaves) the interviewer checks for the completeness of data collected. The purpose was to complete any missing data in addition to facilitate evaluation of the response rate. For example, given that the interview was done anonymously, it would have been extremely difficult to trace the patient afterwards.

At the end of each day, the interviewers convened a meeting to discuss challenges or any difficulties that were encountered in the field in order to find possible solutions.

For the interviewees or participants, a token of 1500 Francs CFA (around 3 US dollars) was given to each person at the completion of the interview, as compensation.

The main researcher was responsible for storing the data safely and confidentially. It was only the local research team (main researcher, researcher assistant and local supervisor) that was allowed access to the data. The data was translated into English afterwards, while data processing took place during and after data collection.

3.2.9 Data analysis

Data were initially entered in EPIINFO version 6 and transferred in SPSS 14.0 for windows (Statistical Package for the Social Sciences version 14 for windows)

The significance level was set at 0.05 for 95% of Confidence Interval (CI).

A preliminary analysis using descriptive statistics and graphs were performed. Outliers were checked and data were cleaned. The following tests were used:

- Independent test
- Chi square test
- Fisher Exact test
- Univariate and Multivariate regressions

3.2.10 Validity and reliability

Validity means that the scientific observation actually measure what they intended to measure and that the conclusions are true. While, reliability means that someone else using the same methods in the same circumstances should be able to obtain the same findings implying that the findings are repeatable. (37).

A workshop was organized and was followed by a pilot test which could increase the validity and reliability of the questionnaire. The English questionnaire was translated into French. The back translation into English permitted a check on the internal validity. Numerous studies in Mali have had interviews conducted in Bambara with the questionnaire written in French (38).

It is noted that the responses to questions may be influenced by phrases or words used in the questions (39). In this case therefore, the questions were asked by using the same words in Bambara by the main researcher and the researcher assistant.

The reliability of the study was assessed during the pre-test period through collection of the data by two people. The interviewers checked answers of informants which particularly helped to verify the conformity of the results.

3.2.11 Representativeness

The HIV/AIDS patients in Bamako were not representative of the whole population of HIV/AIDS patients in Mali. However, this study samples are sufficiently representative to enable generalization of the result to the whole HIV/AIDS patients in Bamako under ART.

3.3 Ethical clearance:

3.3.1 Ethical approval

The research project was approved by the Norwegian ethical committee (annex 7). Also, ethical clearance was obtained from the Malian ethical committee of the FMPOS (annex 8). Before commencement of the research, the protocol was translated into French and closely followed by an oral presentation. The ethical committee's observations have been taken into considerations.

The researcher visited each ARV site (HGP, CESAC and HPG) to seek for permission to conduct the research before starting data collection in the three ARV sites (letter plus ethical approval from the Malian ethical committee of FMPOS and research protocol if necessary). Permission was obtained from these ARV sites.

3.3.2 Informed consent

Informed consent of HIV/AIDS patients and dispenser was sought and obtained. The participants were informed about the purpose of the study and the benefits of the findings. The name of the participant did not appear on the questionnaire, so as to guarantee confidentiality. Each participant got an ID number which is tied to a specific ARV site. Any information provided by an informant remained anonymous and confidential. Participants could withdraw at any time without penalty.

A written consent was signed or thumb-printed. Where circumstance warrants, an oral acceptance would at least be secured from the participant after accepting voluntary participation.

After completing the interview, each participant received the sum of 1500 Francs CFA (around 20 NOK) as compensation in accordance with recommendation from the Malian ethical committee.

3.4 Project management:

The main researcher was the principal manager of the present project. The supervisors were the advisors during the entire process in the project. Contact was maintained through phone and internet communications during the fieldwork.

3.5 Dissemination of findings

The report is written in English. However, a summary of the findings will be translated into French and sent to the MoH; the Malian ethical committee and the Swiss cooperation in Mali. A master thesis is prepared and submitted to the University of Oslo, Norway.

CHAPTER 4: FINDINGS

4.1 Demographic data and respondents' characteristics

There were 210 HIV/AIDS patients under ART for at least one month and 16 dispensers who were interviewed from the three ARV sites in Bamako (HGT, CESAC and HPG).

4.1.1 Patients

Table 2: Distribution of patients between the sites

ARV site	Number	%
HGT	43	20.5
CESAC	106	50.5
HPG	61	29.0

Gender

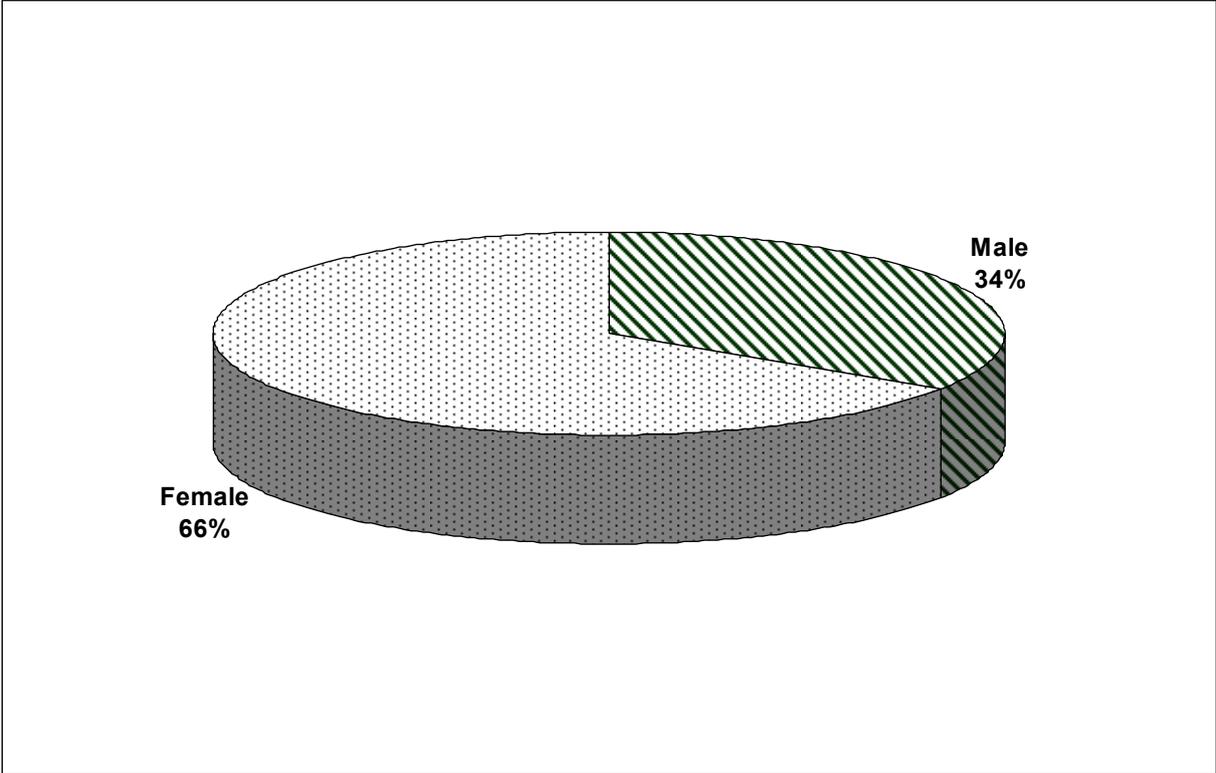


Figure 4: Gender of patients

As shown in Figure 4, 138 of the 210 patients (66%) were female, 72 were male (34%). This correlates with the Health and Demographic Survey (EDS III) of HIV prevalence 2.0% female and 1.3% male (3).

Age

The patients were between 18 to 65 years old. The mean age was 35.17 ± 9.23 years. Figure 5 shows the number of patients by age group.

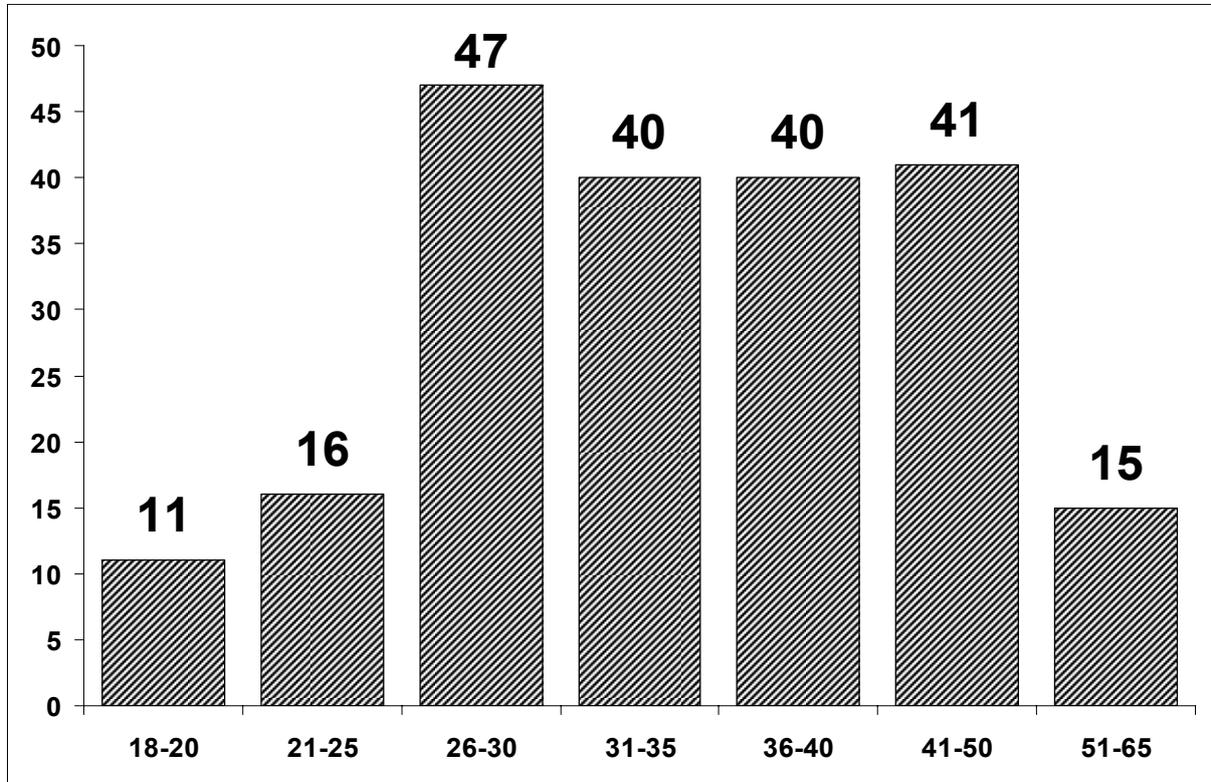


Figure 5: Patients according to age group

In Mali, the highest prevalence was 3.9% in the 30-34 years old age group in 2001(3).

Marital status

Table 3: Patients according to the marital status

Marital status	Number	%
Married	92	43.8
Single	38	18.1
Widowed	55	26.2
Divorced	25	11.9
Total	210	100.0

In this study, 92 patients (43.8%) were married, 55 (26.2%) widowed. The singles and divorced are respectively represented as follows: 38 (18.1%) and 25 (11.9%).

Level of schooling

The patients were categorized into five groups according to the length of their formal education:

Non-schooling (0 year)	109	(51.9%)
Primary school (1-6 years)	34	(16.2%)
Junior high school (7-9 years)	26	(12.4%)
Secondary school (10-12 years)	37	(17.6%)
Higher education (> 12 years)	4	(1.9%)

In Mali the literacy rate was estimated to be 19% in 2004 (2).

Profession

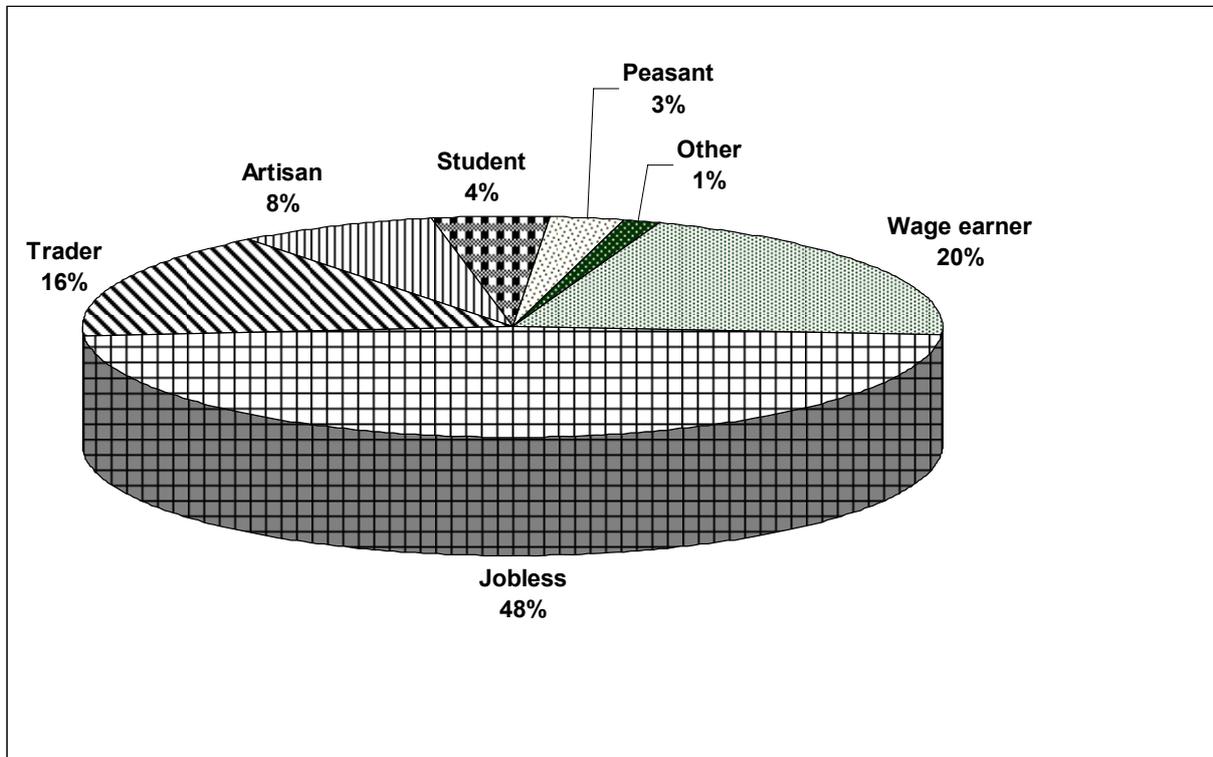


Figure 6: Profession of the patients under ARV treatment

Only 43 respondents (20.5%) were wage earners while 100 (47.6%) were unemployed. Out of these 100 jobless 47 (47%) were housewives.

Residence

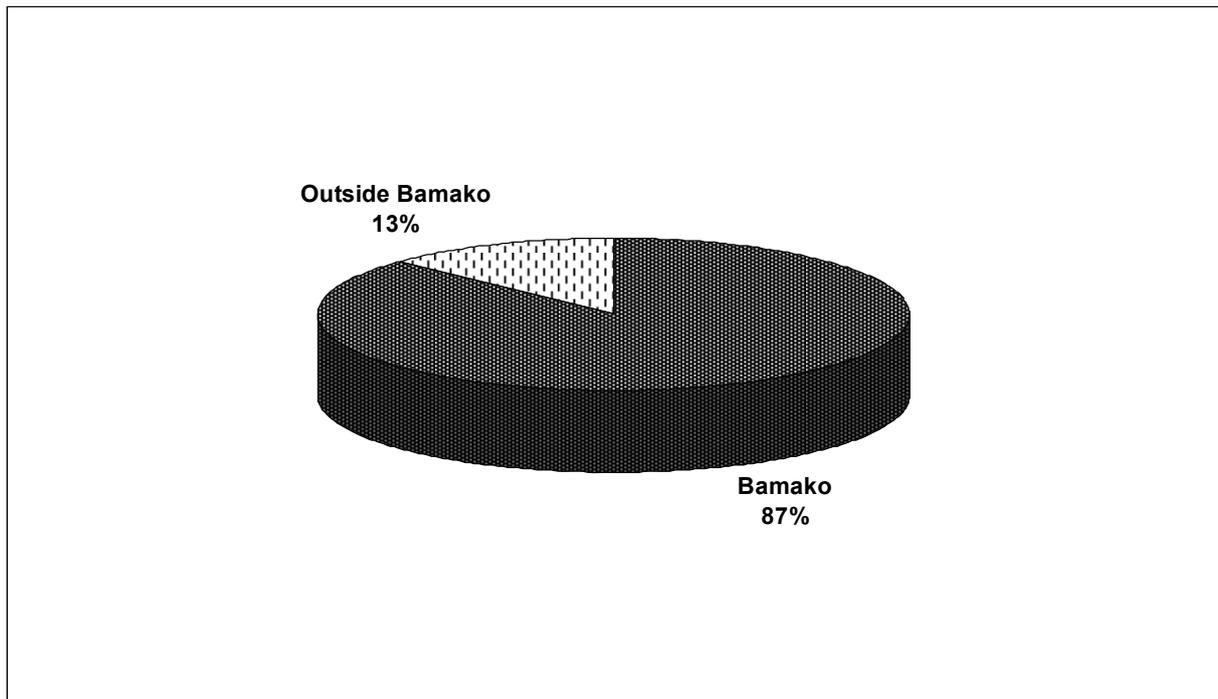


Figure 7: Residence of the HIV/AIDS patients

The majority of the patients 183 (87%) were residing in Bamako while only 27 (13%) were coming from outside Bamako.

Table 4: Distribution of patients between the 6 communes of Bamako

Communes	Number	%
Commune I	51	27.9
Commune II	22	12.0
Commune III	16	8.7
Commune IV	31	16.9
Commune V	29	15.8
Commune VI	34	18.6
Total	183	100

Income

The average monthly income was 60 045.85 FCFA \pm 51 668.07. The income ranged between 7 000 to 315 000 Francs CFA (approximately 14 – 630 dollars US).

NB: 1 dollar US \approx 500 Francs CFA

120 patients (57%) had no income while 90 (43%) had an income.

