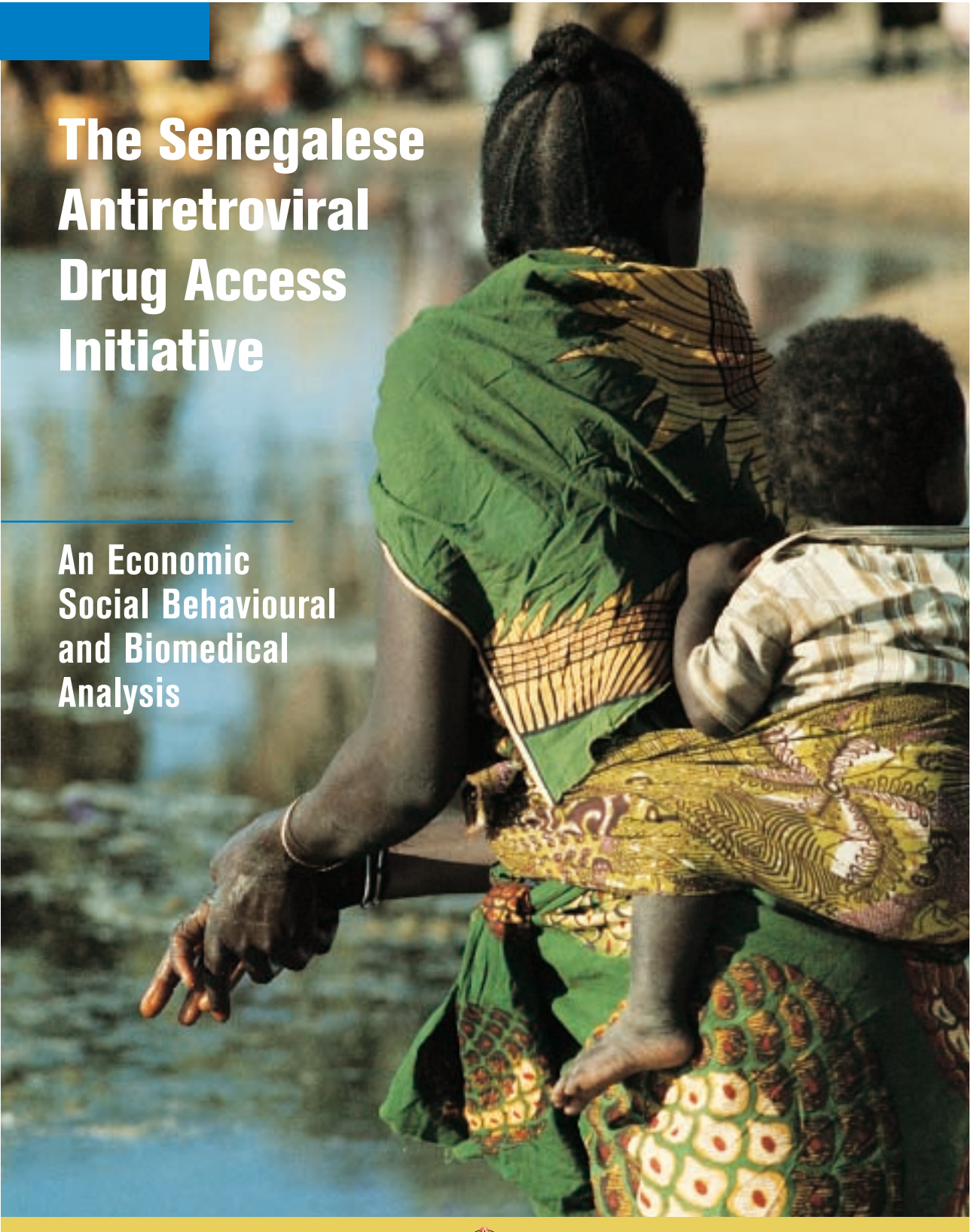
The Senegalese Antiretroviral Drug Access Initiative

An Economic Social Behavioural and Biomedical Analysis



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The Senegalese Antiretroviral Drug Access Initiative

An Economic, Social, Behavioural and Biomedical Analysis

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Abbreviations

3TC	Lamivudine
ABE	Accidental blood exposure
ANRS	Agence nationale de recherches sur le sida (National Agency for AIDS Research)
ARV	Antiretroviral
AZT	Zidovudine (also ZDV)
CDC	Centers for Disease Control and Prevention
CE	Comité d'éligibilité (Eligibility Committee)
CFAF	CFA Francs (100 CFAF = .15 euro)
CMT	Medical Committee (Comité médical technique)
CTAS	Comité pour les aspects sociaux (Welfare Committee)
d4T	Stavudine
ddI	Didanosine
DIAMM	Dispositif itinérant d'assistance aux malades mentaux (Itinerant System for Mental Health Care)
DOTS	Directly observed treatment strategy
EFZ	Efavirenz
ESTHER	Therapeutic Solidarity Network (Ensemble pour une solidarité thérapeutique en réseau)
FSTI	Fonds de solidarité thérapeutique internationale (International Therapeutic Solidarity Fund)
HAART	Highly active antiretroviral therapy (also ART)
HEAR	Hôpital pour enfants Albert Royer (Albert Royer Children's Hospital)
IAS	International AIDS Society
ICASA	International Conference on AIDS & STDs in Africa
IDA	International Development Association
IDV	Indinavir
IHS	Institut d'hygiène sociale (Social Hygiene Institute)
IMEA	Institut de médicine et d'épidémiologie africaines (African Medicine and Epidemiology Institute)
IRD	Institut de recherche pour le développement
ISAARV	Initiative sénégalaise d'accès aux antirétroviraux (Senegalese Antiretroviral Drug Access Initiative)
MAE	Ministère des Affaires étrangères (French ministry of Foreign Affairs)
NFV	Nelfinavir

NNRTI	Non-nucleoside reverse transcriptase inhibitors
NRTI	Nucleoside reverse transcriptase inhibitors
NVP	Nevirapine
PI	Protease inhibitors
PMCT	Prevention of mother-to-child transmission
PNA	Pharmacie nationale d'approvisionnement (National Supply Pharmacy)
PNLS	Programme national de lutte contre le sida (National AIDS Control Programme)
PLWA	People Living with HIV/AIDS
RNP	Réseau national de personnes vivant avec le VIH (National Network of PLWA)
SQV	Saquinavir
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
WHO	World Health Organization

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Summary

This work presents an analysis of the preliminary results of the Senegalese Antiretroviral Drug Access Initiative (ISAARV) and of its evolution over its first three years. A general introduction to ISAARV (Ibra Ndoye et al.) is followed by four parts that explore the essential questions of treatment access, adherence, therapeutic efficacy, and the impact of this treatment programme on the Senegalese health-care system.

Part I. Treatment Access

The first section analyses, from a microeconomic and socio-anthropological standpoint, patients' financial contribution and its impact on treatment access.

In Chapters I.1 and I.2, Isabelle Lanièce et al. outline the terms of patients' financial contribution towards highly active antiretroviral therapy (HAART), the impact of this contribution on the patient selection process, and the social profile of ISAARV's first 170 patients. The evolution of patient fees is described and paralleled with the pharmaceutical manufacturers' price reductions.

Aside from the purchase of antiretrovirals (ARVs), HIV-positive patients must cope with various expenses during their medical treatment. In Chapter I.3, Ana Canestri et al. assess the extra-ARV expenses of the ISAARV programme's first 120 patients, expenses that can affect patients' abilities to follow medical advice or respect their prescriptions.

The regularity of medication provision is essential to the success of a programme such as ISAARV. It entails both managing the regularity of financing and preventing any shortages in stock. In Chapter I.4, Mounirou Ciss et al. describe the procedures for providing antiretroviral medicines, ISAARV's modes of financing, and the economic impact of the reduction in drug prices.