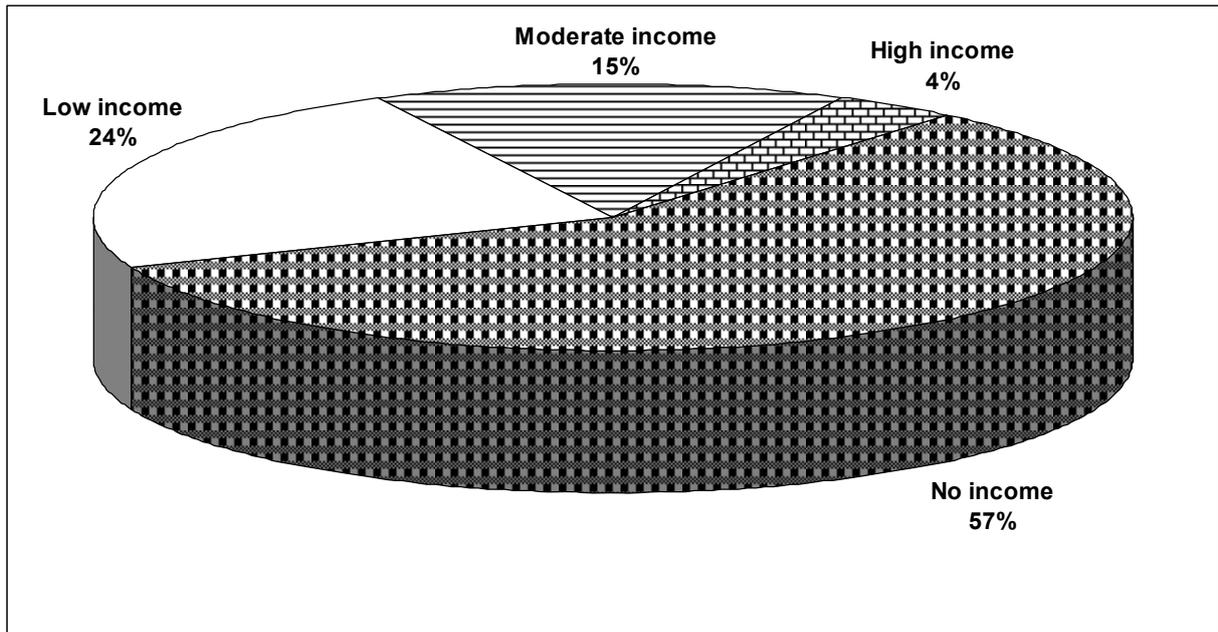


Figure 8: Distribution of the patients according to the income level

The categorisation of the income level was as follows:

- No income = 0 Franc CFA 120 (57%)
- Low income from 7 000 to 50 000 Francs CFA 49 (24%)
- Moderate income from 50 005 to 100 000 Francs CFA 31 (15%)
- High income above 100 000 Francs CFA 8 (4%)

Out of 120 patients without income, 105 (87.5%) received family help to meet their basic needs while 11 (9%) used mutual-help. The remaining 4 did part-time jobs such as laundry, sale of cold water, alms and fortune-telling.

Duration of ART

The patients started treatment from 1 month to 6 years; the mean was 16.45 ± 13.78 months.

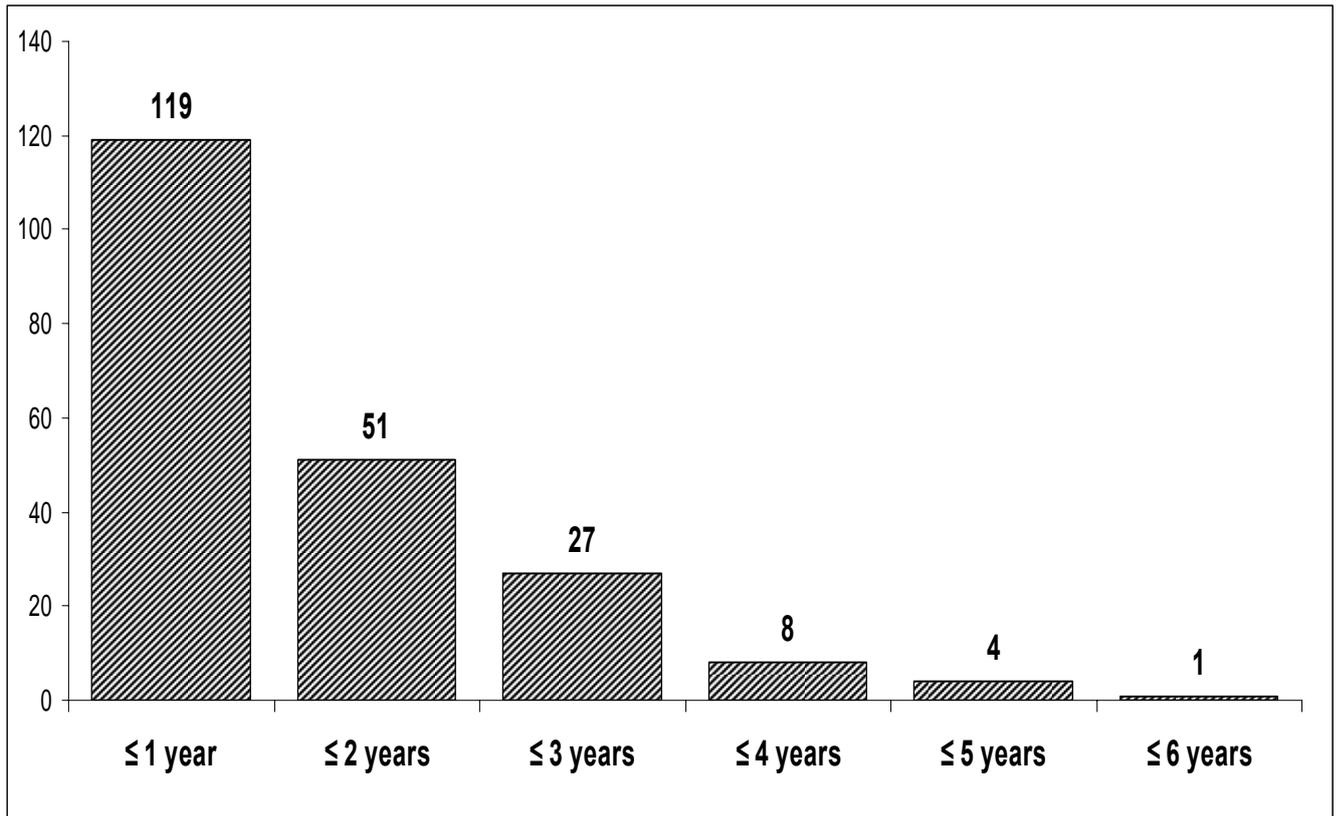


Figure 9: Duration of ARV treatment by year

119 patients (56.7%) were under ARV for one year or less, 51 (24.3%) for 2 years or less and 27 (12.9%) for 3 years or less.

Frequency of ARV reception

107 patients (51%) received their medication each month while 98 (46.6%) received their medication every two months. Only 5 patients (2.4%) received their medication quarterly.

Living conditions

The majority of patients had radio 160 (76.2%) and TV 118 (56.2%) at home.

Opinion about the distance from the ARV site

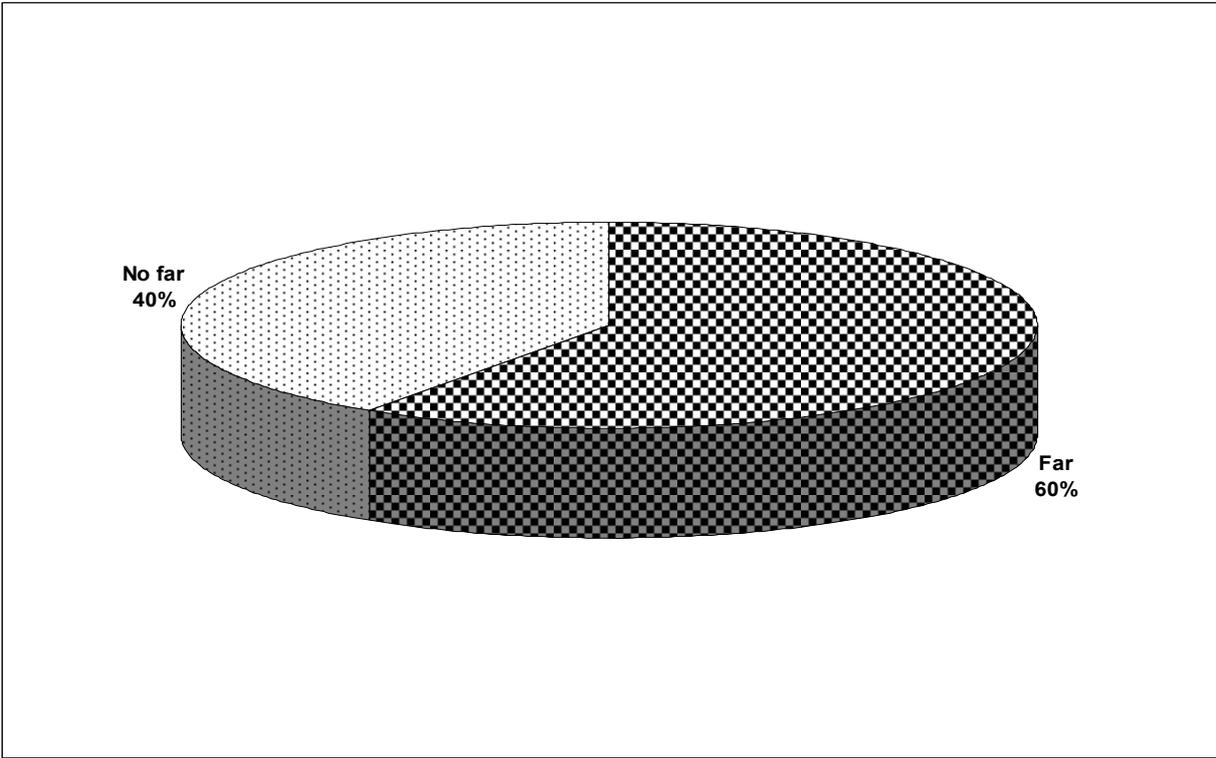


Figure 10: Distance to the ARV site according to patient opinion

125 patients (60%) thought that they lived far from the ARV site while 85 (40%) felt the opposite.

Opinion on the time spent to reach ARV site

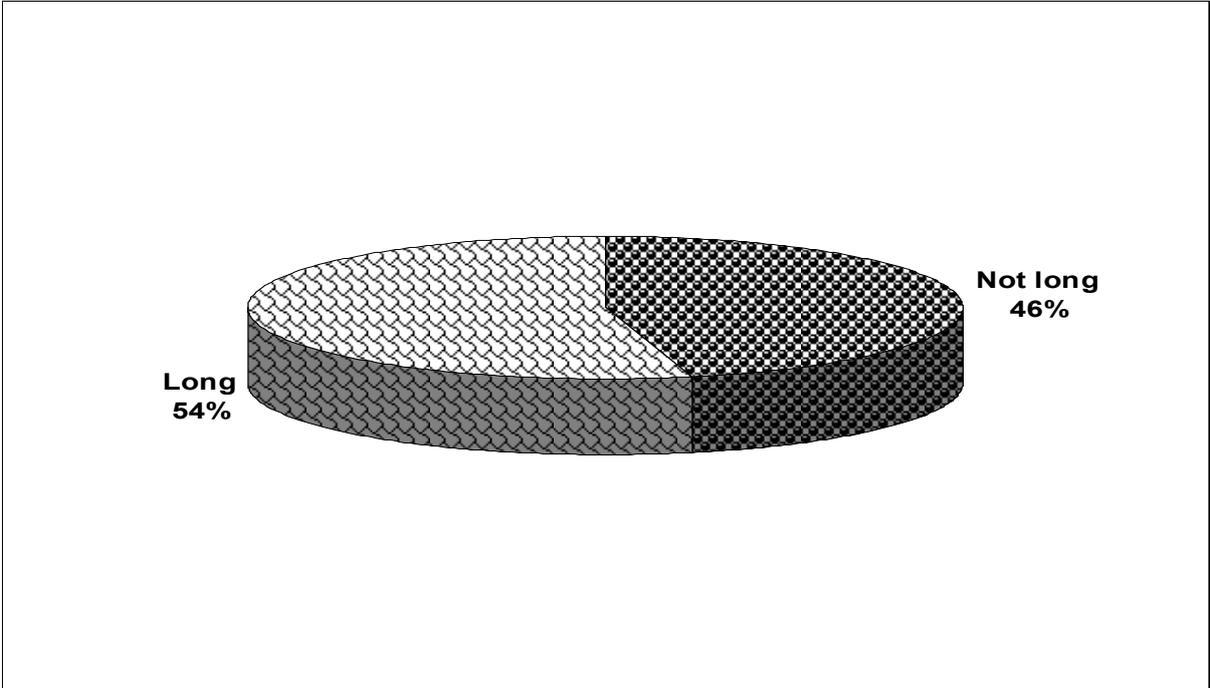


Figure 11: Time spent to reach the ARV site

According to the opinion about the time spent to reach ARV site, 113 patients (54%) responded that they spent longer time while 97 (46%) did not spend long time.

Time spent to get ARV in the treatment site

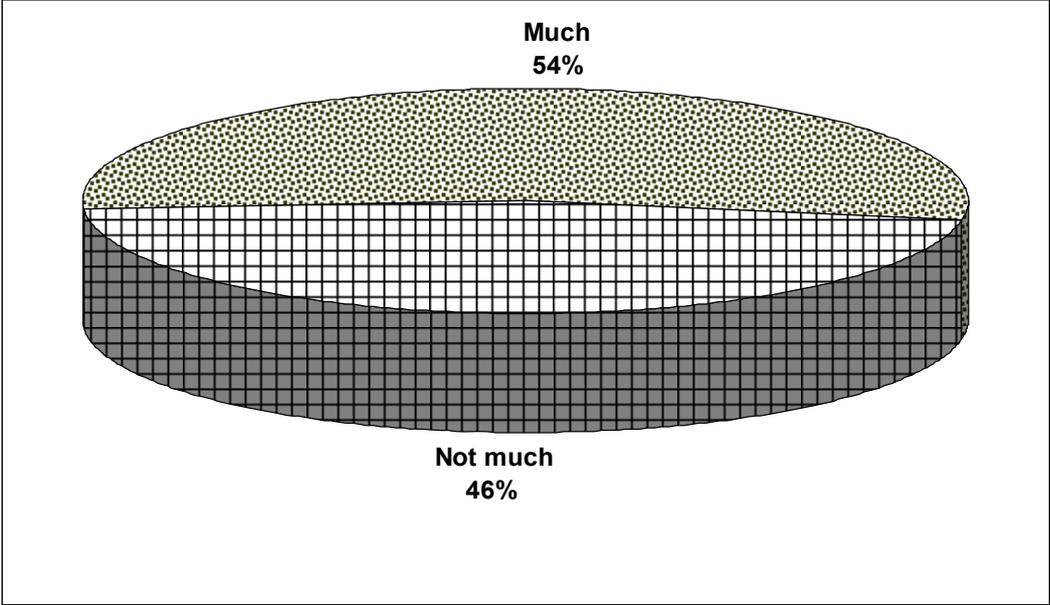


Figure 12: Opinion on the time spent to get ARV in the treatment site

When asked if they thought that it took a long time to get ARV, 113 patients (54%) of the responded that they spent long time while 97 (46%) did not spend long time.

Time spent to get ARV drugs

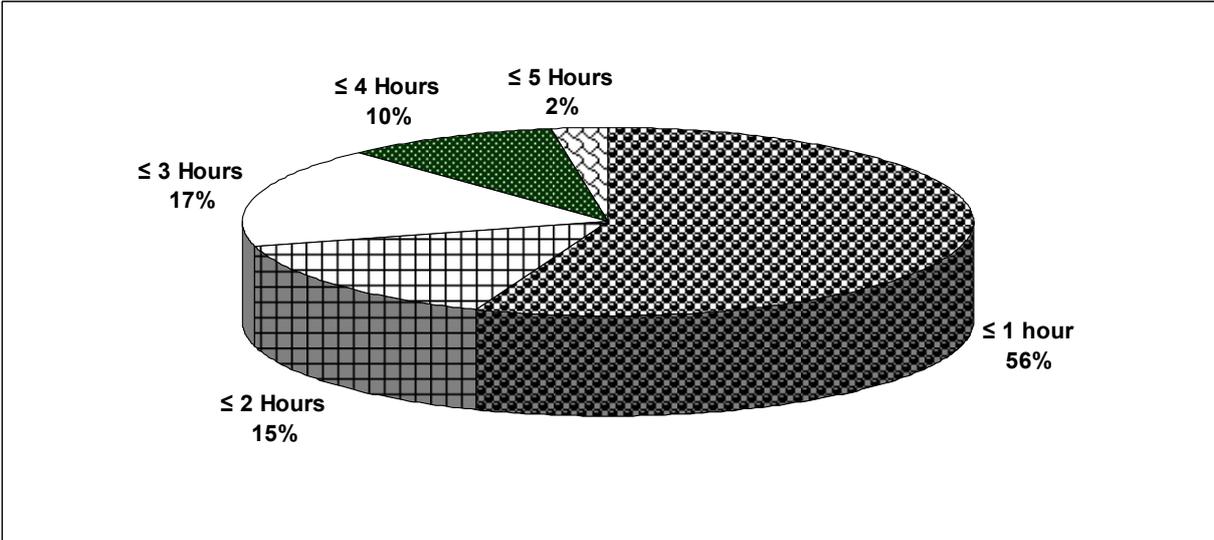


Figure 13: Time spent to get ARV drugs in hours

The time to get drugs at ARV dispensing ranged from 3 to 300min (0.05 to 5hours). 117 patients (56%) spent one hour or less to get ARV.

Time spent to get medical prescription in hours

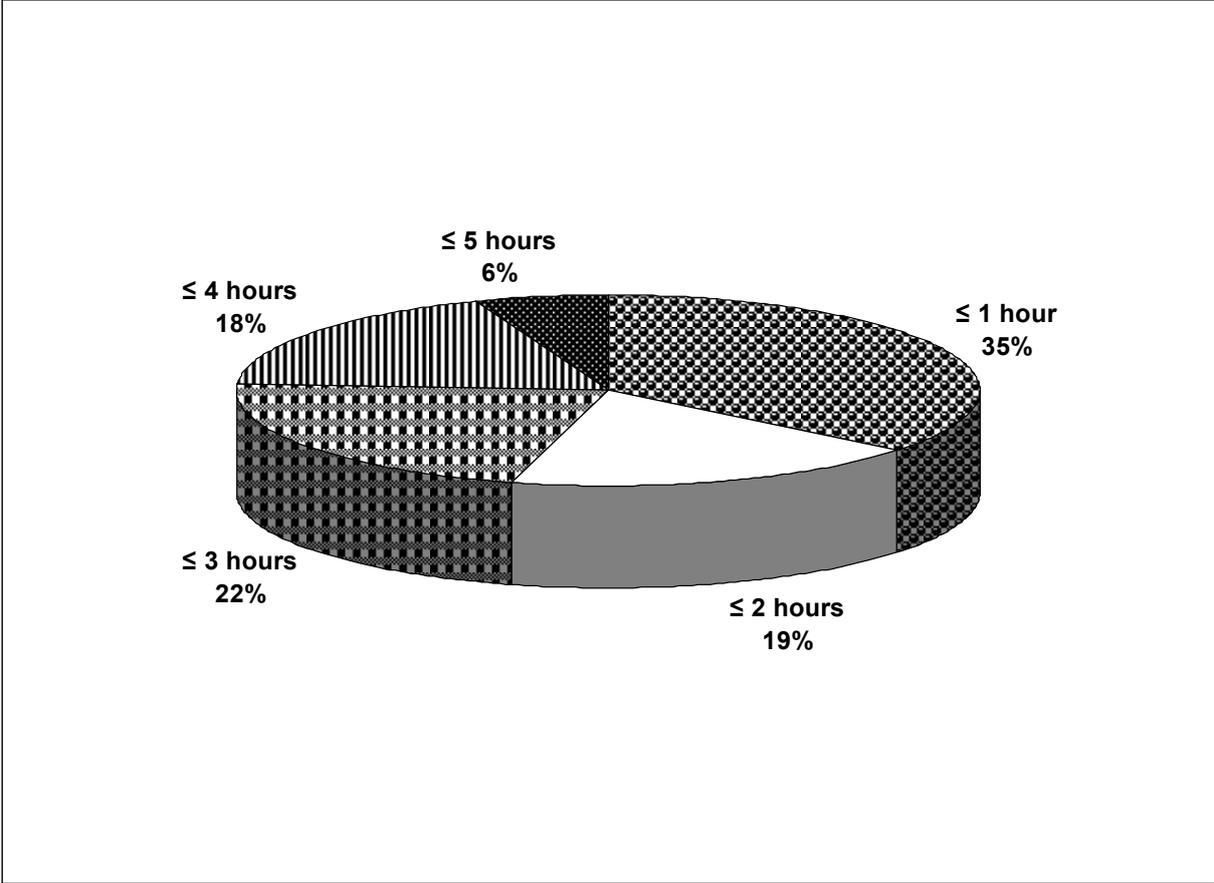


Figure 14: Time spent to get medical prescription in hours

The time to get medical prescription at treatment site ranged from 3 to 300min (0.05 - 5hours). 75 patients (35%) spent one hour or less to get a prescription sheet, 39 (19%) had 2 hours or less. 96 patients (46%) spent 3 hours or more.

The time to get prescription was longer than the time took to get ARV as mentioned by the HIV/AIDS patients during the workshop.

Waiting time at the treatment sites in hours

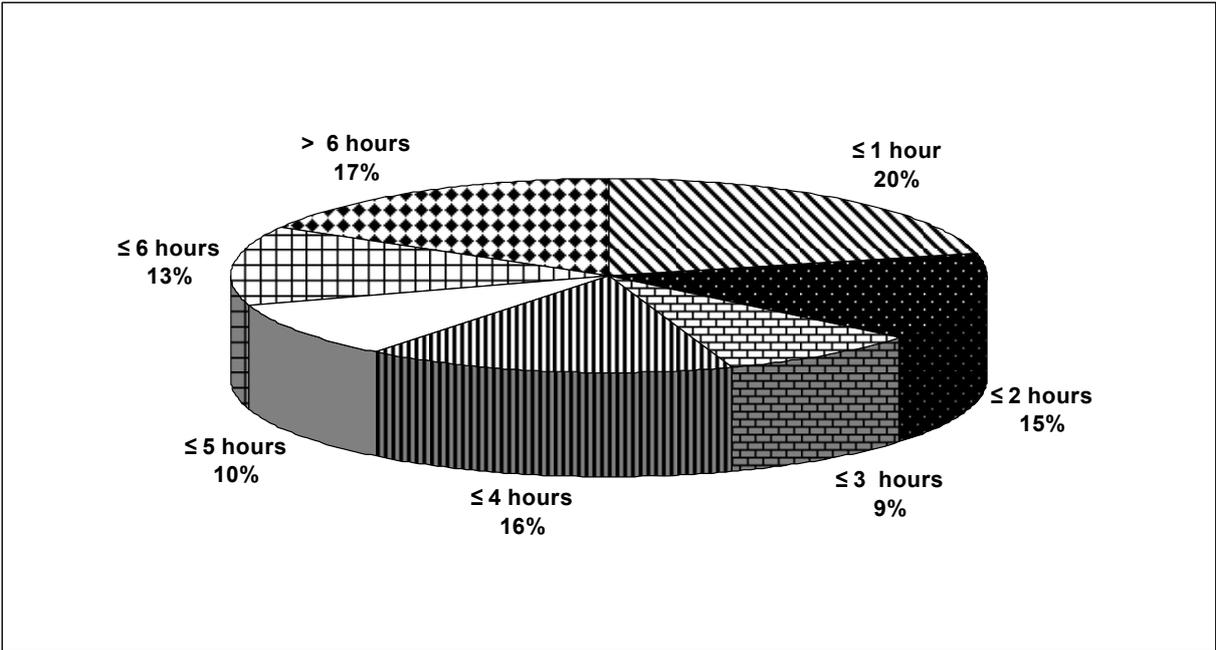


Figure 15: Waiting time at the treatment sites in hours

The waiting time at the treatment site was the time spent to get a medical prescription plus the time spent to get ARV. This time ranged from 6 to 600min (0.10 to 10 hours). 127 patients (60%) spent 4 hours or less as waiting time and 35 (17%) more than 6 hours.

Means of transportation

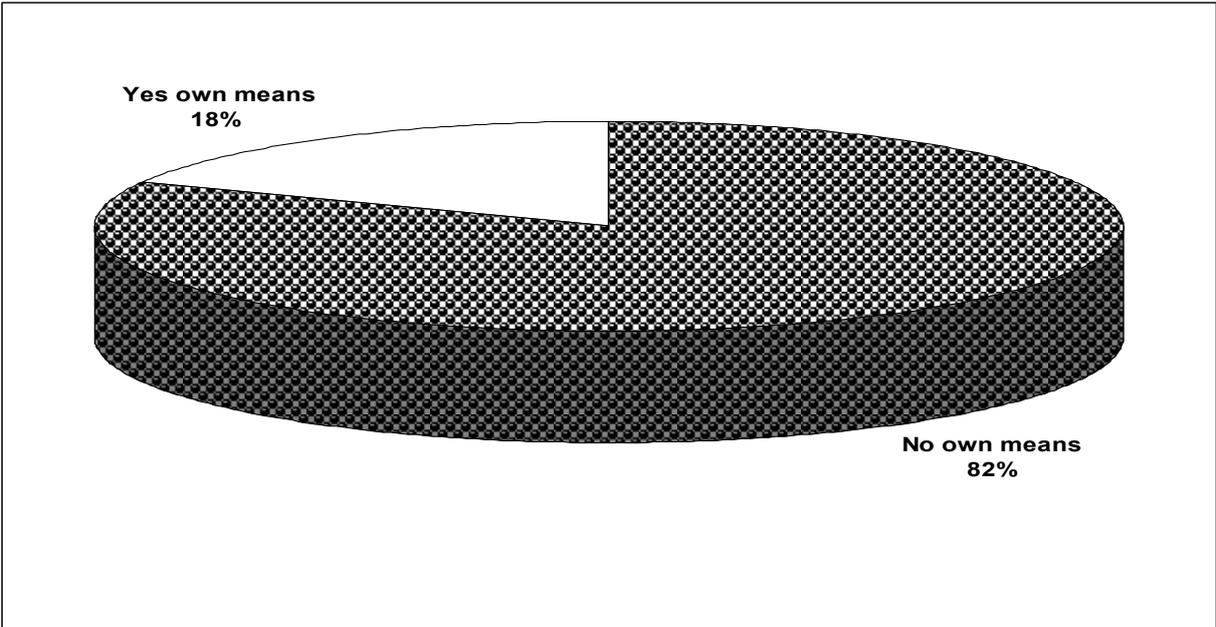


Figure 16: Possession of means of transportation

The majority of the patients 172 (82%) did not have their own means of transportation. Only 38 patients (18%) had their own means and among them 35 (92%) had a motorbike while 3 (8%) had a car.

Table 5: Distribution of the means of transportation

Means of transportation	Number	%
Motorbike	35	16.6
Car	3	1.4
Minibus	90	42.9
Bus	20	9.5
Minibus + Taxi	37	17.6
Taxi	9	4.3
Bus +Taxi	8	3.8
By foot	5	2.4
Minibus + Taxi + Bus	1	0.5
Bus +Taxi + Car	1	0.5
Job's car	1	0.5
Total	210	100.0

166 patients (96%) out of 172 who had no means of transportation used public transportation to reach ARV site. 90 patients (42.9%) used a minibus as means of transportation, 20 patients (9.5%) took a bus. 37 patients (17.6%) used a taxi plus minibus to reach the treatment site at the same time. Only 5 patients (2.4%) walked while 1 patient used his job's car to get his medication.

Money spent on food

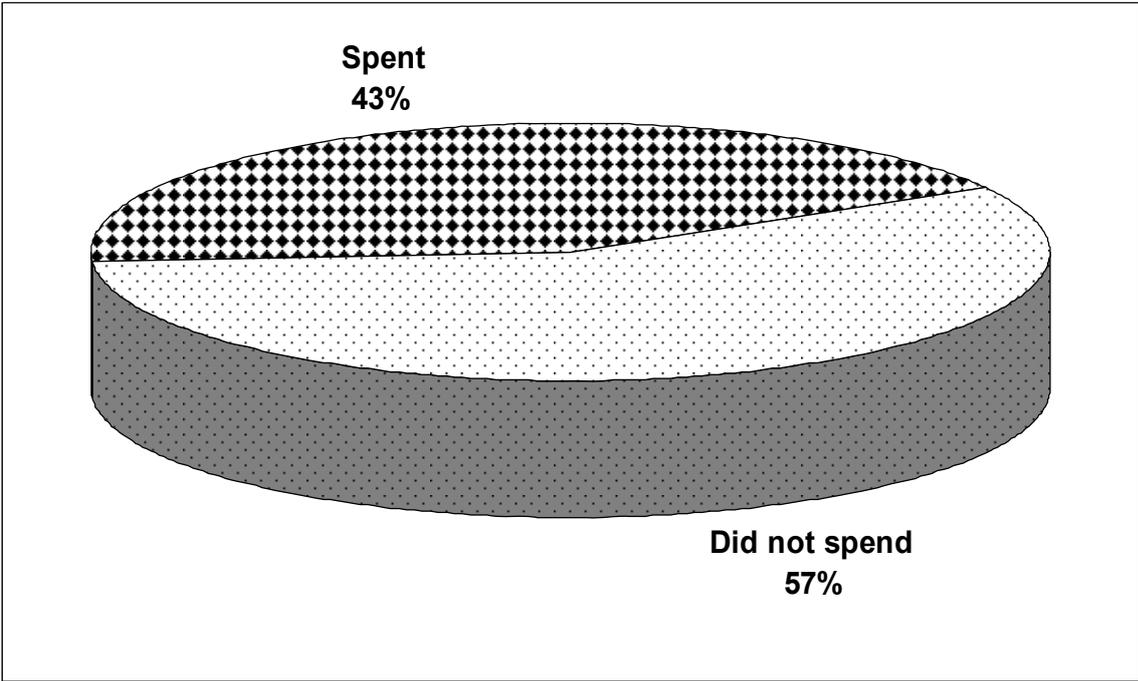


Figure 17: Money spent on food by patients

120 patients (57%) did not spend money to buy food while waiting to get ARV drugs or after; whereas 90 (43%) spent money.

The reason was that the long waiting time made them miss their main meal at home.

Existence of other difficulties to get ARV

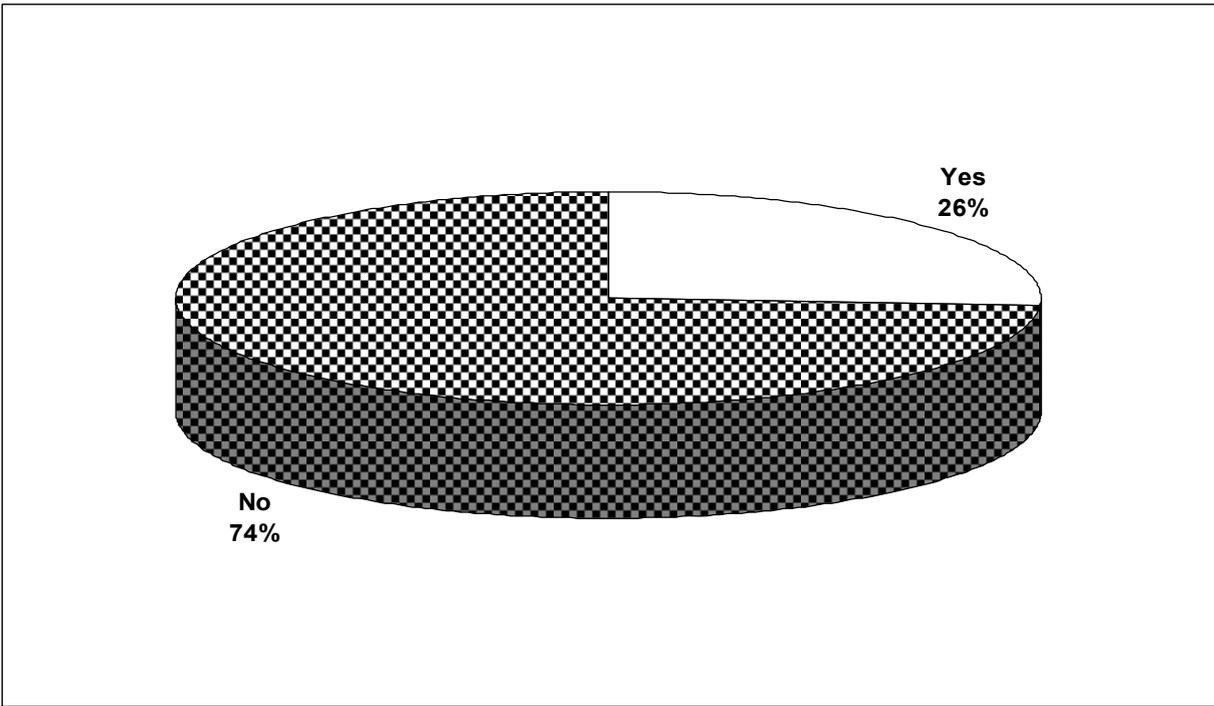


Figure 18: Opinion about difficulties

In addition to the difficulties already mentioned, the majority of patients 155 (74%) in open-ended question did not see any difficulty that prevented them from getting ARV while 55 (26%) mentioned other difficulties.

Table 6: Difficulties mentioned by patients

Difficulties mentioned by patients	Number	%
Lack of money	15	27.3
Long waiting time	11	20.0
Stigma	6	10.9
Difficulty in obtaining permission to leave job	4	7.3
Difficulty of transportation	2	3.3
Health center	1	1.8
Health staff	1	1.8
Other	15	27.3
Total	55	100.0

The main difficulties were related to lack of money, long waiting time, stigma and difficulty to obtain permission to leave job because of non-disclosure of the patients HIV status.

The other difficulties mentioned were

- The long distance to reach the ARV site had been cited
- One patient complained about the location of CESAC site near the market because he was ashamed and worried about being seen
- Having to get very early to the site in the morning for laboratory appointment
- Separate appointments were made for medication and laboratory tests (initiating treatment and follow-up) which means having to travel for laboratory test in addition to travel for medication
- One patient did not know the town and usually was accompanied by a brother who was very busy
- Lack of someone who could take care of the children during the patient absence to get the medication at the ARV site
- For one other patient it was only disease which can prevent to travel for medication

Some patients mentioned the combination of several of these difficulties.

Opinion about accessibility of ARV

Table 7: Opinion about accessibility of ARV drugs

ARV accessibility	Number	%
Accessible	206	98.1
Not accessible	4	1.9
Total	210	100.0

206 patients (98%) responded that ARV were accessible in our study which means they did not face major difficulties to get ARV against 4 (2%) who said that it is not accessible. The main reasons according to those who had no access were

- The waiting time at the treatment site
- The medical prescription being made compulsory
- The doctors appointment being made compulsory
- The waiting time and the distance to the treatment site.

Level of ARV accessibility

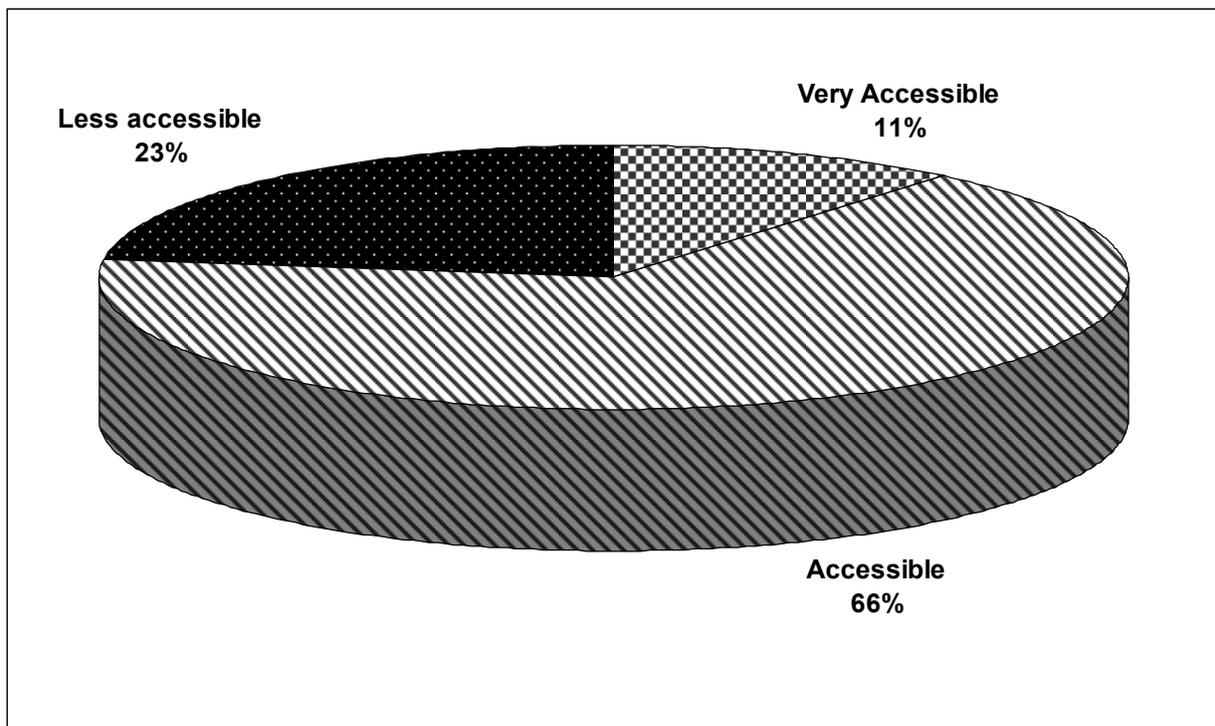


Figure 19: Opinion about the level of ARV accessibility

When asked to give the level of accessibility of ARV drugs, 136 patients out of 206 (66%) maintained that ARV was accessible while 23 patients (11%) thought that ARV was very accessible. However, for 47 patients (23%), ARV was less accessible.