To manage all their health expenses, patients often have no other recourse than to seek their family's help. In Chapter I.5, Khoudia Sow et al. study from an anthropological point of view the forms of solidarity for HIV-positive patients and identify the limits of familial solidarity when confronted with a condition whose treatment is costly and permanent.

Part II. HAART Adherence and Its Determinants

Many chapters herein examine adherence to antiretroviral treatments, since the fear that African patients cannot maintain a level of adherence sufficient for treatment efficacy has long hindered the use of HAART in Africa.

Isabelle Lanièce et al. conducted quantitative analyses of adherence, presented in Chapter II.1, among 164 patients over a two-year period. In addition to average adherence and changes in adherence over time, the analyses examined the

factors differentiating treatment regimes and patient costs. The reasons for non-adherence, declared by patients in monthly interviews conducted at the time of dispensation, were also explored. The authors discuss the results as well as methodological aspects of adherence studies in Southern countries.

At the same time, the qualitative analyses of adherence discussed in Chapter II.2 were carried out over a three-year period by Khoudia Sow et al. These analyses are based on a series of repeated interviews and observations with 30 patients. To recognise the difficulties and limitations patients face in treatment, analysis must take into account the conditions of adherence, as well as its successive stages — from the integration phase, passing through acceptance and appropriation, to the maintenance phase. Each of these phases has its own specific difficulties and constraints, which are overcome mainly with the help of various social relationships developed around adherence.

In Chapter II.3, Alice Desclaux et al. describe and analyse the adherence-support system set up in the ISAARV programme. Defined and then adapted pragmatically, the system is examined in terms of its achievements and limitations. Each of its measures and transverse factors — including those tied to institutional organisation, programme scope, and the distribution of roles among the associational, medical, and social sectors — are then explored, with a focus on their impact on adherence. This analysis will be useful to health officials who wish to establish, in similar contexts, an adherence-support system that requires substantial investments of personnel.

Chapter II.4, by Khoudia Sow et al., concerns patient confidence in HAART — patients' perceptions of treatments, their effectiveness, and the benefit they may bring. Patients modify their a priori confidence — which derives from social perceptions of HAART — once under treatment, according to their own perceptions of the treatment's desirable or undesirable effects on their bodies. Perceived negative side effects and conditions for efficacy are detailed in this chapter: toxicity, exhausted potency, side effects, and improvements viewed as symptoms.

In comparing adherence and confidence, perceptions and practices, support measures and their limits, perceptions and their ambivalences, Chapters II.2 and II.4 explain the high adherence results obtained in the ISAARV programme that are presented in Chapter II.1.

Part III. HAART's Impact and Effectiveness

The clinical and biological efficacy of ARV treatments in a precarious economic, social, and health context, for patients diagnosed and treated at an advanced stage of the illness and infected by non-B strains of HIV-1 — while ARV were developed, tested, and validated for Northern strains (HIV-1 subtype B) — was a major unknown for scientists and public-health decision-makers. In addition, with the increasing dissemination of HAART in Africa, control over the emergence of ARV-resistant strains is a major public-health issue. In Chapter III.1, Christian Laurent et al. describe the virological, immunological, and clinical responses, the emergence of ARV-resistant viruses, and the undesirable occurrences that arose during treatment, and analyse factors associated with mortality. These results show that antiretroviral therapy is feasible and as efficacious in

the African context as in Northern contries, and that triple therapy and a comprehensive treatment programme can delay the emergence of resistant strains.

In Chapter III.2, Khoudia Sow et al. analyse the impact of HAART on Senegalese patients' daily lives. Beyond improving patients' quality of life, the treatment changes couples' relationships, impacting on communication, the sharing of suffering, sexuality, and the desire for children. It alters relationships between the individual and his or her family, as well, due in particular to changes in priorities, and can lead to patients' creating new social networks. These social shifts contribute to individualisation, a major element of contemporary social change in African cities.

Although depression is rarely reported as a factor of non-adherence in surveys, patients' mental health and their needs for psychological care had not been studied in Africa. Guillaume Bronsard et al. present in Chapter III.3 an analysis of patients' non-somatic disorders, which may or may not be connected to being HIV-positive, that often emerge under treatment. This analysis, based on a questionnaire survey and on the study of clinical cases, led to the proposal of a psychological support structure that could be integrated into the health-care system.

Part IV. The Programme's Impact on the Health-Care System

The question of whether or not ISAARV had an impact on the Senegalese health-care system led to a study of three sectors: the association sector, the social welfare domain, and the circulation — commercial or otherwise — of ARVs in Senegal.

In Chapter IV.1, Fatou Mbodj et al. describe and analyse Senegal's association movement by recounting the successive creation of the main anti-AIDS associations, the NGOs involved in treatment, and the self-help associations for PLWA. They examine the role that these associations play within ISAARV, their discourse and attitudes towards HAART, and the impact of the Initiative on their member profile and their activities.

Can the social security system be mobilised to assure coverage of ARV treatments? Gabrièle Laborde-Balen et al. analyse in Chapter IV.2 the capacities and limitations of the Senegalese social security system in a study of the scheme for civil servants, mutual health insurance societies, employer Health Care Provision Schemes (IPMs), and private insurance companies. The financial capacities of these organisations are not at issue: involvement equally depends on, among other things, the competency of the organisation and its personnel in terms of HIV, confidentiality management within the institution, reimbursement procedures, and strategies of employers and patients. For this system to play its proper role for PLWA, the numerous facets discussed in this chapter must be considered.

Will the setting up of a national ARV access programme cause pre-existing supply systems to disappear? In Chapter IV.3 Marc Egrot et al., looking at the evolution of these systems, analyse the ISAARV programme's impact on the activity of wholesalers and private pharmacies and on the circulation and amount of interpersonal, inter-associational, national, and international donations. They

also monitor the emergence of ARVs on the informal medicine market. With these detailed observations, they analyse the relationships between ISAARV and these various sectors.

To conclude this work, the penultimate chapter presents an analysis of the ISAARV programme's successes and limitations from a public-health perspective. This assessment focuses on the accessibility of HAART; the availability of qualified human resources, medicines, and biological reagents; the effectiveness of treatment and its impact in terms of public health; the acceptability of treatment; the programme's sustainability; and on operational aspects of its functioning.

And finally, the last chapter is aimed, by way of perspectives, at organising ARV access and treatment of PLWA in peripheral health structures; defining transparent, cost-effective, and equitable access procedures to allow access for the many patients who are very poor; adapting the flowchart to the expansion of sites; and developing evaluative research at the scaling-up stage.

Introduction

The Senegalese Antiretroviral Access Initiative: An Introduction

I. Ndoye, B. Taverne, A. Desclaux, I. Lanièce, M. Egrot, E. Delaporte, P. S. Sow, S. Mboup, O. Sylla, M. Ciss

In 1998, Senegal became the first sub-Saharan African country to establish a public antiretroviral (ARV) distribution programme, creating the Senegalese Antiretroviral Access Initiative (ISAARV) with government backing. The same year, two other African countries — Uganda and Côte d'Ivoire — also set out to provide access to ARVs under the UNAIDS Drug Access Initiative, with technical support from UNAIDS.

The establishment of a governmental ARV access programme at that time testifies to the attention Senegal paid to combating HIV, attention that translated into strong political will, sustained by international recognition of Senegalese virology work and by Senegal's success in prevention, which was internationally proven with the report on the country's prevalence stability [8].

In 1998, however, the introduction of such a programme presented numerous challenges: the cost of medicine was extremely high relative to national and individual resources; international consensus advocated AIDS prevention over treatment for Southern countries; and no international institution would agree to finance the treatments. Four years later, when the necessity for ARV access in Southern countries is internationally recognised,[1] and in light of its positive results, ISAARV — once considered a gamble — has proven to be farsighted.

A rough sketch of the prevailing international context at the time of ISAARV's creation is essential to understanding the programme's innovative nature; the account below will elucidate public health issues surrounding an ARV treatment access programme in a Southern country. A description of Senegal's epidemiological and health situation will then precede a summary of national strategic principles. An introduction to ISAARV's general organisation, a broad outline of how it functions, and an analysis of its evolution from 1998 to 2002 will follow.

[1] Cf. United Nations, Resolution adopted by the General Assembly, August 2001, A/RES/S-26/2, 18 pp.

History

Programme Issues and International Context

The announcement in 1996, at the XI International Conference on AIDS in Vancouver declaring the effectiveness of highly active antiretroviral therapy (HAART) sparked fervent determination among associations, public-health officials, and leaders in the scientific community to distribute these therapies in Africa. Given the prevailing international scepticism at the time, which regarded the proposition unrealistic, a challenge was posed.

In Africa, commitment to treatment manifested itself notably in the organisation of an international scientific consultation in Dakar in September 1997. Participants at the consultation defined prerequisites for antiretroviral treatment distribution and specified optimal therapeutic protocols [3].[2] At the International Conference on AIDS & STDs in Africa (ICASA) in Abidjan in December 1997, some heads of state brought political support to the discussion, announcing the forthcoming implementation of ARV treatment programmes in a number of African countries. The announcement, however, was not met with general consent.

The establishment of ARV access programmes raised public health problems, relating particularly to 1) insufficient scientific knowledge at the time regarding the effectiveness of these therapies, both for the long term as well as within the health-care context of Southern countries; 2) the complexity of treatments, presumably requiring lifelong adherence and requiring heavy medical follow-up; 3) the need for well-developed health infrastructures to implement these treatments; as well as 4) the high cost of the medications. Like other health programmes, ARV access programmes must prove that they can fulfil the four requirements of public health: equity, optimum cost-effectiveness, accessibility and acceptability for those affected, and sustainability.

For the decision-makers and backers, the primary obstacle concerned the cost of such programmes relative to the budgets of African states [6, 7].[3] ARV treatment, according to some economists, would swallow up the total health budgets of some countries. This argument was sometimes raised to single-handedly quash all reflection on the development of treatment programmes. In addition, in the context of the 1990s, when the functioning of African health systems was seen as requiring "the contribution of populations to health costs" and "cost recovery," as generalised under the "Bamako Initiative," it was considered essential that patients contribute to the purchase of their antiretroviral treatment. Obviously, though, very few people would be able to pay the necessary sums (between US$7000 and US$10,000 per person per year). This called into question the equity and sustainability of programmes, introducing the possibility that efforts towards North-South equity, in the end, only increased the disparity between social classes in Southern countries.

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[2] See [3], with the support of ANRS, ICASA, the European Union, IAS, IMEA, ORSTOM, PNLS/MST of Côte d'Ivoire, PNLS/MST of Senegal, SAA, Secretary of State of the Coopération Française, UNAIDS, WHO.

[3] In 1998, the ratio of ARV treatment cost per person to per capita GNP (were all patients needing treatment actually receiving state-financed ARV multi-drug therapy) is estimated at 12.9% in West Africa, while it is lower than .1% in Western Europe ([7] p. 2206). See also [6].

For the clinicians, the risk of these treatments' failing was high, due in particular to problems in drug adherence, as scientific publications in 1997 showed to be the case in developed countries.[4] Close medical follow-up therefore appeared to be indispensable. Medical response to treatment failures or side effects should be quick. Adherence to antiretroviral multi-drug therapy was crucial, more so than for any other treatment.

For epidemiologists and virologists, difficulties in monitoring, along with inadequate prescriptions by insufficiently trained health professionals and the uncontrolled trafficking of ARV in the informal market, represented a significant risk in the emergence of viral resistances. They feared that the establishment of an ARV access programme would promote inappropriate usage with serious virological consequences.

Public health officials, for their part, feared that these programmes would work to the detriment of other programmes, particularly HIV prevention and testing or treatment of opportunistic infections. Accessibility to HIV testing and to treatment of opportunistic infections was considered by some actors to be a necessary prerequisite for a HAART access programme.

And finally, the pharmaceutical manufacturers declared their position, publicly neutral, seeking to avoid the debate on the price of medications which would inevitably reflect badly on their pricing in Northern countries.

These various fears corresponded to real public-health problems but should have been viewed in a rapidly evolving context likely to change with the emergence of new, less expensive treatments or, conversely, by the discovery that the available ARVs are less effective in the long term [5].

In view of the obstacles, the most cautious attitude was clearly to postpone the creation of ARV access programmes, as was recommended by the main international institutions, who maintained that prevention, because of its cost-effectiveness, was the only imaginable solution for Southern countries. At the same time, other actors in the fight against AIDS argued that the establishment of HAART access programmes would advance testing, prevention, and treatment of opportunistic infections.

When Senegal's National AIDS Control Programme (Programme national de lutte contre le sida; PNLS) committed to ISAARV, strategic choices were determined by what would enable the system to avoid the pitfalls outlined below.

Epidemiological Indicators of HIV Infection and PNLS Objectives and Resources

Since the onset of the epidemic, Senegal has had a low prevalence — under 2% among adults — which appears to be stable.[5] This situation can be attributed in part to the promptness and pertinence of prevention efforts, which were implemented on a national level. This expanded, multi-sectoral response considerably increased condom use in non-marital sex and improved treatment of sexually transmitted infections.[6]

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[4] See the numerous papers presented at the Geneva International Conference and also [9].

[5] Conseil national de lutte contre le sida, République du Sénégal, "Plan stratégique 2002–2006 de lutte contre le sida."

[6] "Acting Early to Prevent AIDS: The Case of Senegal." Best Practices, UNAIDS/99.34E.

Estimated number of people with HIV/AIDS at the end of 2000

Adults	80,000
Women	35,000
Children (under 15)	3000
Adult prevalence	1.4%
New infections	5500
Orphans	20,000
Deaths	5000
Cumulative deaths	30,000

Source: *Bull. Epi. HIV du Comité national de lutte contre le sida du Sénégal,* n° 8, décembre 2000.

In 1998 the PNLS laid out the four following objectives: 1) strengthen prevention efforts (community mobilisation, prevention of blood transmission, improved treatment of sexually transmitted infections, prevention of mother-to-child transmission); 2) improve care for people with HIV; 3) monitor the epidemic's development and evaluate the impact of interventions; and 4) develop operational research.

PNLS budget assessment, 1998 to 2001, in millions of CFAF

	1998	1999	2000	2001
State (total)	375	460	525	1290
Development partners	1165	2430	1997	2156
ISAARV (state)	250	250	300	600
Percentage of state	66%	54%	57%	46%

Source: PNLS 2002

The Groundwork

In early 1998, the PNLS established an antiretroviral multi-therapy intervention programme called the Government Antiretroviral Treatment Initiative. This programme, implemented with 250 million CFAF in government funds, was designed to finance the drug treatments and clinical and biological monitoring of 50 patients for the year 1998. PNLS created a number of administrative organs to manage the initiative. In addition to the PNLS, the following partners participated in the programme: the Ministry of Health, three health-care facilities chosen for patient care — the Infectious Diseases Unit (Services des maladies infectieuses) and Ambulatory Treatment Centre (Centre de traitement ambulatoire) of Fann Teaching Hospital and the Internal Medicine Unit (Service de médecine) at Principal Hospital — and the Sidak Project (IMEA/IRD/ANRS/Coopération française), which provided technical support and scientific monitoring.

Senegal: principal socio-demographic and health indicators

Demographics	
Population (estimated 2000)	9,200,000
Percentage of the population under age 20	57%
Health standard	
Rate of infant mortality	63.5/1000
Rate of infant-juvenile mortality	143/1000
Life expectancy at birth*	53 years
Total fertility rate	5.2 children/woman
Economy	
Per capita GDP (1996–1998)**	US$545
Poverty rate (adults earning less than 392 CFAF/day)	65%

Source: Ministère de la Santé, Direction des études, de la recherche et de la formation, "Enquête Sénégalaise sur les Indicateurs de Santé, 1999," juin 2000.