Suggestions for better access for ARV

Table 8: Suggestions for better access for ARV by patients

Suggestions for better access to ARV	Number	%
Reduce the waiting time	40	78.2
Decentralize ARV sites	5	9.8
Assure or guarantee refund of transportation cost	1	2.0
Make ARV available at private pharmacies	1	2.0
Make all drugs free for opportunistic infections	1	2.0
Initiate early medical check-ups	1	2.0
Make doctors more accessible	1	2.0
Reduce lack of comprehension dispenser/patient	1	2.0
Total	51	100.0

The patients who responded that ARV drugs were less or not accessible were asked about their suggestion on how access could be improved (less accessible 47 patients and not accessible 4 patients).

Forty patients out of 51 (78.2%) wanted the reduction of the waiting time at the ARV site while 5 patients (9.8%) suggested the decentralisation of the ARV sites.

The other patients thought that in addition to free ARV, all drugs for opportunistic infections should be free of charge for HIV/AIDS patients; the transportation cost should be covered; ARV should also be accessible at private pharmacies level etc.

Presence of people during the dispensing

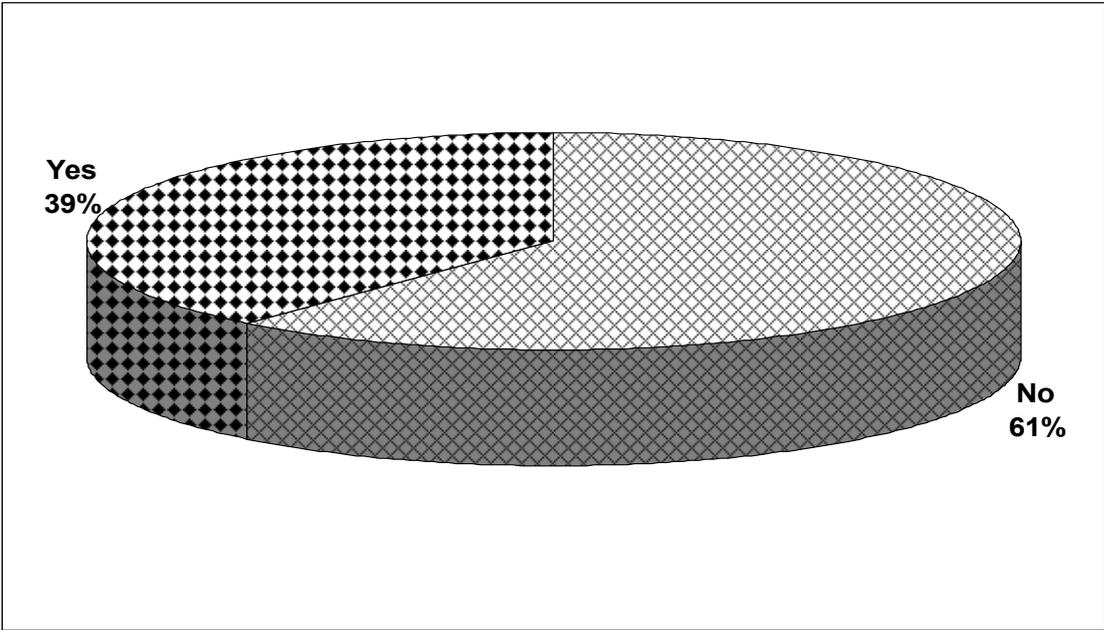


Figure 20: Receiving ARVs in presence of other people

129 patients (61%) maintained that ARV was not given in presence of other people while for 81 (39%) it was done in presence of other people. These other people were the health staff. There were 2 (55.6%), 3 (33.3%) or 4 (11.1%) during the dispensing according to patients.

Opinion about the presence of other people during the dispensing

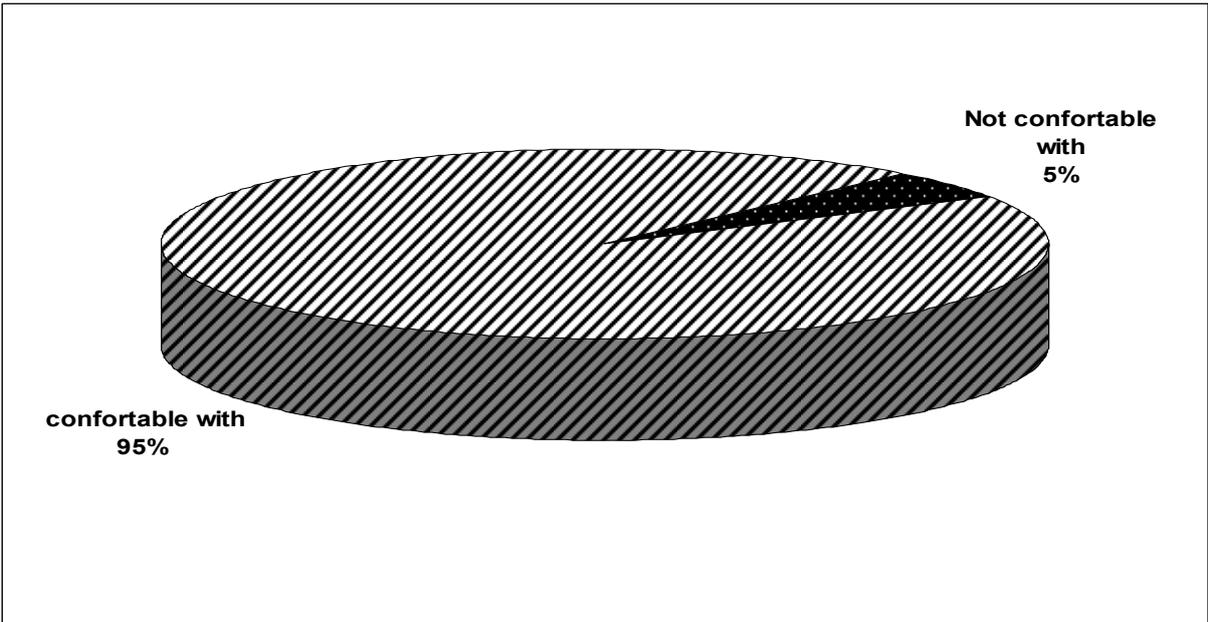


Figure 21: Opinion about the presence of other people during the dispensing

77 patients (95%) out of 81 who received their ARV drugs in presence of other people (health staff) were comfortable with this presence while 4 (5%) were not comfortable. Moreover, one patient was ashamed about the presence of many health workers.

4.1.2 Dispensers

Sixteen dispensers were interviewed during the data collection in the three ARV sites

Table 9: Distribution of the 16 dispensers between the ARV sites

ARV sites	Number	%
HGT	9	56.3
CESAC	3	18.7
HPG	4	25.0
Total	16	100

This was the staff doing the dispensing at the time of data collection. In practice however, the staff permanently allocated for dispensing were the following:

- 1 dispenser for HGT
- 1 dispenser for CESAC
- 2 dispensers for HPG

Gender

With a total number of 16 dispensers, 14 (87.5%) were male while 2 (12.5%) were female.

Age

The ages of the dispensers ranged from 25 to 35 years. The mean age was 28.63 ± 3.26 years.

Qualification of dispenser

Seven dispensers (44%) were pharmacists while the others were respectively 7th year pharmacy students 5 (31%) and 6th year pharmacy students 4 (25%). They were doing their thesis in the ARV sites which means they were not employed at the dispensing site.

Training on ARV dispensing

11 dispensers (69%) had received training on ARV dispensing while 4 (31%) did not received any training. They did the dispensing based on their practice in the ARV sites.

Involvement on ARV dispensing

The experience on ARV dispensing ranged from 2 to 72 months. The median was 12 months.

4.2 Descriptive Statistics for some variables

Table 10: Descriptive statistics for patients attending all three ARV sites

Variables	N	Minimum	Maximum	Mean/Median
Distance to reach ARV site (in km)	210	1	1200	9
Time spent to reach ARV site (in min)	208	10	2400	100.64
Transportation cost	209	0	21700	500
Time spent to get medical prescription (in min)	210	3	300	133.82
Time spent to get ARV (in min)	210	3	300	94.43
Waiting time (in min)	210	6	600	228.26
Waiting time (in hour)	210	0.10	10	3.80

The mean was used when the data were normally distributed. The median was used when the data were not normally distributed because it is not influenced by extreme values (40).

The median was used for the distance to reach ARV site 9km and the transportation cost 500 Francs CFA (\approx 1 dollar US).

The mean was used for the time to reach ARV site, the time to get medical prescription, the time to get ARV and the waiting time (for medical prescription and ARV dispensing).

4.3 Advices during ARV dispensing

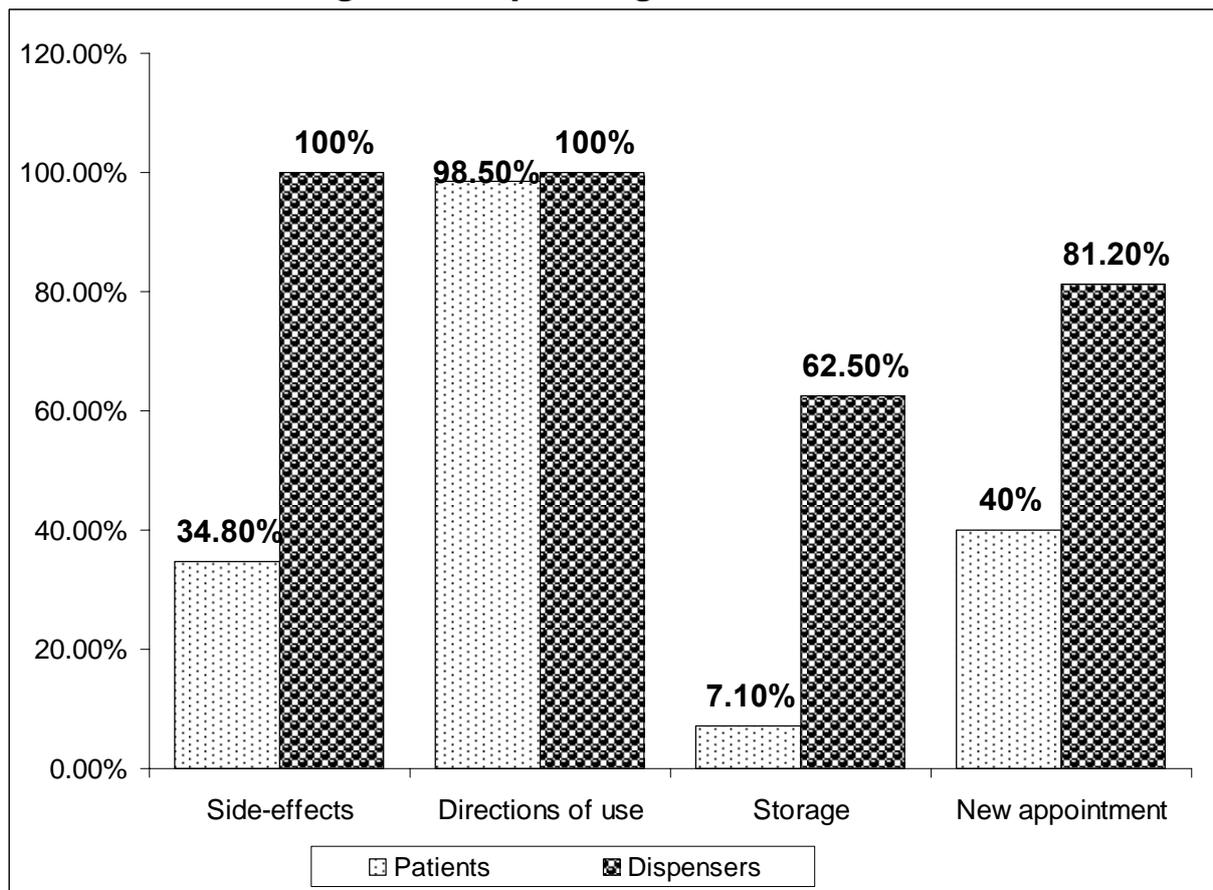


Figure 22: Comparison of advices as reported by patients and dispensers

This figure shows the advices received by patients and given by dispensers.

207 patients (98.5%) received advices on directions for drug use (dosage and administration); 73 (34.8%) on side-effects; 15 (7.1%) on storage; and 84 (40%) on new appointment.

16 dispensers (100%) gave advices on directions for use and side-effects; 10 (62.5%) on storage; and 13 (81.2%) on new appointment.

The responses to the question on advices received by patients and given by dispensers were not consistent. The dispensers said that they gave almost all the advices: directions for use (dosage and administration), side-effects, storage, new appointment and even other advices such as compliance, sexual and nutritional advices etc. However the dispensers did not emphasize on appointment because it was done by the medical doctors and written on the prescription sheet. The regular appointment given by the medical doctor enabled follow-ups on the patients (clinical and biological parameters). The few appointments were given in terms of reminder.

91/210 patients said that they received other advices in addition to those mentioned above. 89 out of 91 (97.8%) received advice about treatment compliance; 1 (1.1%) nutritional advice and 1 (1.1%) sexual advice.

11/16 dispensers said that they gave other advices. 5 dispensers out of 11 (31.3%) gave advice about treatment compliance; 3 (18.8%) sexual advice; 1 (6.3%) drug interaction; 1 (6.3%) sexual plus psychological support and 1 (6.3%) compliance plus nutritional advice.

4.4 Univariate descriptive statistics

Table 11: Estimated means test by ARV site

Variables	Name of ARV site	Mean	Sig.	95% Confidence Interval	
				Lower Bound	Upper Bound
Value of monthly income	HGT	22950.000	0.0001	9170.418	36729.582
	CESAC	18391.509	0.0001	9926.780	26856.239
	HPG	39900.583	0.0001	28649.602	51151.565
Distance covered to reach ARV site (in km)	HGT	37.875	0.07	-3.613	79.363
	CESAC	19.132	0.140	-6.354	44.618
	HPG	87.883	0.0001	54.008	121.758
Time spent to reach ARV site (in min)	HGT	102.500	0.004	32.954	172.046
	CESAC	61.651	0.005	18.929	104.373
	HPG	169.750	0.0001	112.966	226.534
Time spent to get ARV (in min)	HGT	20.325	0.036	1.336	39.314
	CESAC	151.415	0.0001	139.750	163.080
	HPG	46.467	0.0001	30.962	61.971
Time to get medical prescription (in min)	HGT	38.700	0.001	16.628	60.772
	CESAC	174.575	0.0001	161.017	188.134
	HPG	130.833	0.0001	112.812	148.855
Waiting time (in min)	HGT	59.025	0.002	21.703	96.347
	CESAC	325.991	0.0001	303.064	348.917
	HPG	177.300	0.0001	146.827	207.773
Waiting time (in hour)	HGT	.984	0.002	.362	1.606
	CESAC	5.433	0.0001	5.051	5.815
	HPG	2.955	0.0001	2.447	3.463
Transportation cost in FCFA (local currency in Mali)	HGT	1037.625	0.01	240.301	1834.949
	CESAC	689.151	0.006	199.359	1178.943
	HPG	2639.333	0.0001	1988.321	3290.346

The patients from HPG had the highest level of income followed by HGT and CESAC. It was easier to reach CESAC than the other two sites. HPG was still the site which took the longest time to reach followed by HGT and CESAC. The longest time spent in getting ARV was at CESAC followed by HPG and HGT. The longest time spent in getting medical prescription was at CESAC followed by HPG and HGT. CESAC had the longest waiting time followed by HPG and HGT. The highest cost of transportation was experienced in journeys to HPG followed by HGT and CESAC.