* Epidemiological Fact Sheets on HIV and STI, Senegal, 2000, UNAIDS.

** République de Sénégal, "Troisième conférence des Nations unies sur les pays les moins avancés: mémoire présenté par le Sénégal," février 2001

Various ISAARV-related research programmes funded by ANRS, IRD, MAE, and the EU

–Evaluation and support of antiretroviral multi-drug therapy among Senegal's HIV-1 patients (1999–2000), ANRS Project 1215.

–ANRS Trial 1204/IMEA 011: ddI/3TC/efavirenz once daily (1999–2001).

–ANRS Trial 1206/IMEA 012: Evaluation of tolerance and effectiveness of a first antiretroviral treatment combining Zerit® 40, twice daily, and Videx®, Stocrin®, once daily (2000–2002).

–Multi-centre study on accidental blood exposure (2000–2002), ANRS Project 1224.

–Social aspects, adherence, and impact of ISAARV on the medical system (1999–2001), ANRS Project 1216.

–ARV Availability in Senegal: An Anthropological Approach (2000–2002), ANRS Project 1242.

A pilot programme was launched, a strategy in keeping with Recommendation 17 of the Dakar-Abidjan Consensus.[7] It was of modest size, compared to its Ugandan and Ivorian counterparts, but would be expanded if the results from the first group of patients demonstrated the programme's feasibility, accessibility, acceptability, and effectiveness. The innovative and experimental nature of the Senegalese Initiative, combined with the will to set up treatments as quickly as possible for the patients needing them, encouraged a pragmatic approach to the programme's development.

[7] "The planned introduction of antiretroviral drugs in Africa requires the completion of a pilot phase in numerous countries, which will create a means by which to specify, in the context of local conditions, the terms of their use and provide data necessary for the drafting of national directives," "Les traitements antirétroviraux dans la prise en charge thérapeutique de l'infection par le VIH en Afrique sub-saharienne: Déclaration de consensus de Dakar-Abidjan," 1997, 3 pp.

Economic accessibility to the programme was considered from the outset a major issue. Out of concern for equity and social justice, a system of subsidising HAART was established to avoid a selection of patients based on their ability to pay for the medication. The subsidy amount granted to each patient was determined by their resources.

Whereas the initial framework — particularly regarding therapeutic protocols and the terms of clinical and biological monitoring — was defined on the basis of international recommendations and was presented in a number of reference documents [1, 10], the details regarding access and the programme's other social aspects were clarified pragmatically, as individual cases, difficulties,[8] and ethical questions emerged on the ground.

The technical capacity available in Dakar and the competence of its research institutions created favourable conditions for the development of such a project. Nevertheless, the approach was bold, and in 1998, the PNLS was relying on a future reduction in drug prices for the project's continuation beyond the three years initially planned. The scientific support brought to the pilot project by research institutions was simultaneous with the project's implementation, but the financial support of international backers was only obtained afterwards.

Senegal: principal health-care system indicators

Resources and infrastructure (1999)	
Hospital/population ratio	1 hospital for 545,800
Clinic/population ratio	1 clinic for 175,000
Health centre/population ratio	1 health centre for 11,500
Human resources (1999)	
Doctor/population ratio	1 doctor for 17,000
Nurse/population ratio	1 nurse for 8700
Women of childbearing age/midwife ratio	1 midwife for 4600
Financial Resources (2001)	
Health care budget	25.5 million CFAF
Proportion of health expenses in the national budget	8.24%
Health-care funding sources	
State	53%
Partners	30%
Population	11%
Local government	6%

Source: Conseil national de lutte contre le sida, République du Sénégal, "Plan stratégique 2002–2006 de lutte contre le sida."

General Organisation

Institutional Organisation

ISAARV, born of government will, was entrusted to the National AIDS Control Committee (Comité national de lutte contre le sida; CNLS) for its implementa-

[8] These were described in a preliminary study conducted in November 1998, three months after the programme's implementation [4].

tion. Instead of creating a separate institution or handing the project over to experts, ISAARV administrators had practitioners who would execute the programme — doctors, biologists, virologists, pharmacists, social workers — as well as civil society representatives and PLWA, involved in the programme's definition and planning. Most of these actors belonged to clinic-counselling, epidemiological, ethical, or legal CNLS groups.

This strategy of involvement was dictated by budgetary constraints and fulfilled two functional requirements: it could optimally adapt the project and its procedures to difficulties that would emerge in practice, and it could adapt the terms of treatment to scientific advancements, available drugs, and treatment costs in this rapidly changing field

ISAARV Institutional Organisation

Four committees were created to run ISAARV.

A first committee defines the project's direction and serves as the Initiative's control and monitoring organ. Issues relating to organisation, resource management, and personnel, as well as the evaluation of virological, bio-clinical, public-health, and social aspects; of the status of medicine and reagent stocks; and of negotiations relating to medicine or reagent purchasing, are all raised in the course of the committee's monthly meetings. Decisions are taken collegially, after discussion and agreement among committee members.

From the start of enrollments, this committee, now the Eligibility Committee (Comité d'éligibilité; CE), is responsible for patient recruitment. The committee statutorily comprises 20 people (doctors; biologists; pharmacists; Medical Association, Pharmacists' Association, and Dental Surgeons' Association representatives; religious and legal representatives; representatives from the Ministries of Finance, Public Health, and Social Action; psychologists/psychiatrists; and representatives of PLWA, social workers, NGOs, partners, and the Office of the Prime Minister). In the future, this committee will also be responsible for patient follow-up care, but the more precise "Eligibility and Follow-Up Committee" has not yet officially replaced the original denomination.

The Medical Committee (Comité medical technique; CMT) defines and periodically revises the programme's medical aspects (enrolment criteria, therapeutic protocols, monitoring of adverse reactions, etc.). In monthly meetings, it reviews the medical files of patients who will be recommended for treatment and gives its opinion on the accuracy of the combination therapy chosen by the clinician. This committee groups prescribing doctors, biologists, and pharmacists.

A Welfare Committee (Comité technique pour les aspects sociaux; CTAS) defines options relating to non-medical aspects of project access, and provides support to follow-up. It coordinates social surveys among patients recommended for treatment. The committee consists of PNLS health professionals (pharmacists, psychiatrists, etc.) and social workers.

The Drugs and Reagent Management and Supply Committee (Comité de gestion et d'approvisionnement en medicaments et réactifs; CGAMR) is responsible for managing, in addition to drug supply, the organisation of dispensation sites and relations with wholesalers, who imported the drugs before the creation of ISAARV.

Finally, an independent structure, in the form of a foundation, was envisaged to handle the collecting of private funds for the programme. It has not yet, however, come into being.

Functional Organisation

ISAARV was designed to be accessible to anyone needing antiretroviral treatment, whatever their nationality or socioeconomic status, provided that they lived in Senegal. From the beginning, the criterion of nationality, with its concomitant sensitive political issues, was eliminated in favour of residency. This was done also to assure optimal medical follow-up for the patient — which was considered impossible for a patient living outside the country — and to avoid making an "open call" to patients in neighbouring countries who would be prepared to travel to Senegal for less expensive medicine.

Criteria and channels for patient recruitment

The introductory medical criteria for treatment were based on the Dakar Consensus of 1997, revised in October 2000.[9] So, for adult patients (the only patients enrolled in ISAARV's first year), the criteria were as follows:

–patient is asymptomatic with a CD4 count of less than 350/mm^3 with a viral load greater than 10,000 copies/ml, or
–patient is symptomatic stage B with a CD4 count of less than 350/mm^3 or stage C (1993 CDC classification). A Karnofsky index of less than 70 and the presence of certain clinical signs are the exclusion criteria.

Similarly, the criteria for administering treatment to children and for establishing protocols for their care — prevention of mother-to-child transmission and prophylactic treatment of accidental blood exposure, initiated in June and July 2000, respectively — were modelled on international recommendations adapted to Southern countries and to the drugs available in Senegal. These were also revised in October 2000.[10]

Patient access procedures and itineraries

Patients are initially recruited and treated at three facilities: the Infectious Diseases Unit of Fann Teaching Hospital and its Ambulatory Treatment Centre, and the Internal Medicine Unit of Principal Hospital. Doctors selected patients at one of the three sites based on immunovirological and clinical criteria (see above). After the CMT reviews the patient's clinical file, a social worker completes a survey with the patient, which is designed to assess the patient's economic resources and the quality of his or her social support (familial, relational); identify others in the household who may be HIV-positive; and ensure that the patient understands the constraints of the treatment. The resources considered include both salaries and revenues as well as supplementary resources (social insurance, employer contribution, family support). After CTAS studies the survey results, the patient's complete file (bio-clinical and social), is rendered anonymous to guarantee equitable consideration by the CE. The CE then discusses the file, endorses the decision for treatment, and sets the amount of financial contribution to be asked of the patient in accordance with a pricing grid (see Table 1 in Chapter I.1).

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[9] "Africa: Antiretroviral Treatments for People Infected with HIV. Updated Recommendations," October 2000. ANRS, IMEA, IRD, Société africaine contre le sida (African Society Against AIDS), UNAIDS, PNLS-Senegal, PNLS-Côte d'Ivoire, IAS (ANRS, ed., French and English versions).

[10] Cf. footnote 9.

In a subsequent consultation, the doctor informs the patient of the CE's decision; if the contribution amount seems feasible to her or him, the patient is included in the programme once s/he reads an information letter and signs an informed consent.

The clinical and para-clinical follow-up of ARV treatment is overseen by the programme and thus costs nothing to the patient. Treatment of intercurrent infections, however, as well as possible associated biological tests, are the patient's responsibility, according to the variable terms of the treatment sites. In addition, supplementary fees (transportation to consultations, certain supplementary tests, etc.) are not paid for by the Initiative.

Patients are asked about the programme's economic accessibility each month when they pay for their treatment.

Medical and psychosocial monitoring

Patients' medical follow-up is given in medical consultations on Day 1, 7, 14, 30, and then monthly, based on the patient's bio-clinical log. During each consultation, the doctor writes a prescription, a copy of which he keeps. The patient then goes to the pharmacy, where the prescription is filled and the pharmacist discusses treatment with the patient, filling out an adherence follow-up log. The patient gives his financial contribution to the pharmacist.

Patients' social follow-up was intended to comprise several meetings, which was not possible beyond the first 180 patients enrolled. The patients had access to group discussion and information sessions, which were held monthly at one of the sites. Social intervention consisted mainly of adherence support in the discussion and information sessions and in the socioeconomic surveys, which were required to access ISAARV. These discussion and information sessions were not, however, regular or large enough for all patients to benefit from them. PLWA associations, which were less involved in drug-adherence support, did not develop support groups until after the pilot project had ended.

The entire system guarantees patient anonymity and confidentiality of treatment through the use of codes. Only the doctor and social worker know patients' names.

A number of problems emerged in the programme's early months, mostly relating to economic issues: a high proportion of rejections of patients in lower socioeconomic groups, and enrolled patients stopping treatment after a few months. These difficulties suggested that the way in which the initial social surveys were carried out allowed for overestimates of patients' financial capacities; discussion was reopened on the initial strategy for treating poor patients and ensuring programme equity. In addition, the proposed support measures could not be set up for a number of reasons, mainly due to the workload of programme personnel (in particular the social workers), who are public-health employees and did not have extra time to lead programme activities.

Development

From Pilot Project to National Programme

Following the XIII International Conference on AIDS in Durban in 2000, which marked a turning point in mobilising Northern institutions for treatment access in the South, the CNLS planned an expansion of ISAARV. This expansion included first, the enrolment of patients from two clinical trials[11] and patients from a mother-to-child-transmission prevention programme, and then the enrolment of new patients and decentralisation through the opening of new recruiting sites. This growth of ISAARV, defined in the 2000-2003 action plan in September 2000,[12] was made possible by the drop by about 75% in ARV prices, announced October 2000 and in effect for patients in November 2000.

This development was not independent of the change in the economic environment or in international strategy. The HAART access programme in Abidjan experienced problems (related to patient procedures and inclusion deadlines) and poor results in terms of treatment effectiveness (in particular with the formerly used two-drug regimens and with frequent interruptions due to economic reasons [2]); other HAART access programmes in African countries (Uganda, Kenya) held patients responsible for treatment costs; and new programmes, in the process of being developed, have not so far obtained any real results. And so, the Senegalese pilot programme was internationally considered a success, and UNAIDS encouraged its replication. In 2000, missions were organised for advocates of HAART access programmes in other West African countries to learn from the Senegalese experience. At the end of 2000, ISAARV was being promoted in neighbouring countries because of its relatively unusual nature, even though it involved just 166 patients.

ISAARV's expansion announced at the end of 2000 answered simultaneously to CNLS's own national strategy and to international expectations, all while taking advantage of the results of negotiations with pharmaceutical firms. Development of ISAARV and of a sufficient monitoring and support structure, maintenance of acceptable drug adherence, and improvement of equity in ARV access were challenges for the programme's second phase. It was now clear that ARV use was feasible in pilot centres — university hospitals that are specialised and competent in clinical research. The next step was to set up HAART access in non-university health-care structures likely to attract a greater number of patients: as was emphasised by P. Piot, "before treating tens of millions of Africans who are affected, start with the thousands."[13] In terms of feasibility, the challenge was no smaller than in the first phase.

Developing the System

At the end of 2000, the passage from ISAARV's pilot phase to expansion phase was announced by the CNLS, which presented its 2000–2003 action plan. Some elements of the initial system were reviewed and refined, but the expan-

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[11] ANRS 1204/IMEA 011 and ANRS 1206/IMEA 012.

[12] Ministère de la Santé/PNLS, 2000. ISAARV. Plan d'action 2000-2003. Rapport. Dakar, septembre 2000, 31 pp.

[13] "Un fonds unique contre le sida," Libération, jeudi 26 avril 2001, p. 19.

sion did not call into question the aforementioned structure. The four administrative organs defined in the first phase would remain in place, and their staff would be enlarged to include new service professionals.

The programme expansion applied initially to the city of Dakar, which saw the opening of new prescription and dispensation sites. First, a site was opened at the Social Hygiene Institute (IHS) for adult patients. Albert Royer Children's Hospital, the paediatric unit of Principal Hospital, and the paediatric clinic at Guediawaye Health Centre were then involved in children's treatment, while the maternity wards of Principal Hospital, Le Dantec Teaching Hospital, and Guediawaye Health Centre were entrusted with the treatment of pregnant women. The protocol for treating children and pregnant women, as defined by the International Therapeutic Solidarity Fund (Fonds de solidarité thérapeutique internationale; FSTI) in the framework of a prevention of mother-to-child transmission (PMCT) programme, was implemented.

The operation was to be extended across ten regions of the country. On December 1, 2001, the first decentralised site was opened in Kaolack; the other nine were to be established over the following years. The number of ARV-prescribing doctors in ISAARV went from 9 in 1998 to 24 in early 2002.

Treatment Protocols for ISAARV's Expansion

Adults

The treatment protocols for adults were revised. Dual therapies were no longer recommended. The biological criteria for enrolment did not change, but were reduced: viral load was no longer required.

Initially, triple therapies consisting of 2 NRTI + 1 NNRTI or 2 NRTI + 1 PI were thought to have comparable effectiveness. Combinations including 1 NNRTI were of particular interest because they appeared to have better patient adherence.

The choice of an NRTI cocktail among the four products available at the end of 2000 (zidovudine, didanosine, lamivudine, and stavudine) took into account drug interactions (zidovudine-stavudine is the only combination not recommended) as well as side effects (neurotoxicity, anaemia, etc.).