4.5 Dependant variables

4.5.1 Geographical accessibility

4.5.1.1 Geographical accessibility by distance covered to reach ARV site

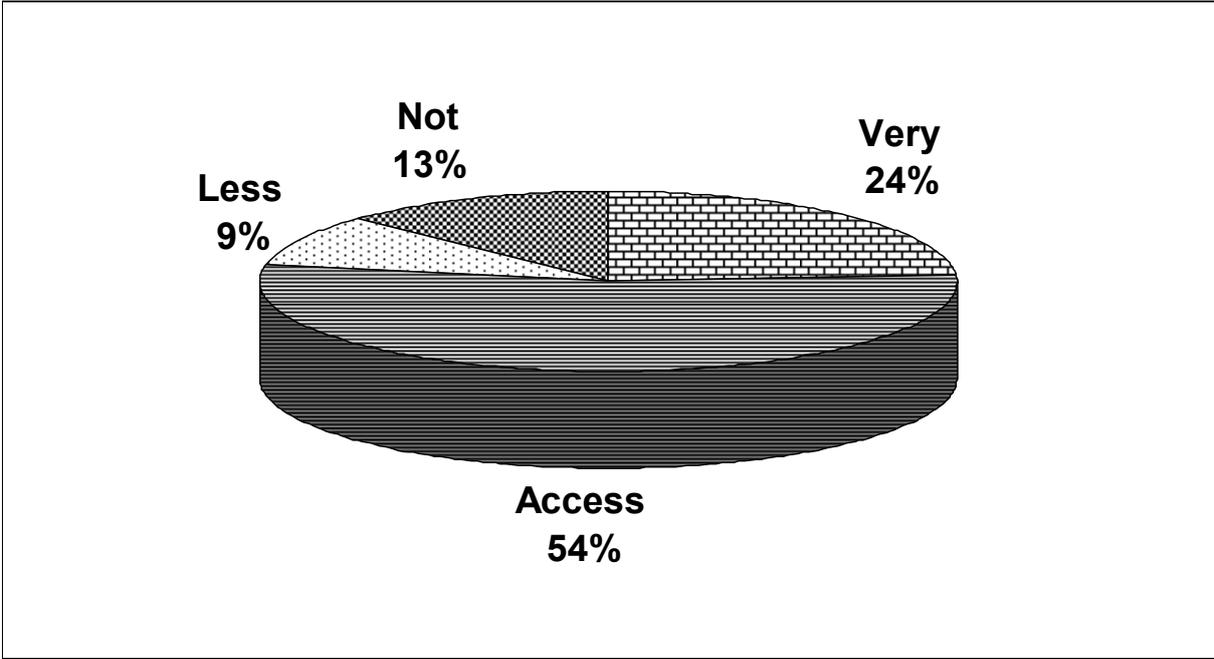


Figure 23: Geographical accessibility by distance covered to reach ARV site

The categorisation of the geographical accessibility by distance covered was done according to the distance covered by patients to reach the ARV site:

- Very accessible ($\leq 5\text{km}$) for 50 patients (24%)
- Accessible ($>5 - \leq 15\text{km}$) for 114 patients (54%)
- Less accessible ($> 15 - \leq 30\text{km}$) for 19 patients (9%)
- Not accessible ($> 30\text{km}$) for 27 patients (13%)

4.5.1.2 Geographical accessibility by time spent to reach ARV site

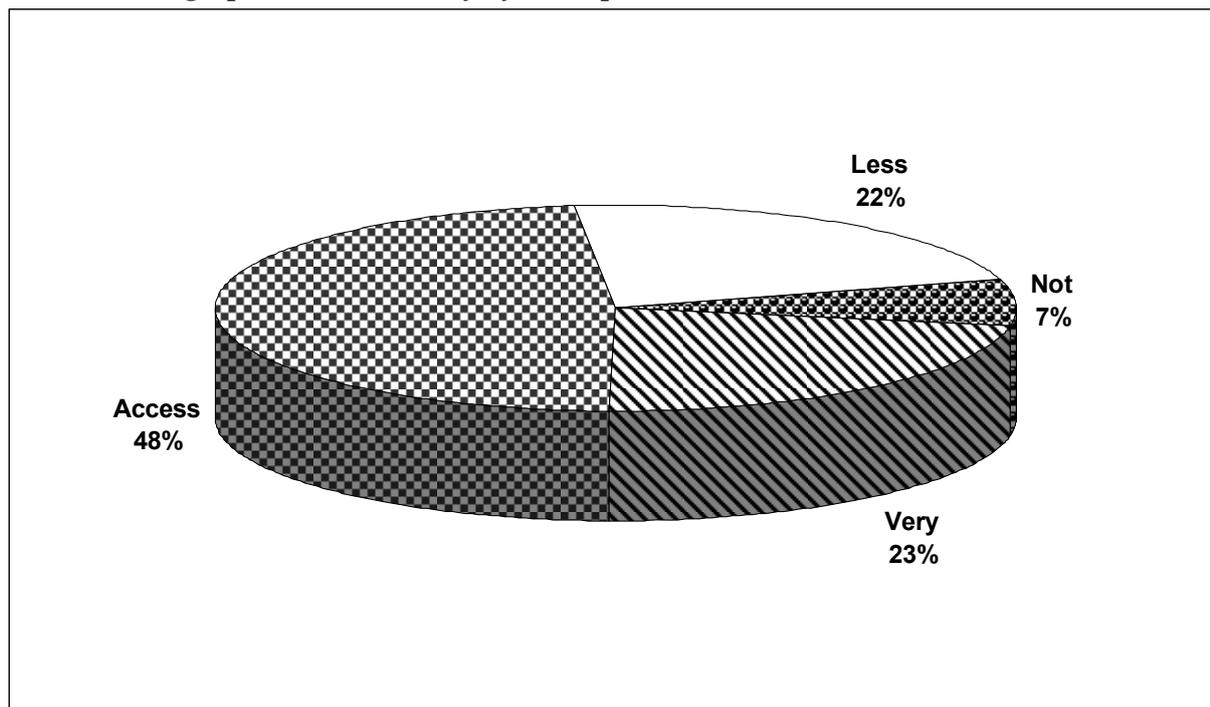


Figure 24: Geographical accessibility by time spent

The categorisation of the geographical accessibility by time spent was done according to the time spent by patient to reach the ARV site:

- Very accessible (≤ 30 min) for 47 patients (23%)
- Accessible (31- 60min) for 100 patients (48%)
- Less accessible (61- 180 min) for 46 patients (22%)
- Not accessible (> 180 min) for 15 patients (8%)

4.5.2 Financial accessibility

Table 12: Financial accessibility of ARV by patients

Financial accessibility	Number	%
Very accessible ($< 5\%$)	72	82.8
Accessible (5 - 10%)	8	9.2
Not accessible ($> 10\%$)	7	8.0
Total	87	100

The financial accessibility was the cost of transportation in percentage of patient's income.

In this case ARV was accessible for the majority of the patients 80 (92%) who had an income and from whom we obtained information on the income value. The ARV was not accessible for only 7 patients (8%).

4.5.3 Opinion of informants about accessibility of ARV

a) Patients

The following categorisations were done according to patients responses

- Very accessible 23 (10.9%)
- Accessible 136 (64.8%)
- Less accessible 47 (22.4%)
- Not accessible 4 (1.2%)

b) Dispensers

The dispensers' opinions were categorised as following

- Very accessible 2 (12.5%)
- Accessible 11 (68.7%)
- Less accessible 1 (6.3%)
- Not accessible 1 (6.3%)
- No opinion 1 (6.3%)

4.5.4 Quality of dispensing

Table 13: Quality of dispensing

Quality of dispensing	Number	%
Poor quality (≤ 3)	69	32.9
Acceptable quality (4-5)	114	54.2
Good quality (>5)	27	12.9
Total	210	100.0

After data collection, we reviewed the categorisation of the quality of dispensing. Confidentiality was not a concern for patients. The appointment was given by the medical doctor. In this case we emphasized principally on the directions for use (dosage and administration) and the side-effects. The scores were attributed in terms of importance of advices as follows:

- Directions for use 3
- Side-effects 2

- Storage 1
- Reminder about new appointment 1

The quality of dispensing was categorised according to the number of scores. 114 patients (54.2%) received an acceptable quality of dispensing, 69 (32.9%) had a poor quality. Only 27 patients (12.9%) received a good quality of dispensing

4.5.5 Patient’s satisfaction with dispensing manner

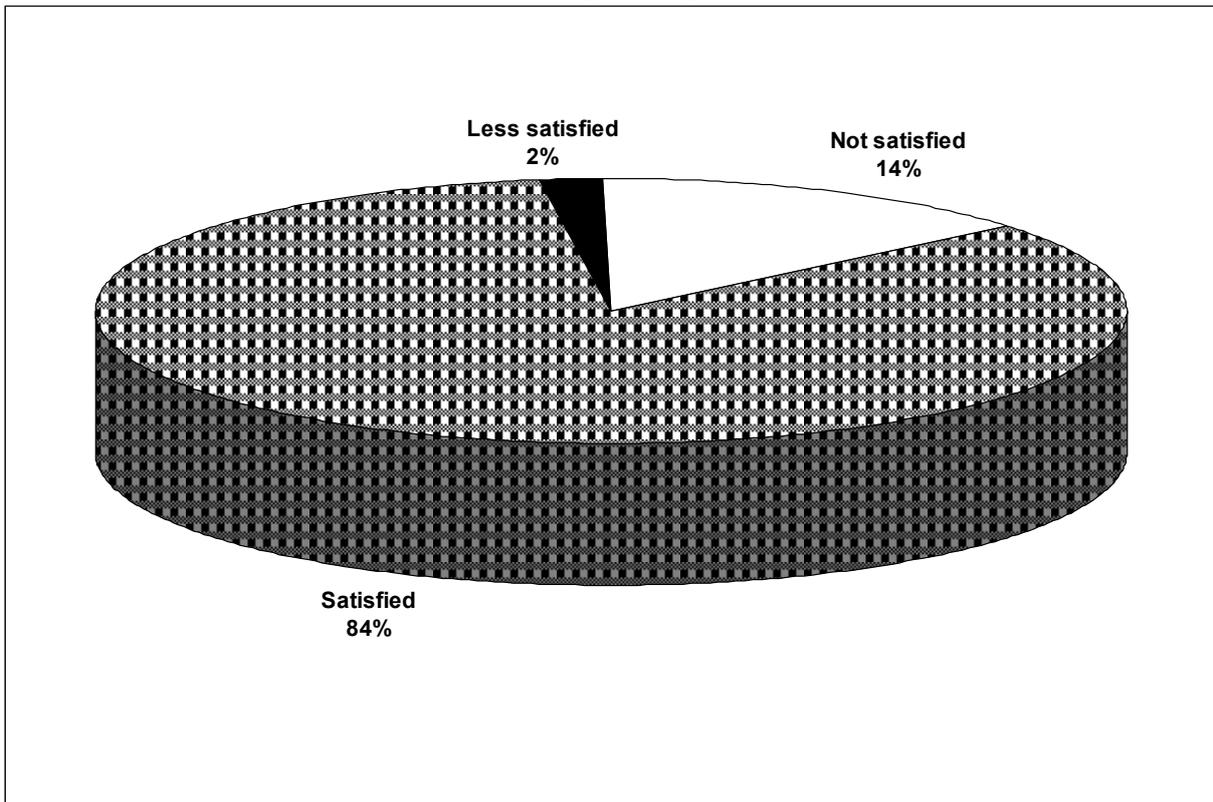


Figure 25: Opinion of the patients about dispensing manner

176 patients (84%) were satisfied about the dispensing manner (friendly service) while 30 (14%) were not satisfied. Only 4 (2%) were less satisfied.

4.5.6 Staff coverage for dispensing

The staff coverage for dispensing during the data collection was estimated by the ratio of patients/dispensers which was the following: $6\ 343/16 = 396$ patients per dispenser.

By ARV site the ratio was the following:

- HGT $1\ 299/9 = 144$
- CESAC $3\ 199/3 = 1\ 066$
- HPG $1\ 845/4 = 461$

This ratio could explain the long waiting time at the dispensing site. This waiting time could be even longer without any help from assistants (6 and 7th year Pharmacy students).

By considering only the staff allocated for dispensing (permanently assigned staff) at HGT and CESAC it was really all patients for one dispenser while in HPG the patients was divided between the two dispensers $3\ 199/2 = 1\ 600$ patients.

4.6 Analytical findings

Table 14: Geographical accessibility by distance covered for each dispensing site

Geographical accessibility by distance covered (in km)	Name of ARV site			Total
	HGT	CESAC	HPG	
Very accessible (≤ 5 km)	12	36	2	50
	28.0%	33.9%	3.3%	23.8%
Accessible ($>5 - \leq 15$ km)	25	59	30	114
	58.1%	55.7%	49.2%	54.3%
Less accessible ($> 15 - \leq 30$ km)	1	4	14	19
	2.3%	3.8%	22.9%	9.0%
Not accessible (> 30 km)	5	7	15	27
	11.6%	6.6%	24.6%	12.9%
Total	43	106	61	210
	100.0%	100.0%	100.0%	100.0%

The comparison between the ARV sites by geographical accessibility in terms of distance covered by patients to reach the sites was investigated by using Fisher's Exact test. The test revealed a statistically significant difference to reach the ARV sites in Bamako $p < 0.05$. HPG was the least accessible dispensing site with the longest distance covered by patients.

Table 15: Geographical accessibility by time spent for each dispensing site

Geographical accessibility by time spent (in min)	Name of ARV site			Total
	HGT	CESAC	HPG	
Very accessible (≤ 30 min)	8 19.5%	31 29.0%	8 13.1%	47 23.0%
Accessible (31- 60min)	22 53.7%	55 52.0%	23 37.7%	100 48.0%
Less accessible (61- 180 min)	8 19.5%	18 17.0%	20 32.8%	46 22.0%
Not accessible (> 180 min)	3 7.3%	2 2.0%	10 16.4%	15 7.0%
Total	41 100.0%	106 100.0%	61 100.0%	208 100.0%

The comparison between the ARV sites by geographical accessibility in terms of time spent by patients to reach the sites was investigated by using Fisher's Exact test. The test revealed a statistically significant difference between the sites. HPG was still the geographically least accessible dispensing site, with the time spent to reach the site ranging between 10 min to 2400 min $p < 0.05$

Table 16: Financial accessibility for each dispensing site

Financial accessibility of ARV	Name of ARV site			Total
	HGT	CESAC	HPG	
Very accessible ($< 5\%$)	13 65.0%	38 95.0%	21 78.0%	72 83.0%
Accessible (5 - 10%)	4 20.0%	1 2.5%	3 11.0%	8 9.0%
Not accessible ($> 10\%$)	3 15.0%	1 2.5%	3 11.0%	7 8.0%
Total	20 100.0%	40 100.0%	27 100.0%	87 100.0%

A Fisher's Exact test was conducted to compare the financial accessibility of the sites. The test revealed a statistically significant difference between the sites $p < 0.05$.

The lack of income could constitute a real problem for access to the sites. CESAC was the most accessible site financially.

Table 17: The opinion of the patients on the dispensing manner for each ARV site

Opinion on the dispensing manner	Name of ARV site			Total
	HGT	CESAC	HPG	
Satisfied	39 90.7%	82 77.4%	55 90.0%	176 83.8%
Less satisfied	0 .0%	1 0.9%	3 5.0%	4 1.9%
Not satisfied	4 9.3%	23 21.7%	3 5.0%	30 14.3%
Total	43 100.0%	106 100.0%	61 100.0%	210 100.0%

The comparison between the ARV sites about the satisfaction with manner of drug dispensing was assessed by using Fisher's Exact test. The test revealed a statistically significant difference between the sites $p < 0.05$. It was shown that 23 patients (21.7%) from CESAC had the most complaints about the manner of drug dispensing. But in all the three ARV sites the majority of the patients were satisfied.

Table 18: Opinion on the time spent to get ARV for each ARV site

Long time to get ARV	Name of ARV site			Total
	HGT	CESAC	HPG	
Yes	7 16.3%	72 68.0%	18 29.5%	97 46.2%
No	36 87.3%	34 32.0%	43 70.5%	113 53.8%
Total	43 100.0%	106 100.0%	61 100.0%	210 100.0%

72 patients (68%) from CESAC said that they spent a long time in getting ARV while 36 (87.3%) and 43 (70.5%) patients at HGT and HPG respectively did not spend long time.

A Chi-square test revealed a statistically significant difference between the sites $p < 0.05$.

Table 19: Means of transportation by ARV site

Name of ARV site		Number	%
HGT	By foot	3	7.0
	Bus	5	11.6
CESAC	Taxi	3	7.0
	Car	1	2.3
	Motorbike	9	20.9
	Minibus	20	46.5
	Bus + Taxi	2	4.7
	Total	43	100.0
	By foot	2	1.9
	Bus	13	12.3
	Taxi	3	2.8
	Motorbike	21	19.8
Minibus	67	63.2	
Total	106	100.0	
HPG	Bus	2	3.3
	Taxi	3	4.9
	Car	2	3.3
	Taxi + Minibus	37	60.7
	Motorbike	5	8.2
	Bus + Taxi	1	1.6
	Taxi + Bus + Minibus	8	13.1
	Taxi + Bus + Car	2	3.3
	Job's car	1	1.6
	Total	61	100.0

48 patients from HPG (78.7%) used more than one means of transportation for travelling.

Opinions on ARV accessibility and presence of other people during dispensing

A Fisher's Exact test was conducted to compare opinions of patients on the presence of other people (health staff) during the dispensing of ARV.

The test revealed no statistically significant difference between the groups $p > 0.05$. This means that the presence of health staff during the dispensing did not influence the opinion of patients about ARV drugs accessibility. We can assume probably that there is not a concern or problem of confidentiality during the dispensing.

Time to get ARV and opinion about time spent

A Chi-square test was conducted to compare the time spent by patient to get ARV at the treatment site and the opinion of the patients about this time. The test revealed a statistically significant difference between the groups $p < 0.05$.

Of the patients who had to wait longer than 60 min, more got tired of waiting than those with less than 60 min waiting time.

Table 20: Association between the means of transportation and having an income

Means of transportation	Income		Total
	No	Yes	
Own or personal means	6 5.0%	32 35.6%	38 18.1%
Public means	111 92.5%	55 61.1%	166 79.0%
By foot	3 2.5%	2 2.2%	5 2.4%
Job car	0 .0%	1 1.1%	1 0.5%
Total	120 100.0%	90 100.0%	210 100.0%

A Fisher's Exact test was conducted to see the association of the means of transportation used by patients to reach ARV sites and the existence of an income. The test revealed a statistically significant difference between the groups of income and no income $p < 0.05$.

In the 2 X 2 comparison of the patients under ART using their own means and those using public ones, having an income had a influence $P=0.00000001$ (highly significant). 32 patients (35.6%) who had had an income used their own means of transportation to reach ARV sites. The majority of patients who had no income 111 (92.5%) used public means of transportation

Association of waiting time and expense at the treatment sites

An independent-samples t-test was conducted to compare the waiting time of patients at the treatment sites and the expense for food or/and drink. The test revealed a statistically significant difference between the groups $p < 0.05$

The longer the waiting time was, the more money they spent to buy food at the treatment site, and this came in addition to the transportation cost.

The expenses were proportional to the length of waiting time to get ARV.

Opinion on ARV access and existence of other difficulties

Almost all the patients 154 (99%) who responded that there were no other difficulties that prevent them from getting ARV thought that ARV was accessible. Despite that, 204 patients (98%) responded that ARV was accessible even though some difficulties still exist. The main difficulties were related to the lack of money, the long waiting time and stigma Fisher's exact test, $p < 0.05$

Comparison of income and spending for transportation

Table 21: Income and transportation fee

Payment of transportation fee by who	Income		Total
	No	Yes	
No fee	3 2.5%	4 4.4%	7 3.3%
Myself	30 25.0%	78 86.7%	108 51.4%
Husband	23 19.2%	4 4.4%	27 12.9%
Brother	22 18.3%	4 4.4%	26 12.4%
Sister	12 10.0%	0 .0%	12 5.7%
Friend	7 5.8%	0 .0%	7 3.3%
Other	9 7.5%	0 .0%	9 4.3%
Father	9 7.5%	0 .0%	9 4.3%
Son	5 4.2%	0 .0%	5 2.4%
Total	120 100.0%	90 100.0%	210 100.0%

78 patients (86.7%) out of 90 who had an income paid the transportation fee themselves. However for those who had no income, their transportation fee was paid mainly by themselves 30 (25.0%), husband 23 (19.2%), brother 22 (18.3%) and sister 12 (10.0%). The lack of income could be a major cause of the under frequentation of the treatment site Fisher's exact test, $p < 0.05$.