A second treatment option was considered in case of treatment failure among adherent patients or in case of intolerance to treatment; side effects, possible major mutations (indicated by genetic characterisation), and expected increased resistance were taken into account.

In case of an interruption of HAART, the same schema is reintroduced if the interruption concerned all molecules in the cocktail. If the interruption was only of one or two of the drugs, the continuation of these molecules is discussed according to the results, viral load, and research on viral mutation (if possible).

Particular attention was given to medicinal interactions likely to occur with treatments for opportunistic infections, in particular with anti-tuberculosis treatment.

It was recommended that treatment of HIV-2 patients follow the same enrolment criteria, with a multi-drug therapy of 2 NRTI + 1 PI; the NNRTI were excluded because of natural resistance.

Children

When ISAARV was extended to children in July 2000, patient criteria were:

–any symptomatic child at stage B or C, whatever the CD4 count;
–asymptomatic or paucisymptomatic (N or A) children over 12 months with a CD4 count lower than 15%; and
–infants (under 12 months) whose HIV diagnosis was confirmed by two positive PCR; in practice, this mainly includes children in the PMCT programme whose HIV-positive status was fixed before the age of 4 months.

Viral load therefore, it is important to note, does not play any role in treatment initiation.

Pregnant women

To prevent mother-to-child transmission, the protocol decided upon was: oral AZT treatment for the mother starting at the 34th-36th week of amenorrhoea and AZT orally every three hours during childbirth (or intravenously if necessary), followed by treatment of the newborn for six days. An alternative treatment of nevirapine can be given at the time of birth and for the newborn if the mother was unable to take AZT in due course.

Accidental blood exposure

Finally, a network for reporting and treating accidental blood exposure was set up, accompanied by the wide dissemination of information to health centres about the treatment programme. A preventative triple therapy could be given for one month according to a specific protocol for evaluating the probability of transmission.

Access and Follow-up in the Second Phase

The patient route is the same as that in ISAARV's first phase, though patient access was transformed by the implementation of new pricing and the availability of new treatments (following the objective to accelerate the inclusion of new patients). Simplified monitoring tools were finalised in November 2001 for clinical follow-up and in January 2002 for psychological follow-up.

Increase in Patient Enrolment

In the first 39 months of ISAARV's operation, the pattern of recruitment varied with treatment access procedures (Figure 1)

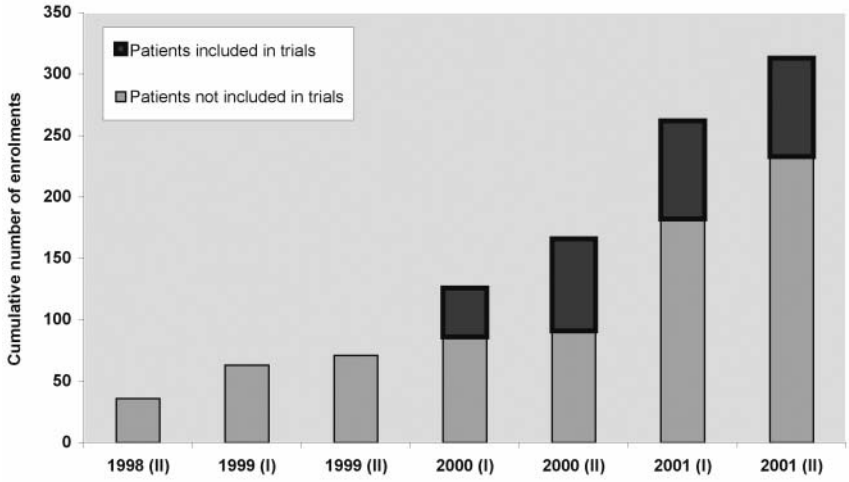

Figure 1

Recruitment in ISAARV's first 39 months (August 1998 to October 2001).

The reduction of ARV prices on the international market played a decisive role in the acceleration of new patient enrolment: the treatments became more affordable for patients, and were available in greater quantities for the programme. In the 27 months prior to the price slash, three-quarters of new patients outside clinical trials had entered ISAARV in the first 12 months; recruitment had slowed down. Once the new pricing took effect, enrolment accelerated and continued to do so throughout 2001: the number of new patients tripled monthly in the 12 months following the price reduction.

"Off-Programme" Treatment

The Biomedical Sector

Before ISAARV was initiated, some patients were already taking ARV treatment. The few people who could afford to do so travelled to Northern countries for treatment by doctors there. In Dakar, 20 patients managed to pay between 80,000 to 320,000 CFAF monthly for the purchase of drugs[14] prescribed by doctors already involved in AIDS treatment. Patients bought the medicines at one of three wholesalers or in a few private pharmacies, or received them through donations.

Some of these patients enrolled in ISAARV upon its launch or in the following years. Others continued with their initial means of treatment (purchasing drugs at ISAARV dispensing sites) and from then on were considered "off programme" — because they could not benefit from the state subsidy as a result of their relatively high economic level, or because of their foreign residency, concerns over privacy, or, less commonly, ignorance about the programme access criteria. From 2000 to 2002, the number of off-programme patients fluctuated by

[14] From "improved" mono-therapy (Videx®, Hydréa®, chloroquine), which was prescribed by a few clinicians at the start of ARV access, to triple therapies with protease inhibitors.

between 20 and 30. Enrolment in ISAARV, meanwhile, went from 80 in April 2000 to 450 in April 2002. "Off-programme" patients therefore, whose numbers remained stable, came to represent a smaller percentage of patients obtaining ARVs through the ISAARV system (from 25–30% in 2000 to less than 7% in 2002).

The doctors prescribing medicines to "off-programme" patients are ISAARV clinicians, corporate doctors, and some doctors with private practices:

–Most (seven) of the doctors are from ISAARV, and have therefore been involved in treating HIV for several years; their reputations are good and their consultations attract many patients.

–Corporate doctors provide another institutional framework for care of patients taking HAART. The doctors of seven large Dakar businesses participated in AIDS training in 2000, and since 2002, four of them have been actively involved in treatment. Some patients coming from countries in which these companies are established (CAR, Chad, Mali, etc.) and others living in Senegal were integrated into ISAARV. Corporate doctors prescribing ARVs and ISAARV clinicians are well acquainted and exchange information via an informal network.

–Some doctors practicing in the private sector devote part of their medical work to AIDS. The private doctors who prescribe HIV testing refer patients to ISAARV in case of seropositivity. In early 2002, only two were prescribing HAART extensively; a third was doing so infrequently.

The Traditional and Neo-Traditional Medical Sector

In addition to biomedical treatment, most patients turn to traditional and neo-traditional medicine. This health service is very diverse; it should not be misunderstood but will not be discussed here. A research programme is expressly pursuing the subject, which will be covered in future publications.

Conclusion

ISAARV was profoundly innovative, a pioneer among programmes introducing HAART in Africa. In 1998, it was born of the joint vision of politicians and public health decision-makers, while the AIDS association movement played a marginal role in the programme's launch. Its development was progressive, guided by the monitoring of various operational research projects and gradually incorporating new resources that came with the involvement of new partners (EU, FSTI, IDA, ESTHER, and the Global Fund to Fight AIDS, Tuberculosis and Malaria). The pharmaceutical industry also agreed early on to employ preferential pricing for the Initiative, and then renewed some price reductions in the wake of UNAIDS's ACCESS Initiative.

With its pilot experience widely successful, ISAARV transformed in its third year into a large-scale public-health programme with the objective of treating thousands of patients in all the regional capitals of Senegal by the year 2006. Maintaining quality treatment in these less-than-favourable circumstances is the challenge ISAARV faces in its second phase.

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ISAARV in Context: A Time Line

		International context	PNLS/ISAARV
1996	July	XI International Conference on AIDS in Vancouver (Canada). Demonstration of effectiveness of HAART and advocacy for its use in Southern countries	
1997		Drafting of recommendations for the use of HAART in Africa	
	June	Announcement of UNAIDS Initiative in four pilot sites (Uganda, Chile, Côte d'Ivoire, Vietnam)	
	September		Dakar Workshop drafts recommendations for the use of HAART in Africa
	November	Official launch of pilot phase of UNAIDS Initiative	
	December	X ICASA in Abidjan; Announcement of public involvement by heads of state Creation of FSTI	Presentation of Dakar recommendations at ICASA (Abidjan)
1998			Development of Senegalese HAART access programme Definition of clinical and biological follow-up protocol
	June	XII International Conference on AIDS in Geneva (Switzerland)	
	August	Start of recruitment in Abidjan under UNAIDS Initiative	Start of recruitment Methodological support
	October		Mission to assess social aspects Definition of social support measures
1999	June	Suspension of enrolment in UNAIDS Initiative in Abidjan	
	November	XI ICASA in Lusaka (Zambia) Resumption of enrolment for UNAIDS Initiative in Abidjan	Presentation of ISAARV in Lusaka

2000	January		Start of enrolment for ANRS 1204/IMEA 011 Presentation of ISAARV to ECI (Enhancing Care Initiative) Symposium
	May	Launch of the Accelerating Access Initiative (ACCESS) by the World Bank, WHO, UNFPA, UNICEF, and UNAIDS	Start of FSTI's PMCT programme
	June	Announcement of ARV price reduction to the Global South by five pharmaceutical companies Paris Workshop	
	July	XIII International Conference on AIDS in Durban (South Africa)	Presentation of ISAARV results in Durban
	October	Within ACCESS, pricing agreements with four pharmaceutical firmsinvolving, for Africa, Senegal, Rwanda, and Uganda Workshop for revising Dakar clinical recommendations UNAIDS and the World Bank promote ISAARV in other African countries	First ISAARV price reduction Beginning of enrolment in ANRS 1206/IMEA 012 Drafting of 2000-2003 ISAARV plan of action and announcement of its expansion
2001	January		Meeting on ISAARV's 2001 decentralisation into five regions
	February	CIPLA offers a triple therapy for US$600 (420,000 CFAF) per year to Southern governments	Establishment of simplified tools for social follow-up Opening of a second dispensation site (IHS)
	April	End of Pretoria trial WTO-WHO workshop on financial accessibility to HAART	
	June	Extraordinary session of United Nations General Assembly in New York to define a global strategy to fight AIDS	
	October		International workshop in Dakar on social aspects of HAART (Gorée Workshop)
	December	XII ICASA in Ouagadougou (Burkina Faso); Gorée 2001 recommendations, social aspects, HAART's role in the treatment of PLWA in Africa	Presentation of ISAARV results in Ouagadougou Announcement of decentralisation HAART access

Part I
Treatment Access

Chapter I.1
Terms of Selection and Patient Social Profile

I. Laniècе, A. Desclaux, O. Sylla, B. Taverne, M. Ciss

Health care always involves a passive patient selection process, more or less explicit, which depends on the population's level of knowledge, their contact with a screening or diagnostic programme, therapeutic habits, fees charged, etc.

In 1998, access to antiretroviral (ARV) medication in Africa was particularly limited, due to the medicines' exorbitant cost relative to government and patient resources. The ISAARV programme, designed to make highly active antiretroviral treatment (HAART) accessible to everyone who was medically eligible, sought from the outset to guarantee equity in the patient recruitment process. The objective of social justice in a context of limited resources led to the establishment of a two-pronged financing mechanism: patients would contribute to the purchase of ARVs and the government would grant a subsidy in order to avoid patients' financial capacity becoming the primary selection criterion. As the number of available treatments was limited by the governmental budget allotment, a two-stage selection process was developed based on validation of the medical condition and the setting of a sliding-scale fee payable by the patient.

The purpose of this chapter is, firstly, to present the eligibility system that was set up, including procedures and terms of access, and the adjustments that the system underwent with the evolution of the program. Secondly, it will describe social, economic, and demographic characteristics of patients at the time of enrolment and during treatment.

The Study: Patients and Methods

The study of ARV access procedures was conducted retrospectively for the first 15 months of ISAARV's operation, then prospectively in the 24 months that followed. Information was collected from various sources: Welfare Committee (Comité technique pour les aspects sociaux; CTAS) and Eligibility Committee (Comité d'éligibilité; CE) meetings — or the minutes of these meetings — and interviews with doctors, pharmacists, social workers, and administrators involved in ISAARV.

Patients' demographic, social, and economic profiles were drawn from a prospective quantitative study. Individual interviews based on a questionnaire were conducted by social workers at three clinical monitoring sites throughout the study (November 1999 to October 2001). Patients' first social surveys took place either in pre-enrolment, for those enrolling during the study, or in the course of treatment, for those who had already begun treatment.

Two subsequent surveys were conducted at six-month intervals. The procedure for the surveys (questionnaire and interviewers) was identical for patients, regardless of whether or not they were participating in clinical trials. The questionnaire consisted primarily of closed questions and was created by CTAS members, some of whom conducted the interviews. A sociologist and an epidemiologist supervised the collection of data, which was recorded and analysed with Epi Info 6.04cfr software. Analysis was usually descriptive; subgroups of the cohort were compared with the Kruskal-Wallis test for quantitative variables and the Chi^2 test for qualitative ones.

Analysis of access procedures applied to all adult patients enrolled outside clinical trials from ISAARV's launch (August 1998) to the end of the study period (October 2001) — a total of 232 patients. A detailed study of patients' social situations was conducted with the first 180 adult patients enrolled in the ISAARV programme, who were still in follow-up during the study period; they numbered 170.

ISAARV Access Procedures and Pricing Terms

Terms and criteria for access were established with the intention of extending HAART to the most underprivileged, while seeking to adjust government aid to patient resources and those of his or her family. This concern over equity and assessment engendered a centralised and complex procedure of subsidy allocation.

From ISAARV's beginnings, the terms of treatment access included two successive selection processes (see “ISAARV: An Introduction”). First, biological and clinical criteria were examined, followed by an evaluation of the patient's ability to adhere to the treatment, including his or her capacity to guarantee regular purchase of the drugs (cf. Figure 2). There has never been a social criterion of exclusion from the programme, aside from the Senegalese residency requirement. In fact, the social criteria for enrolment remained loose, so as not to create obstacles to treatment.

Any adult patient seeking enrolment in the ISAARV programme and selected by the Medical Committee (Comité médical technique; CMT) undergoes a social survey, supplying the information needed to evaluate her or his capacities of adherence and her or his ability to pay for the ARVs, as well as a fee that s/he can manage. Once this social file is completed by a social worker at one of the sites, the CTAS reviews it and proposes a monthly amount for the patient to contribute toward purchase of the drugs. Then, each social file, with the CTAS’s proposals, is submitted to the CE, which fixes the patient's monthly financial contribution. This important stage evaluating the patient's financial capacity determines the patient's eligibility (according to his or her ability to pay the minimum required) and his or her adherence to the treatment (according to the acceptability, for the designated period, of the financial obligation). The fee asked of each patient is based on a set of social and economic factors drawn from the social survey (see “The Study: Patients and Methods,” above); there lacked, however, simple, mono-factorial, easily recognisable and widely known indicators that could be objectified in the survey and that could