4.7 Gender analysis

Marital status by gender

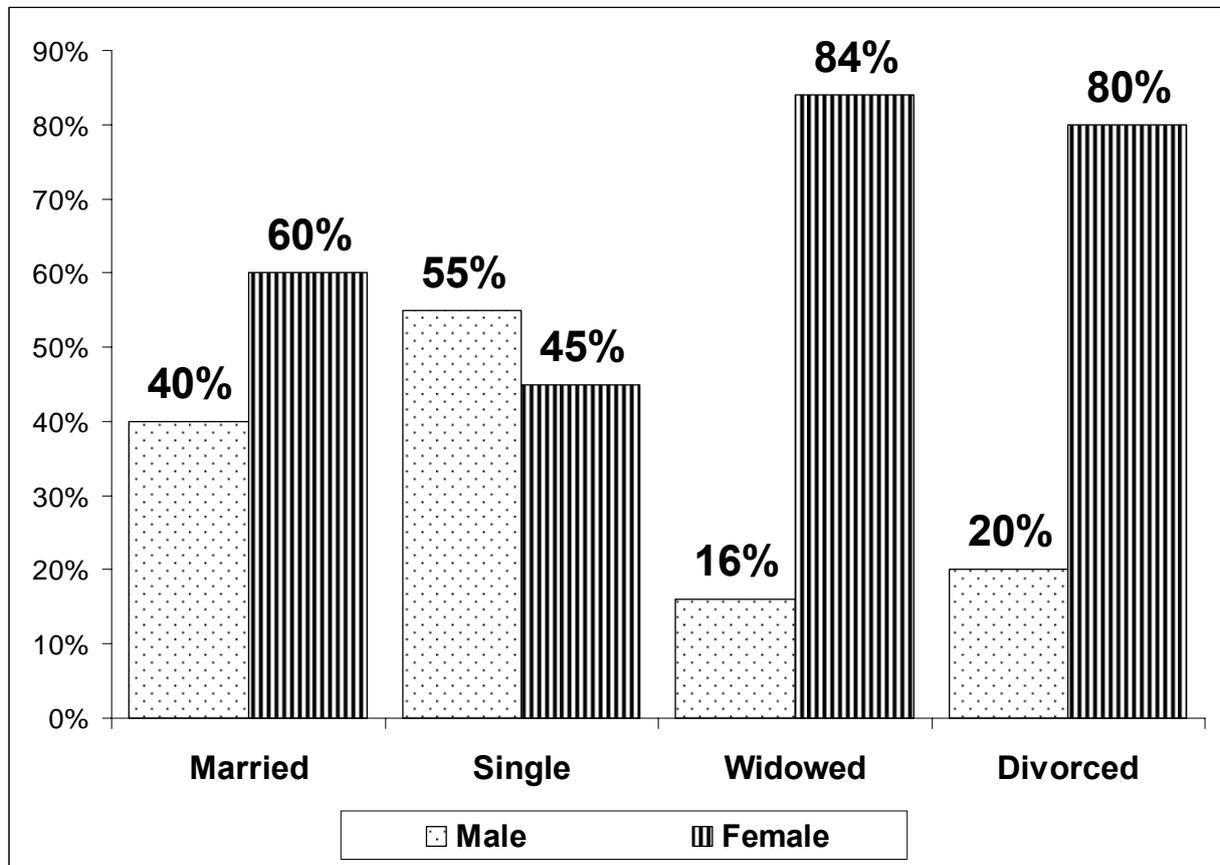


Figure 26: Marital status according to gender

The majority of widowed patients was female 46/55 (84%) and divorced 20/25 (80%).

Among the divorced female, 6/20 (30%) were abandon by their husband.

Means of transportation by gender

Table 22: Means of transportation according to gender

Means of transportation	Gender		Total
	male	female	
Own means	29	9	38
	40.3%	6.5%	18.1%
Public means	41	125	166
	56.9%	90.5%	79.0%
By foot	1	4	5
	1.4%	3.0%	2.4%
Job car	1	0	1
	1.4%	.0%	0.5%
Total	72	138	210
	100.0%	100.0%	100.0%

Males and females used different means of transportation to reach the ARV sites. The Fisher's Exact revealed a statistically significant difference between the gender $p < 0.05$. However, in the 2 X 2 comparison of the use of the own means and public means between gender, the majority of female 125 (90.5%) used public means to reach the ARV sites while it was 41 males (56.9%). 29 male patients (40.3%) had their own means of transportation while it was only 9 female patients (6.75%) $p=0.000001$ (highly significant).

Income by gender

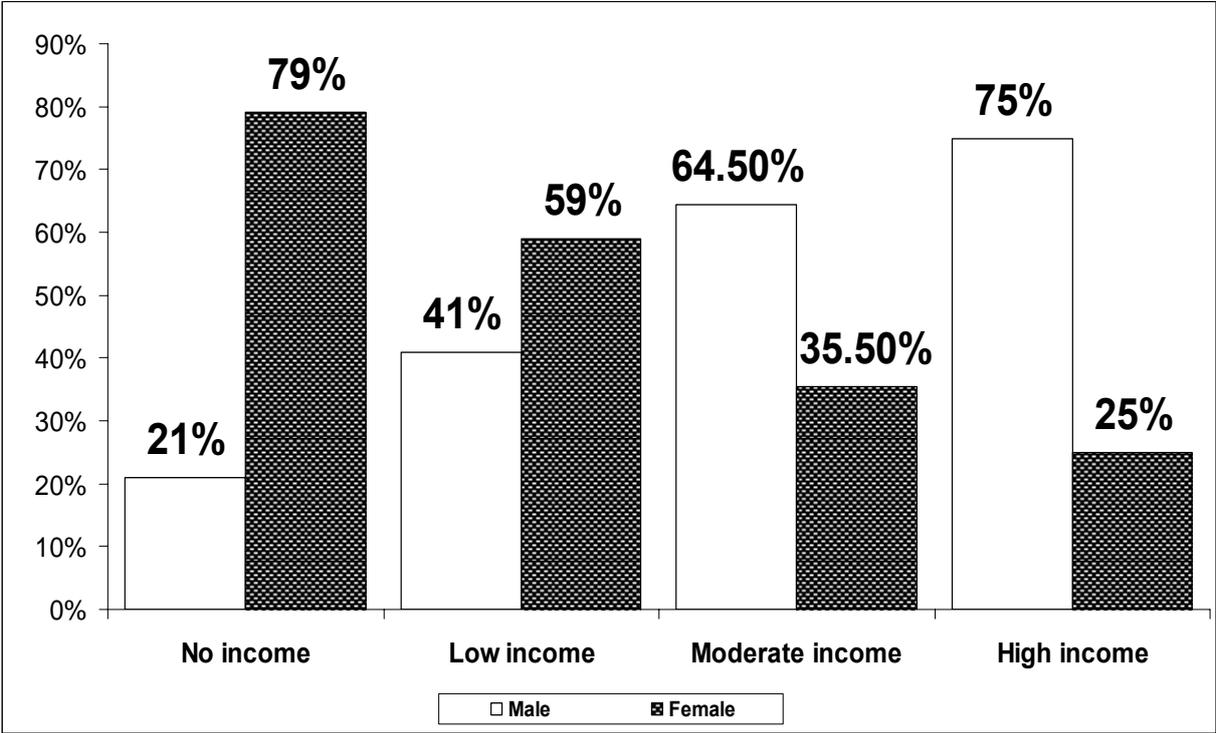


Figure 27: Comparison of patients' income by gender

There was a difference between the genders in terms of income. There were significantly more males than females in the moderate and high income categories, 20 (64.5%) and 6 (75%) respectively. The majority of the female patients 95 (79%) had no income while only 25 (21%) male patients had no income. The Fisher's Exact test revealed a statistically significant difference between the gender $p < 0.05$.

Summary of some answers and opinions according to gender

Chi-square or Fisher Exact test was used to find gender difference for some answers and opinions.

We did not show any significant difference between genders ($p > 0.05$) for the following variables:

- Quality of dispensing
- Directions for use
- Side-effects
- Storage
- Opinion on dispensing manner
- Frequency of ARV reception
- Financial accessibility
- Time spent to get prescription (in hour)
- Time spent to get ARV (in hour)
- Waiting time (in hour)

However, for advice on new appointment there was difference between male and female $p < 0.05$. The majority of male patients 51 (71%) did not received this advice. 63 female patients (46%) received it against 21 male patients (29%).

CHAPTER 5: DISCUSSION

The aim of this study was to assess potential difficulties which can limit ARV drugs access even though these drugs are free of charge for HIV/AIDS patients at the treatment site in Bamako, Republic of Mali.

A cross sectional survey was used. The material was a questionnaire administered through a face-to-face interview with the participants. The questionnaire was constructed in open and closed questions. The interviews were performed in Bambara (language of Bambara ethnic group) for patients and in French for dispensers.

The validity and reliability were discussed in the methodology part.

5.1 Strengths of the study:

Cross-sectional survey is a suitable design when little is known of the phenomenon under investigation.

The workshop and the pilot test helped to find an understandable way to ask questions. The face-to-face interviews provided a high rate of response. The interviews did not reveal any major communication barrier. The questionnaire assured the confidentiality of the information.

Our findings give baseline data which can help policy-makers to improve ARV drugs accessibility even though these are free of charge to HIV/AIDS patients.

5.2 Limitations

Some patients still do not have access to ARV and our study did not address this group of patients. The study did not reach the patients who missed their appointments nor those who came on Saturday for special reasons. Because of this, the findings can not be generalised at the country level. This study was conducted in Bamako where there were several means of transportation and good roads. Future studies are needed in the regional sites to assess the general accessibility of ARV in Mali.

Health facility based study may be easier to conduct, but the results may not be representative of the entire population of HIV/AIDS patients.

Our study did not include the PMTCT sites which dispense mostly mono-therapy. PMTCT concerns pregnant women who were not included in our study.

Convenience sampling (non-probability sampling) was used which is not optimal for a survey and limits the generalisation of the findings. The interviews were done consecutively at the dispensing sites.

5.3 Discussion of findings

5.3.1 Characteristics of the respondents

210 HIV/AIDS patients under ART for at least one month and 16 dispensers were interviewed from the three ARV sites in Bamako (HGT, CESAC and HPG).

a) Patients

The majority of the patients 138 (66%) were female. The national HIV prevalence rate was 1.7%. 2.0% for female and 1.3% for male(3).

The patients were between 18 and 65 years old. In Mali, the highest prevalence was 3.9% in the 30-34 age group in 2001. The district of Bamako, with 2.5%, had the highest rate of HIV prevalence inside the country followed by the regions of Kayes, Ségou and Koulikoro 1.9% each (3).

In this study, 92 patients (43.8%) were married, 55 (26.2%) widowed and 25 (11.9%) divorced.

109 patients (51.9%) were illiterate which is lower than the general illiteracy rate in Mali which was 81% in 2004 (2).

Only 43 patients (20.5%) were wage earners and had regular income while 100 (47.6%) were unemployed. Out of these 100 jobless 47 (47%) were housewives.

120 patients (57%) out of 210 had no income. 105 (87.5%) of those without income received family help to meet their basic needs in addition to the transportation cost. In Mali the social network is very important where the health insurance is not extended to the whole population.

The majority of the patients 183 (87%) were residing in Bamako and distributed between the six communes of Bamako while the ARV sites were located only in second (HGT) and third (CESAC and HPG) communes. Several patients inside or outside Bamako could go to the nearest site or regional ones which will be easier to reach in terms of distance, time and money. More over, one patient from the north of Mali travelled 1 200km to get his medication. This patient passed through 3 ARV sites (Gao, Mopti and Ségou) to reach Bamako. These patients tried to avoid stigma by travelling as far as possible from home.

The decentralisation of ARV sites will improve the geographical and financial accessibility but will not solve the problem for those who want to avoid stigma.

The majority of the patients 119 (56.7%) were under ARV for one year or less.

107 patients (51%) received their medication each month while 98 (46.6%) did so every two months. Only 5 patients (2.4%) received their medication quarterly.

160 patients (76.2%) had radio and 118 (56.2%) had TV at home. This is an important observation because the awareness campaign on HIV is diffused through radio and TV emissions.

b) Dispensers

Sixteen dispensers were interviewed during the data collection in the three ARV sites (9 at HGT, 3 at CESAC and 4 at HPG).

14 dispensers out of 16 (87.5%) were male. The ages of the dispensers ranged from 25 to 35 years. 7 dispensers (44%) were pharmacists. They were helped by 6th or 7th year pharmacy students doing their thesis at the dispensing site.

The majority of dispensers 11 (69%) received training on ARV dispensing. The rest had an experience based on their practice in the ARV sites. There was no guideline to follow for ARV dispensing at the ARV sites.

The experience on ARV dispensing ranged from 2 to 72 months. The regular staff (pharmacists allocated for dispensing) had the longer experience while the assistants' 6th and 7th year pharmacy students were working temporarily to finish their thesis at the dispensing site.

5.3.2 Difficulties experienced

Distance to ARV site

The median distance was 9km. 50 patients (23.8%) had to travel 5km or less. A considerable number of patients on treatment 164 (78%) had to travel 15km or less to the treatment site. In Bamako 95% of the population had access to health care facilities within 5km and 99% within 15km in 2004 (5). Access to health care is still low for HIV/AIDS patients.

The travel distance to reach the treatment site ranged from 1 to 1200km while it was 1 to 184km in Uganda and the maximum was 200km in Botswana (41). In Morocco (26), the distance was still a problem for the patients who lived far from the treatment site.

Time to reach ARV site

The travel time to reach the treatment site ranged from 10 to 2 400min. This time could not be justified knowing that Mali has at least one site in each of the main towns as follows: Kayes, Koulikoro, Sikasso, Ségou, Mopti, Toumbouctou, Gao and Kidal. Further, it takes less time for patients to reach some of these towns.

Means of transportation

The majority of the patients 172 (82%) did not have their own means of transportation.

166 patients (96%) out of 172 who had no means of transportation used public transportation to reach ARV site while only 5 patients (3%) preferred to walk. In Mali, walking is not preferred when one can afford other transportation, no matter how short is the distance.

The fact is that 15 patients had only 2km or less of travel distance. In Morocco also only 3 patients out of 88 walked to the treatment site (26). Among the other patients 63 used a bus, 13 a train, 6 a taxi and 3 a car. This probably shows that the habit is not only Malian.

90 patients (42.%) used a minibus as means of transportation which is very quick while bus was formal (regular schedule) and takes longer time even though it was more or less the same price as minibus.

Having an income influenced also the means of transportation to reach the ARV site. The majority of patients who used public means of transportation 111 (67%) had no income.

The majority of patients from HPG 48 (78.7%) used more than one means of transportation for travelling.

Cost of transportation

The transportation cost to the treatment site ranged from 0 to 21 700 Francs CFA. The median transportation cost was **500 Francs CFA (≈1 dollar US)**. In Tanzania (41), the transportation cost have been seen as a burden for some patients. However in Morocco (26), the cost of transportation was subsidized. The longer the distance was, the higher the transportation cost was.

The majority of patients 92 (86.7%) who had an income paid the transportation cost themselves. Those who had no income had their transportation cost paid mainly by themselves or by the family' members. Therefore lack of income could be a major cause of the under-utilization of the treatment site as it was reported in Morocco' study. This is because AIDS can lead to dismissal from work, unemployment, discrimination etc. It is not enough to make ARV free of charge. There is an additional necessity for financial support (26).

Waiting time/ Organisational issue

The mean waiting time (waiting for medical prescription and ARV dispensing) was 3.8 ± 2.65 hours. The waiting time ranged from 0.10 to 10 hours (6 to 600min).

Our findings showed that the major issue at the treatment site was the length of time spent or waiting time.

The majority of patients 127 (60%) reported spending at least 4 hours at the treatment site. This is near to the Botswana study (41) which found that 53% of respondents spent at least four hours at the clinic. In Botswana, waiting time was found to be a challenge to adherence. In Uganda (same study) the average waiting time was 5 hours in the public facility and one hour in the private facility (41).

Even though the ARVs were made available and being provided free of charge at dispensing site, challenges still existed. Such challenges were found in: waiting time, cost of transportation to and from ARV site and cost of food while waiting to get ARV (41)

The longer the waiting time was, the more the patients spent money to buy food at the treatment site. This also came in addition to the transportation fee. The reason was that the long waiting time made them miss the main meal at home. In Mali, usually people live in family and each member is required to be available or on time for meal unless there is a known reason for a family member's absence.

The expenses were proportional to the length of waiting time to get ARV.

Unlike South Africa (42), in Mali ARV dispensing was under the responsibility of pharmacist. ARV was delivered by pharmacist or assistants (6 or 7th year student of pharmacy preparing their thesis).

As in South Africa (42) the ARV was handed out on the basis of "first come, first served". Usually, HIV/AIDS patients spent the whole day at the treatment site after arriving two hours ahead the opening time (7h 30 am) in Mali. But sick patients were prioritised and allowed to first see the medical doctor and also in getting ARV drugs.

In Mali all patients were required to see a medical doctor to get a prescription before receiving the ARV. The medical prescription was also compulsory even for refill. This contributed to increasing the waiting time of the patients at the treatment site. While in South Africa (42), patients did not see a medical doctor unless it was necessary.

5.3.3 Opinions of patients

125 patients (60%) thought that they are living far from the ARV site.

113 patients (54%) responded that they spent long time to reach ARV site.

Almost all patients 206 (98%) in our study responded that ARV were accessible which means they did not perceive any difficulty to get ARV.

To the level of accessibility 47 patients out of 206 (23%) thought that ARV was less accessible.

40 patients out of 51 (78.4%) who responded that ARV drugs were less or not accessible wanted the reduction of the waiting time at the ARV site while 5 patients (9.8%) suggested more decentralisation of the ARV sites inside the city of Bamako.

81 patients (39%) received ARV in presence of other people (health staff) and the majority of them 77 (95%) was comfortable with this presence. This explains that the confidentiality was not a concern for patients which was opposite to the conclusion of Koumaré et al. (29).

A possible reason for this is that the patients assume that health staff is obliged to protect the confidentiality of information about their patients. According to the International Pharmaceutical Federation (FIP) every country should have a code of ethics for pharmacists, obliging them to respect patient confidentiality (43). The national council of pharmacists of Mali is a member of FIP and had developed a national code of ethics. In Mali the protection of confidentiality is a general requirement for all health personnel.

Despite that, the majority of patients responded that ARV was accessible even though some difficulties still exist. 55 patients out of 210 (26%) of noticed the existence of other difficulties that prevent to get ARV. The main difficulties that these patients notified were related to: the lack of money 15 (27%); long waiting time 11 (20%); stigma 6 (11%); and difficulty in obtaining permission to leave job because of non-disclosure of patient's HIV status 4 (7%).

5.3.4 Dispensing manner

There were discrepancies between the answers, for examples the advices received by patients and given by dispensers were not consistent. All dispensers 16 (100%) affirmed giving advices on side-effects while only 73 patients (34.8%) said receiving this advice.

In Botswana, a study revealed that 58% of ARV users experienced side-effects (41).

Dispensers should emphasize on this advice even monitor it though a well organize system of pharmaco-vigilance.

In Tanzania, patients complained about side-effects of ARV (41) which can limit the adherence of HIV causing wastage of the scare resources in poor setting. Several studies have found that side-effects can cause non-adherence to treatment. A literature survey showed that 19 – 25% of patients quoted side-effects as a cause for non-adherence (44).

Weiser et al. found that 51% of patients experienced side-effects, and 9% of them considered this as a barrier to adherence (21).

There are similar results from Botswana, 58% and 8% respectively (41). In order to improve adherence, Stone recommends that patients should be informed about possible side-effects and how they will be managed (45).

Fortunately almost all patients 207 (98.5%) received advice about the directions for use (dosage and administration). In Mali, the procurement of ARV is based on tendering system. ARV drugs can be found in several dosages, presentations and from different manufacturers. In Brazil, changes in packaging of ARVs have been reported as an obstacle to optimal treatment (27). The patients get confused and either stop treatment or take their medication incorrectly. Poor literacy skills probably add to the confusion. In Botswana, 3% of patients reported having misunderstood instructions as a reason for missing medications (41). In this case it is very important to have advices on the directions for use.

5.3.5 Descriptive statistics by site

Univariate analysis sorted out detailed results by ARV site (HGT, CESAC and HPG) for some variables. The following observations were made:

- HGT had the shortest waiting time and appeared to be the most accessible
- CESAC had the shortest travel time and distance but the longest waiting time. CESAC is less accessible in terms of waiting time at the site. However it was the most accessible site financially.
- HPG had the longest distance, leading to the longest travel time and the highest travel cost. Consequently, HPG was the site which was least accessible in terms of distance, time and cost of transportation. In addition, the patients who visited this site had the highest income.

The lack of income could constitute a real problem for the accessibility of ARV sites.

5.3.6 Dependant variables

Geographical accessibility

The categorisation for the geographical accessibility by time spent and distance covered showed that ARVs were accessible for the majority of the HIV/AIDS patients.

Financial accessibility

ARV was accessible for 80 patients out of 87 (92%) who had an income and for whom we obtained information on the income value.

Opinion of informants about accessibility of ARV

The majority of HIV/AIDS patients and dispensers felt that ARV was accessible.

Quality of dispensing

According to the importance of advices received by patients, 114 patients (54.2%) had an acceptable quality of dispensing while 69 (32.9%) had a poor quality of dispensing. Only 27 patients (12.9%) received a good quality of dispensing. This showed that the quality of dispensing in terms of advices should be improved by the dispensers.

Patient's satisfaction with the manner of dispensing

The majority of the patients 176 (84%) were satisfied with the manner of dispensing. They received friendly service at the dispensing site even though the waiting time was the longest at CESAC. However, many of them complained about the dispensing manner at CESAC.

Staff coverage for dispensing

Between May 2005 and July 2006 the number of patients on ART in Bamako increased from 3 102 to 6 343 more than the double (29). In July 2006 there were 16 ARV dispensers, giving a ratio of 396 patients per dispenser. However, the number of dispensers per site did not match the number of patients. In CESAC each dispenser had to cope with 1 066 patients, in HPG 461 and in HGT only 144 patients. The difference between the sites is reflected in the long mean of waiting time in CESAC (two and a half hours), and the patients' opinion about waiting time to get ARV: 74% said that they spent a long time, compared to 19% in HPG and 7% in HGT. Each dispenser can, in theory, be available for dispensing 1 680 hours per year (7 hours, 5 days, 48 weeks).

When planning to introduce ART in the public sector in Botswana (46), it was estimated that total pharmacist + pharmacy technician time per patient per year would be 0.6 + 2.0 hours. Assuming that this estimate is relevant for the situation in Bamako, each dispenser could be able to dispense for a total of 646 patients per year. In this case, the dispensers in CESAC are already overstretched, whereas there could be some spare capacity in HGT.

Only four of the 16 dispensers available in July 2006 were permanently allocated for dispensing, the others were pharmacy students. If the students are not replaced when they finish their studies, there will be a dramatic reduction in dispensing capacity. This, combined

with the expansion of the ART programme, could endanger the whole ART programme. Either more pharmacists must be recruited, or other solutions found to increase dispensing capacity.

A similar situation has been experienced in other countries, e.g. in Tanzania where the increase in number of patients lead to heavy work loads for health care staff (41). A shortage of health care workers is a general problem in many African countries. Mali has only 1.9 health care workers for 1000 people (47).

In order to increase capacity to deliver HIV services, WHO has started to promote so-called task-shifting, by moving some tasks from highly qualified health staff to less specialized personnel (47). The feasibility in Mali of training other categories of personnel in ARV dispensing, could be explored.

5.3.7 Disclosure challenge

Stigma and discrimination are two of the greatest barriers to dealing effectively with the HIV epidemic. They deter people from finding out about their HIV status, and prevent HIV positive people from taking steps to protect others and seeking treatment for themselves.

In a study in Botswana in 2000, Weiser et al. found that 15% of patients answered that stigma was a barrier (21) . In a summary of three country studies, Hardon et al. reported that after disclosing their HIV-positive status, some patients had lost their jobs, others were abandoned or badly treated by their partners, or were isolated by community members (41). In Botswana, 27% of patients said that they feared to lose their job because of HIV status (48).

In this study 6 of the 210 patients (2.9%) answered that they considered stigma as a problem that could prevent them from getting ARV. However, some of the patients' answers to other questions indicate that stigma might be a more widespread problem:

- One patient travelled a much longer distance than necessary to the treatment site, presumably to avoid disclosure
- Four patients had difficulties leaving their jobs to get ARV because they had not disclosed their HIV status.
- There were 20 divorced females among the 210 patients (80% of the divorced patients), 6 of them said that they had been abandoned by their husbands
- Some patients even reported that they have to use other excuses in order to go to the treatment site

In Morocco, more female patients were divorced than male (26).

A study from Tanzania showed that the disclosure of HIV status increased support/care from family members (49). Another study from South Africa reported that the disclosure of HIV status was important for treatment adherence (42). Similarly, Klitzman et al. reported that HAART lead to increase in HIV disclosure and support (50).

5.3.8 Gender analysis

There was gender difference in terms of income, means of transportation and advice on new appointment. The majority of female patients 125 (90.5%) used public means to reach the ARV sites while 29 male patients (40.3%) had their own means of transportation

In Morocco for example the gender did not influence the means of transportation (26).

However gender did not influence the travel distance, cost of transportation, waiting time, frequency of ARV reception, existence of difficulties, satisfaction on dispensing manner, advices on ARV and quality of ARV dispensing. This shows equity on ARV access according to gender at the treatment site.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSIONS

Cross sectional quantitative study was conducted in Bamako, the capital city of the Republic of Mali in the three ARV sites HGT, CESAC and HPG.

The study included 210 HIV/AIDS patients under ART for at least one month (43 at HGT; 106 at CESAC; and 61 at HPG) and 16 dispensers (9 at HGT; 3 at CESAC; and 4 at HPG).

The sex ratio for patients was 1.9, approximately two female for one male. The mean age for patients was 35.17 ± 9.23 years. The majority of the patients 183 (87%) were residing in Bamako while only 27 (13%) were coming from outside Bamako.

According to respondents' opinion and the dependant variables on geographical (distance covered and time spent to reach ARV site) and financial accessibility (percentage income by cost of transportation), ARV drugs were accessible for the majority of the HIV/AIDS patients. Also the majority of patients were satisfied with the dispensing manner.

But some difficulties still existed. The findings of this study enabled observation and demonstrated some organisational issues and lapses at the treatment sites such as the long waiting time at CESAC for example, compulsory medical check-up even if not necessary. This time leads to an additional expense for food and drink. There were discrepancies between the responses of patients and dispensers according to the advices given by dispensers and those received by patients.

The stigma appeared to be a big issue even though it was under-reported by HIV/AIDS patients. This could be illustrated by the high number of divorce among female patients or those being abandoned by their husbands, the long travel distance and time covered by some patients. The difficulty experienced in getting permission from job has also been cited.

The study showed differences between the three ARV sites and between genders.

This study enabled identification of the impact of some risk factors which might limit the accessibility of ARV even though some were more important than others. Generally, it pointed out some logistic, socio-economic, and organisational issue of health staff. These can be explored by performing an analytic case control or cohort studies for a better elucidation of this public health matter. However another study should permit also to explore the patients who still have no access at all to ARV drugs.

6.2 RECOMMENDATIONS

The attainment of the specific objectives as outlined at the beginning of the study, in the three ARV sites at Bamako, Mali (HGT, CESAC and HPG) on HIV/AIDS patients and dispensers facilitating the following recommendations:

To the health authorities:

- A need to provide guidelines for ARV dispensing especially in connection with ways of improving communication or advices to HIV/AIDS patients. The guidelines are to be issued by the National High Council for AIDS control (Haut Conseil National de Lutte contre le Sida HCNLS)
- A need to organise specific unit for pharmaco-vigilance to monitor the side-effects of ARV. This responsibility is directly required from the Direction of Pharmacy and Medicines (Direction de la Pharmacie et du Médicament DPM)
- To establish a motivation plan (incentives: salary, training/education, etc) for the health staff
- To institute a curriculum on ARV dispensing at the pharmacy schools
- To included the same subject in the curriculum of medical schools
- To give practical training to students on ARV dispensing and supportive supervision
- To subsidize transportation cost for HIV/AIDS patients which incur on their journey to the treatment site
- To decentralise the ARV administration or dispensing sites as much as possible like TB drugs. This will make the drugs more accessible through the district health centers and community health centers.
- To improve and monitor counselling
- To encourage research collaborations on AIDS and ARV

To the ARV dispensers:

- To improve the organisation of dispensing by drawing up realistic appointment schedules to reduce the long waiting time. Additionally, to endeavour and integrate or engage other health staff in the process such as nurses while ensuring that responsibility remains with the pharmacist.
- To train the non-pharmacists in procedure of making proper dispensing of ARV according to the guidelines.
- To follow the dispensing guidelines for ARV.

- To intensify IEC (Information, Education and Communication) on way of caring for HIV/AIDS patients.
- To organise weekly speeches on the side-effects of ARV for the patients and those accompanying them.
- To emphasize on how to deal with the side-effects of ARV

To HIV/AIDS patients:

- A better ARV adherence and compliance
- The respect of appointment and advices on ARV drugs
- The need to disclose HIV/AIDS status, as this will help them to get care and support from family or community.

To community and organisations such as PLWHA:

- To reduce stigmatization towards the HIV/AIDS patients, by encouraging people to disclose their HIV status.
- A community mobilisation by involving the leaders (opinion and religious), NGO for purposes of improving understanding on the use of ARV and respect of appointment at the treatment site.
- To construct eating places or canteens at the ARV sites so as to reduce the nutritional risks due to ARV and AIDS as well as reducing the aggregate expenditure for getting ARV.

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LIST OF ANNEXES

Annex 1: Questionnaire for patients

Questionnaire number:

ID number

Interviewer's name:

Interview date:

Name of ARV site:

A SOCIO-DEMOGRAPHIC DATA

1 Background on antiretroviral therapy (ART)

1.1. How long are you involve in ART? (in month) -----

1.2. At what rate (rhythm) do you get ARV drugs?

1. Weekly 2. Monthly 3. Quarterly 4. Other

If Other specify -----

2 **Sex** 1. Male 2. Female

3 **Age**

How old are you? (years) -----

4 Level of schooling

4.1. Have you been to a formal school? Yes No

4.2. If No go to 5

4.3. If Yes at which year do you drop?

1. 1-6 years 2. 6-9 years

3. 10-12 years 4. More than 12 years

5 Marital status

Could you please tell me which of the following describe your marital status?

(Check only one category)

1. Married Yes No

2. Single Yes No

3. Widowed Yes No

4. Divorced Yes No

6 Profession

What is your profession?

- | | | |
|--|---------------|------------|
| 1. Civil servant | 2. House wife | 3. Trader |
| 4. Peasant (herds-man, farmer and fisherman) | | 5. Artisan |
| 6. Student | 7. Unemployed | 8. Jobless |
| 9. Other (specify) | ----- | |

7 Income

- | | | |
|--|-------|----|
| 7.1. Do you have a regular income? | Yes | No |
| 7.2. If yes, how much do you earn per month? (In FCFA) | ----- | |
| 7.3. If no, could you tell me your average income per month? (In FCFA) | ----- | |

8 Residence

- | | | |
|--|-----------|-------------------|
| 7.1 Where are you from? | ----- | |
| 7.2 Where do you live? | 1= Bamako | 2= outside Bamako |
| If the person lives in Bamako please specify the area "quartier" | ----- | |

9 Living condition

9.1 Do you have the following items at home?

- | | | |
|------------------------|-------|----|
| 1 Radio | Yes | No |
| 2 TV | Yes | No |
| 3 Bike | Yes | No |
| 4 Motorbike | Yes | No |
| 5 Car | Yes | No |
| 6 Refrigerator/Freezer | Yes | No |
| 7 Other (specify) | ----- | |

9.2 Do you have your own house? Yes No

If yes which type of house? 1 Concrete 2 Mud

3 Other (specify) -----

If no in which type of house do you live?

1 Concrete 2 Mud

3 Other (specify) -----

9.3 Do you have access to tap water in household? Yes No

9.4 Do you have access to electricity in household? Yes No

9.10 Could you tell me please what kind of toilet you have in household?

1 Traditional toilet 2 latrine 2 Modern toilet (running water)

3 Other (specify) -----

6 Additional cost

6.1. Do you spend money for anything else except transport cost while waiting for ARV drugs (food, water etc)?

1 Yes 2 No

If No go to 7

6.2. If yes, are you spend money on what? -----

6.3. How much do you spend? (In FCFA) -----

7 Other barriers

Do you think that there is any other barrier (problem) that prevents you to get ARV drug?

1 Yes 2 No

If No go to C

If yes do you have barrier relative to:

1 Family

2 Stigma

3 Nutrition

4 Heath center

5 Other (specify) -----

C OPINIONS ABOUT ARV DRUGS ACCESSIBILITY

1 Do you think that ARV drugs are accessible?

1 Yes 2 No 3 Don't known

If no, why? -----

If yes, please could you tell me how accessible the drugs are in your opinion?

1. Very accessible

2. Accessible

3. Less accessible

If less accessible what are your suggestion for better access to ARV drug?

Annex 2: Questionnaire for dispensers

Questionnaire number:

Interviewer's name:

Interview date:

Name of ARV site:

ID number:

Staff assigned for dispensing (only to site manager):

Staff doing dispensing (only to site manager):

Do you have a specific training for dispensing? 1 Yes 2 No

At what rate (rhythm) do you give ARV 1. Weekly 2. Monthly

3. Quarterly 4. Other (specify) -----

A SOCIO-DEMOGRAPHIC DATA

1 **Sex** 1. Male 2. Female

2 **Age**
How old are you (years) -----

3 **Qualification of dispenser**
1. Pharmacist 2. Medical doctor 3. Nurse 4. Midwife 5. Other
If other specify -----

4 **Experience in dispensing**
How long are you involve in ARV drugs dispensing? (In month) -----

B TRAINING

1 Did you receive training for ARV drugs dispensing?
1 Yes 2 No
If Yes which kind of training? -----

2 How many times did you receive training? -----

3 How long was it? -----

Annex 3: Questionnaire for patients (in French)

ACCESSIBILITE DES MEDICAMENTS ANTIRETROVIRAUX AUX MALADES DU VIH/SIDA A BAMAKO, MALI (Afrique de l'Ouest)

Questionnaire pour le patient

Numéro questionnaire :

Numéro d'identification :

Nom de l'interviewer :

Date de l'interview :

Nom du site ARV :

A DONNEES SOCIO-DEMOGRAPHIQUES

1. Généralités sur le traitement antirétroviral

1.1. Depuis combien de temps êtes-vous sous ARV? (en mois) (*E ye waati joli ke furaba taalila? (a kalo hake)*).....

1.2. A quel rythme recevez-vous les médicaments ARV? (*Furaba be d'e ma cogodi?*)

1. Hebdomadaire (*Lokokun ni lokokun*) ; 2. Mensuel (*Kalo ni kalo*) ; 3. Trimestriel (*kalo saba o kalo saba?*) ; 4. Autre (*cogowese*), spécifier

2. Sexe 1. Masculin 2. Féminin

3 **Age** : Quel âge avez-vous? (années) (*N'Fa/N'Ba, Ala ye si sanjoli kalifa i la?*).....

4 Niveau d'instruction

4.1. Avez-vous été à l'école : (*I kalan na wa?*)

Francophone Oui Non

Medersa Oui Non

Autres (préciser) :

4.2. Si Non, aller à la question 5

4.3. Si Oui, à quel niveau vous avez arrêté (*I ka kalan dan na hake joli la?*)?

1. Ecole primaire (1 – 6 ans); 2. Second cycle (7 – 9 ans)

3. Niveau secondaire (Lycée, CAP, BT) ; 4. Supérieur

4.4. Savez-vous lire (*I be se ka seben kalan wa?*) Oui Non

4.5. Savez-vous écrire (*I be se ka sɛbenni kɛwa*) ? Oui Non

5. Statut matrimonial

S'il vous plaît, pouvez-vous me dire votre statut matrimonial (*Haketo, i furelen do wa / N'Fa/N'ba walima, i be haketo an b'af'a be so yan wa* ?

(Cocher seulement une catégorie)

- | | | |
|-----------------------|-------|-----|
| 1. Marié (e) | Oui | Non |
| 2. Célibataire | Oui | Non |
| 3. Veuf (ve) | Oui | Non |
| 4. Divorcé (e) | Oui | Non |
| 5. Autre (préciser) : | | |

6. Profession

Quelle est votre profession (*I be bara jumɛ na / kɛ*) ?

1. Salarié (*Kalosara bara*) : spécifier
2. Ménagère (*gwa/tobili*) ;
3. Commerçant (*jagokɛla/jula*) ;
4. Paysan (éleveur = *bagankɛla*, cultivateur = *cikɛla* et pêcheur = *monikɛla / bozo*) ;
5. Artisan (*bololabarakɛla*) ;
6. Etudiant (*Ekolidenkunbaba/Kalansobakalanden*) ;
7. Sans emploi (*barakɛbali*) ; 8. Vendeur (*fɛrelɛkɛla*) ;
9. Autre (spécifier) :

7. Revenu

7.1. Avez-vous une source de revenu (*Wari soro da b'ibolo wa*) ? Oui Non

7.2. Si Oui, combien gagnez-vous approximativement par mois? (en FCFA) (Ni awɔ, i ka

Sɔɔ be se jolima tilenkɔɔ walima kalokɔɔ)

7.3. Si Non, comment arrivez-vous à subvenir à vos besoins de base (*ni ayi, e b'i ka musaka*

sɔɔ cogodi/E be jɔ ni ka musakaw ye cogodi) ?

1. Famille (*Mansaw/Balimaw*) ;
2. Association (*Demɛjɛkunlu/Tɔn*) ;
3. Entre-aide (*Demɛbolo/Demɛbolosira*) ;
4. Autre (préciser) :

8. Résidence (*sigiy ɔɔ/dagay ɔɔ*)

7.1 De quelle région ou pays venez-vous (*I be bɔ min / I be bɔ dugujumɛ ŋa*) ?

7.2 Où habitez-vous actuellement (*I sigilen be mi sissan*) ?

1= Bamako ; 2= en dehors de Bamako (spécifier) :

Si la personne vit à Bamako veuillez spécifier le quartier:

9. Conditions de vie

9.1 Avez-vous les matériels suivants à la maison (*Ni fin ninuw b'i bolo so wa*) ?

1	Radio	Oui	Non
2	Télévision	Oui	Non
3	Vélo	Oui	Non
4	Moto	Oui	Non
5	Voiture	Oui	Non
6	Frigo/Congélateur	Oui	Non
7	Autre (spécifier) :		

9.2 Avez-vous votre propre maison (*I yere halalaso b'i bolo/b'i fe wa*) ? Oui Non

Si Oui, quel type de maison (*so sugu jumε*)? 1. Ciment/parpain ; 2. Ciment/béton ; 3. Banco

4 Autre (spécifier) :

Si Non, où vivez-vous ? (*I be so jumε kɔnɔ?*)

1. Location 2. Concession familiale 3. Maison de service

4. Autre (spécifier)

Dans quel type de maison vivez-vous ? (*I be si so sugu jumε kɔnɔ?*)

1. Ciment/parpain ; 2. Ciment/béton ; 3. Banco ; 4. Autre (spécifier) :

9.3 Avez-vous de l'eau courante à la maison (*Orobine b'aw ka dukɔnɔ wa*) ? Oui Non

9.4 Avez-vous l'électricité à la maison (*Kuran be du kɔnɔ wa*) ? Oui Non

9.5 Pouvez-vous me dire quel genre de toilette vous avez à la maison (*i be haketo jegen sugu jumε b'a ka so*)?

1. Toilette traditionnelle (*farafin jegen*) ; 2. Latrine (*latirini*) ; 3. Toilette moderne (chasse-eau : *tubabu jegen*) ; 4. Autre (spécifier) :

B DONNEES CONCERNANT LES BARRIERES

1. Distance couverte

1.1 Pensez-vous que vous êtes éloigné du site ARV (*I hakilila k'i ka yɔɔ ka jan furaba tayɔɔ la wa*) ? 1. Oui 2. Non 3. Ne Sait Pas

1.2 Quelle est la distance pour arriver au site ARV (par kilomètre) (*I ka yɔɔ ni furaba tayɔɔ ce be kilohake joli bɔ*) ?

6 Coût additionnel

6.1. Dépensez-vous de l'argent en dehors du prix du transport pendant que vous attendez de recevoir vos médicaments ARV (nourriture, eau, etc) (*I be waari wèrè bò i mago la furaba makònò ni na, n'i ba fô dumuni, ji walima fin wèrè sanni na wa*)? 1.Oui ; 2. Non

Si Non, aller à la question 7.

6.2. Si Oui, qu'est-ce que vous achetez (*I be mun ni mun san*) ?.....

6.3. Combien dépensez-vous (*I ka waari bôlé be se fô joli ma*) ? (en FCFA).....

7. Autres barrières

Pensez-vous qu'une autre chose ou problème peut vous empêcher d'avoir les médicaments ARV (*I hakila ko fin wèrè be se ka gèlèya do i ka furaba sôrôli la wa*) ? 1.Oui ; 2. Non

Si Non, aller à la rubrique C des questions

Si Oui, avez-vous une barrière relative à (*ni awô, yali balanyôro bè wa*):

- 1 Famille (*I somôgôw fanfèn wa ?*)
- 2 Stigma (stigmatisation = *bolokôni yiralin fanfèn wa ?*)
- 3 Nutrition (alimentation = *duminidèsè walima dumunigèlèya fanfèn wa ?*)
- 4 Center de santé (*dôgôtôrôso yèrè taali la wa ?*)
- 5 Personnel de santé (*dôgôtôrôso barakèlaw fanfèn wa ?*)
- 6 Autre (spécifier) :.....

C. OPINION SUR L'ACCESSIBILITE DES MEDICAMENTS ARV

1 Pensez-vous que les médicaments ARV sont accessibles (*I hakilila ko furaba lasôrôli ka nôgô wa*) ? 1. Oui ; 2. Non ; 3. Ne Sait Pas

Si Non, pourquoi (*ni ayi, munna*) ?

Si Oui, pouvez-vous me dire votre opinion sur le degré d'accessibilité des médicaments ARV (*Ni awô, i be se k'i ka hakilina/ta jôn-jôn fô n'ye furaba lasôrôli kan wa*) ?

1. Très accessibles (*sôrôka diya !*)
2. Accessibles (*sôrôka nôgôn !*)
3. Peu accessibles (*sôrôka gèlèma/sôrôli gèlèya !*)

Si peu ou pas accessibles, quelle est votre suggestion pour un meilleur accès aux médicaments ARV (*N'a sôrôli ma nôgô/ka gèlèn walima na te sôrô yèrè, fèrè jumè be se ka tigè min b'a tò, a sôrô be diya aw fè !*) ?.....

D. MANIERE DE DISPENSER

1. Confidentialité

Avez-vous reçu vos médicaments ARV en présence d'autres personnes (*I ka furaba be deli ka d'i ma jama yana wa*) ? 1. Oui 2. Non

Si Non, aller à la question 2.

Si Oui, qui sont-elles (*Ni awô, môgô jumèw*) ? :

Combien sont-elles ? (*Môgô joli*) ? :

Que pensez-vous de leur présence (*E hakilina ye jumèw ye (i ka furaba dili ye o môgôw nyana)*)? :

.....

2. Conseils

Recevez-vous des conseils quand on vous donne vos médicaments ARV (*Yali, kunnafo ni be d'i ma i ka furaba di tô wa*) ? 1. Oui 2. Non

Si Non, aller à la rubrique E des questions.

Si Oui, quel genre de conseils (*Ni awô, o ye kunnafo ni jumèw ye*) ?

- | | | | |
|----|--|-----|-----|
| 1. | Dosage et mode d'administration (<i>furaba denhake n'a ta cogo</i>) | Oui | Non |
| 2. | Effets secondaires (<i>furaba tali bese ka dengun walima tôrô min se i ma</i>) | Oui | Non |
| 3. | Conservation (<i>furaba lasago cogo nyuma</i>) | Oui | Non |
| 4. | Rendez-vous (<i>A ka nyôgôn kunnafo ni / Arandevu</i>) | Oui | Non |
| 5. | Autre (spécifier) (<i>Kunnafo ni wèrè</i>) : | | |

E SATISFACTION PAR RAPPORT A LA DISPENSING

Pouvez-vous me dire votre opinion sur la manière de dispenser (*I be k'i hakilinata/miiriya fô n'ye furaba di cogo kan wa*) ?

- 1 Très satisfait (*I wasalen kosebè* !)
- 2 Satisfait (*I wasalen* !)
- 3 Non satisfait (*I ma wasa* !)
- 4 Pas du tout satisfait (*I ma wasa fiyeu* !)

I nin ce a kè dèmè ni ka timinandiya la (Je vous remercie de votre participation et patience) !

Annex 4: Questionnaire for dispensers (in French)

ACCESSIBILITE DES MEDICAMENTS ANTIRETROVIRAUX AUX MALADES DU VIH/SIDA A BAMAKO, MALI (Afrique de l'Ouest)

Questionnaire pour le dispensateur

Numero questionnaire : -----

Nom de l'interviewer: -----

Date de l'interview: -----

Nom du site ARV: -----

Numéro d'identification: -----

Staff assigné pour la dispensing (seulement au gestionnaire du site): -----

Staff faisant la dispensing (seulement au gestionnaire du site): -----

A quel rythme donnez-vous les ARV ?

1. Hebdomadaire 2. Mensuel 3. Trimestriel 4. Autre

Si Autre, spécifier -----

A DONNEES SOCIO-DEMOGRAPHIQUES

1 **Sexe** 1.Masculin 2. Féminin

2 **Age**

Quel âge avez-vous? (années) -----

3 **Qualification du dispensateur**

1. Pharmacien 2. Médecin 3. Infirmier 4. Sage-femme 5. Autre

Si autre, spécifier -----

4 **Expérience en dispensing**

Depuis combien de temps dispensez-vous les médicaments ARV? (en mois) -----

B FORMATION

1 Avez-vous reçu une formation pour la dispensing des médicaments ARV?

1 Oui 2 Non

Si Oui, quel genre de formation? -----

2 Combien de fois avez-vous reçu une formation? -----

3 Durée de la ou des formation (s)? -----

Annex 5: Consent form for patients (in French)

Formulaire de consentement volontaire éclairé / Patient

Salutations d'usage :

Je suis de.....

Nous aimerions vous demander de prendre part à notre projet de recherche.

1. But de l'étude :

Le but de l'étude est de voir en quoi, le fait de la gratuité des médicaments ARV, les personnes vivant avec le VIH ou malades du SIDA sont confrontés pour l'accessibilité aux ARV.

2. Objectif général

Identifier les barrières potentielles de l'accessibilité des médicaments ARV aux malades du VIH/SIDA.

3. Mode de recrutement du participant :

La personne vivant avec le VIH ou malade du SIDA sera recrutée en fonction de l'ordre de dispensing des médicaments ARV au niveau du site d'étude. Toute personne vivant avec le VIH ou malade du SIDA disposée à participer à l'étude après avoir reçu son médicament sera interviewée (malade qui fera partie des critères d'inclusion). Le choix du lieu de l'interview relevant des convenances du sujet participant à l'étude.

4. Avantages/Bénéfices :

Il n'y a pas d'avantages directs pour votre participation, mais les résultats de notre recherche pourraient aider les décideurs à améliorer l'accessibilité des médicaments ARV aux personnes vivant avec le VIH et aux malades du SIDA. Une compensation en terme de frais de transport ou de rafraichissement sera offerte au malade. Elle s'élève à 1 500 FCFA.

5. Risques possibles encourus :

La participation à cette étude est volontaire. Le risque encouru pourrait être le non respect de la liberté, dignité ou/et du droit du participant en matière d'intimité, d'anonymat ou de confidentialité. A cet effet, nous donnons l'assurance au sujet participant qu'à aucun moment, son nom n'apparaîtra ni sur le questionnaire ni dans les rapports, publications ou tout autre document issu de cette étude.

Chaque participant aura un numéro d'identification en fonction du site ARV. Tous les renseignements fournis par l'informateur resteront anonymes et confidentiels. A tout moment le participant peut se retirer de l'étude sans aucun préjudice.

L'acceptation ou le refus de participer n'affectera en rien les relations ou/et les soins que vous obtiendrez ici au site du traitement.

Vous êtes libre de nous poser des questions que vous désirez et de prendre contact avec notre principal responsable, superviseur local de nos études de terrain, le Dr Cisse Hama. Cellulaire : 00 223 675 23 52 ; Email : h2cisse@yahoo.fr/hama.cisse@sdc.net.

Vous pouvez également, à tout moment, prendre contact avec le président ou le secrétaire permanent du comité d'éthique de la Faculté de médecine, de pharmacie et d'odontostomatologie (FMPOS), Université de Bamako au 00 223 222 52 77

Fax : 00 223 222 96 58.

Etes-vous d'accord pour participer à cette étude? 1. Oui ; 2. Non

Si oui, êtes-vous d'accord pour le consentement verbal ou signé?

1. Verbal ; 2. Signé

Signature de l'interviewer.....

Signature du participant ou empreinte digitale

Signature du témoin ou empreinte digitale.....

Code du participant. : /...../...../...../...../...../...../...../...../ ; Date : /...../...../...../

Annex 6: Consent form for dispensers (in French)

Formulaire de consentement volontaire éclairé / Dispensateur

Salutations d'usage :

Je suis de.....

Nous aimerions vous demander de prendre part à notre projet de recherche.

1. But de l'étude :

Le but de l'étude est de voir en quoi, le fait de la gratuité des médicaments ARV, les personnes vivant avec le VIH ou malades du SIDA sont confrontés pour l'accessibilité aux ARV.

2. Objectif général

Identifier les barrières potentielles de l'accessibilité des médicaments ARV aux malades du VIH/SIDA.

3. Mode de recrutement du participant :

Tous les dispensateurs des 3 sites ARV de Bamako seront recrutés. Tout dispensateur disposé à participer à l'étude sera interviewé. Le choix du lieu de l'interview relevant des convenances du sujet participant à l'étude.

4. Avantages/Bénéfices :

Il n'y a pas d'avantages directs pour votre participation, mais les résultats de notre recherche pourraient aider les décideurs à améliorer l'accessibilité des médicaments ARV aux personnes vivant avec le VIH et aux malades du SIDA. Une compensation en terme de frais de transport ou de rafraichissement sera offerte au participant. Elle s'élève à 1 500 FCFA.

5. Risques encourus :

La participation à cette étude est volontaire. Le risque encouru pourrait être le non respect de la liberté, dignité ou/et du droit du participant en matière d'intimité, d'anonymat ou de confidentialité.

A cet effet, nous donnons l'assurance au sujet participant qu'à aucun moment, son nom n'apparaîtra ni sur le questionnaire ni dans les rapports, publications ou tout autre document issu de cette étude.

Chaque participant aura un numéro d'identification en fonction du site ARV. Tous les renseignements fournis par l'informateur resteront anonymes et confidentiels. A tout moment le participant peut se retirer de l'étude sans aucun préjudice.

L'acceptation ou le refus de participer ne vous causera aucune répercussion négative.

Vous êtes libre de nous poser des questions que vous désirez et de prendre contact avec notre principal responsable, superviseur local de nos études de terrain, le Dr Cisse Hama. Cellulaire : 00 223 675 23 52 ; Email : h2cisse@yahoo.fr/hama.cisse@cdc.net.

Vous pouvez également, à tout moment, prendre contact avec le président ou le secrétaire permanent du comité d'éthique de la Faculté de médecine, de pharmacie et d'odontostomatologie (FMPOS), Université de Bamako au 00 223 222 52 77

Fax : 00 223 222 96 58.

Etes-vous d'accord pour participer à cette étude? 1. Oui ; 2. Non

Si oui, êtes-vous d'accord pour le consentement verbal ou signé?

1. Verbal ; 2. Signé

Signature de l'interviewer.....

Signature du dispensateur.....

Code du participant. : /...../...../...../...../...../...../...../...../ ; Date : /...../...../...../

Annex 7: Ethical approval from Norway



UNIVERSITY OF OSLO
FACULTY OF MEDICINE

To the relevant authorities

**Institute of General Practice and
Community Medicine**
Section for International Health
P.O. Box 1130 Blindern
NO-0318 Oslo

Date: June 23rd 2006
Your ref.:
Our ref.:

Telephone: + 47 228 50 640
Telefax: + 47 228 50 607
E-mail: g.a.bjune@samfunnsmed.uio.no
URL: www.med.uio.no/ism/inthel

Ethical Review

Investigator's name: Sangho Fanta

**Title of the project: Antiretroviral drug accessibility to HIV/AIDS patients in Bamako, Mali,
(West Africa)**

Due to a re-organization in the Norwegian system for ethical review of research students' projects involving a second country, the project proposal has not been subject to a national review process this year.

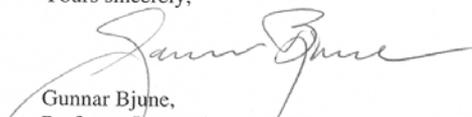
The students have filled in the ordinary national form for ethical review of research projects involving human subjects and supplied the protocol for their project. A group of experts (medical research ethics, medical anthropology and clinical medicine) in our department have read the applications carefully and made their comments. The investigator's project is found to abide to international regulations, and the comments (below) are to guide the investigators to clarify, elaborate or modify some point(s) before they apply to their national authorities. In case there are such comments in this letter, the investigator's application will be corrected accordingly.

Comments of the reviewers:

The project is both interesting and important. In the consent form you should give a little more information about the project its aims and purpose.

One question about the method. Are you really going to interview 200 persons or is it just to give them some aid in filling out the form?

Yours sincerely,



Gunnar Bjune,
Professor International Health
Head of M.Phil. education in International Community Health



M.PHIL PROGRAMME
INTERNATIONAL COMMUNITY HEALTH
FACULTY OF MEDICINE
UNIVERSITY OF OSLO, NORWAY

Annex 8: Ethical approval from Mali

MINISTERE DE L'EDUCATION NATIONALE

» » » **UNIVERSITE DE BAMAKO** » » »

**FACULTE DE MEDECINE DE PHARMACIE ET
D'ODONTO-STOMATOLOGIE / BP 1805**

☎ : (223) 222 52 77

☎ : (223) 222 96 58

Bamako – MALI

Le Président du Comité d'Ethique
Prof. Mamadou Marouf KEITA

N° 45 /FMPOS

Bamako, le 29 août 2006

(-)/u **Docteur SANGHO Fanta**
Section for International Health
Institute of General Practice and Community
Medicine (IASAM) University of Oslo,
P. O. Box 1130, Blindern, N-0318, Oslo, Norway

Cher Docteur,

J'ai le plaisir de vous informer que votre projet de recherche intitulé : «**Accessibilité des médicaments antirétroviraux aux malades du VIH/SIDA à Bamako, Mali**» a été examiné par le comité d'éthique de la Faculté de Médecine, de Pharmacie et d'Odonto-Stomatologie de l'Université de Bamako au cours de sa séance du 26 août 2006 à 09 heures. Le comité d'éthique a décidé de vous donner son accord pour le démarrage de vos travaux car vous avez satisfait aux conditions suivantes :

1. Prendre en compte toutes les observations faites par les membres du Comité d'Ethique.
2. Informer le Comité d'Ethique sur l'état du budget avant le début des travaux.
3. Fournir les compléments des CV des chercheurs (les 2 superviseurs de Norvège).

Le Comité institutionnel d'Ethique de la FMPOS vous souhaite plein succès.

**LE PRESIDENT
DU COMITE D'ETHIQUE**



Prof. Mamadou Marouf KEITA