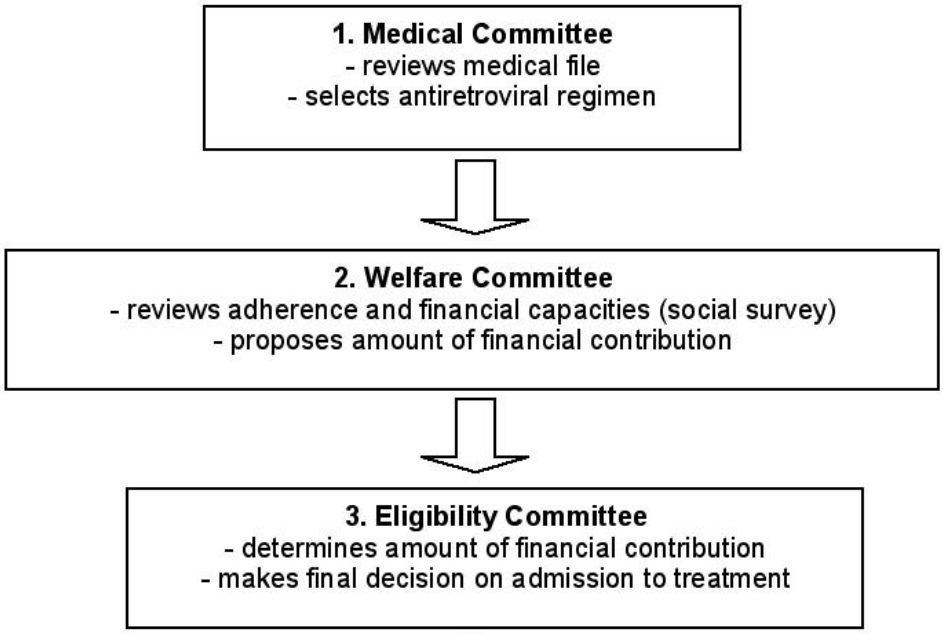

Figure 2.

Decision-making route for a candidate's enrolment in a multi-drug antiretroviral regimen

systematically determine a grant amount in a quick turnaround. Only exemption from payment was given systematically — and thus quickly — to health personnel and to active members of the National Network of People Living with HIV/AIDS (Réseau national de PvVIH; RNP), who were exempt from financial contribution since ISAARV's launch.

Pricing in ISAARV's First 39 Months

The definitions of patient contribution levels were fixed and open to review by the Drugs and Reagent Management and Supply Committee (Comité de gestion et d'approvisionnement en médicaments et en réactifs; CGAMR). In 1998, a number of pricing tables were established, corresponding to various treatment combinations: the tables for two-drug regimens included four levels of subsidies and the three-drug regimen tables included seven. Aside from higher contribution levels, the levels were almost identical for all therapy combinations. From ISAARV's start, the available ARVs included only patented medicines. Pricing categories were modified for numerous reasons, the main one being the reduction of ARV prices on the international market. Other modifications resulted from situations encountered in the programme's first 27 months, namely, the difficulty some patients had in paying for treatment and operational constraints in management. The development of pricing categories for triple therapies is recapitulated in Table 1. The evolution of ARV prices is presented in detail in Chapter I.4.

Table 1
Pricing changes in ISAARV's first three years (CFAF)

ISAARV period	August 1998 to October 2000	November 2000	February 2001	July 2001
Pricing categories for patients (CFAF)	198,000	100,000	100,000	
	150,000		60,000	60,000
	64,000	60,000	40,000	40,000
	50,000	20,000	20,000	20,000
	40,000		10,000	10,000
	20,000	5,000	5,000	5,000
	0 *	0	0	0
Minimum cost of a three-drug regimen	320,000	100,000	100,000	60,000

*Free access was granted to health professionals and active members of AIDS associations.

Major changes took place in November 2000, following the price cut in ARVs that was negotiated by Senegal and UNAIDS with four pharmaceutical firms in October 2000. The effect on pricing for patients was immediate, applying to:

–the maximum payment amount, aligned with the average cost of a three-drug regimen on the world market;

–the minimum payment amount, with the introduction of a full subsidy for the poorest patients; and

–the reduction in the number of intermediary categories (from five to four) and the creation of levels with prices lower than the former minimum level.

Upon November 2000's pricing revisions, management was simplified thanks to a change in the way patient fees were calculated. Formerly, prices corresponded to a percentage of the cost of drugs for ISAARV; they varied, therefore, according to the type of treatment and dosage. Thus, a patient who, putting back on weight, exceeded 60 kg would add a dose to his former daily treatment and consequently pay more. Likewise for a patient who changed medicines, even within the same treatment category.

Beginning in November 2000, an invariant fixed rate was established for patients according to their treatment regimen (dual or triple therapy). For patients enrolled before November 2000, the price drop translated immediately into a fourfold reduction in their fees.[1]

[1] This reduction was applied generally, without re-examining patients' situations, based on the translation of their former contribution level to a new, lower price category. For example, all patients enrolled at the former minimum level (20,000 CFAF) had their fee fixed at 5000 CFAF.

Pricing Terms

The committees study patient files in a precise order: CMT, CTAS, and then CE. Medical criteria are reviewed before social criteria, and only patients selected by the CMT complete the social survey, so as not to raise false hopes. Reaching a conclusion on a patient's eligibility in a reasonable period of time depends on the pace at which his or her file progresses through the committees. For patients fulfilling the bio-clinical requirements, social surveys and a CTAS review should be completed between the CMT and CE meetings. Social dossiers cannot always be prepared and reviewed by CTAS if the meetings are held too close together, particularly given the increased number of prospective patients since 2001. The CMT and the CE met on average every two months before the ARV price cut in late 2000. After the price cut, which allowed for higher patient enrolment, the two committees met almost monthly. Before November 2000, the CE meetings were sometimes several months apart due to the unavailability of biological reagent stocks to quantify viral load or enumerate CD4s, results necessary for the pre-enrolment assessment. The number of available treatments was limited, as well. Thus, in the second half of 1999, recruitments were rare (eight new patients initiated treatment), and the wait for selected patients to reach the committees was often long, sometimes requiring a renewal of the costly biological assessment. The scheduling of committee meetings, therefore, "passively" regulated enrolments according to the programme's operational capacity.

The last case studies (4 to 7), below, illustrate the cumbersomeness of the system and the difficulty of assessing patients' financial capacity. They also demonstrate that the terms of access and pricing could, in practice, dictate the rejection of a candidate based on social criteria, and that neglect of treatment can become lethal. These case studies reflect situations that are relatively rare but indicative of the system's inadequacies. The procedures and terms of enrolment can, in their daily practice, yield results contrary to the very principles they were supposed to ensure.

We will return in Chapter I.2 to the question of financial accessibility of HAART within the ISAARV programme, as well as to its evolution in light of the drugs' price reduction and the shift in programme scale.

Programme Case Studies

The terms and process of enrolment are illustrated below in cases from ISAARV's first 27 months.

–Case no. 1: 36-year-old man, shoemaker, unmarried, no children, with monthly income of about 90,000 CFAF from selling drinks. CMT decided on medical indication of antiretroviral multi-drug therapy in December 1999. The social survey was completed in February 2000, and the dossier was reviewed by the CE in April 2000. The social worker requested the minimum payment for the patient (around 21,000 CFAF), which was agreed to by the CE. The patient started his treatment in August 2000.

–Case no. 2: 56-year-old woman, widowed with two children, unemployed, residing 120 kilometres from Dakar. Her medical dossier was accepted by the CMT in February 2000, the social survey was carried out the same month, and her file was presented to the CE in April 2000. A sister who was a jurist guaranteed regular payment of the minimum fee, which the CE assigned. The patient began treatment in May 2000, with a monthly contribution of 21,000 CFAF.

–Case no. 3: 55-year-old woman, widowed, no children, unemployed and with no income. She is materially and morally supported in treatment by her nephew, a medical student, who was informed of her HIV status. Antiretroviral treatment was proposed by the CMT in November 2000, and her case was presented to the CE in February 2001. Her monthly contribution to the cost of treatment was set at 5000 CFAF, and she initiated treatment in February 2001.

–Case no. 4: 43-year-old woman, divorced, supporting six of her nine children, her work in "small" commerce interrupted 12 months earlier for health reasons. Her ex-husband does not contribute at all financially except to provide her with a room. The three older children support the family. Medical recommendation for treatment was given by the CMT in November 1999, and her dossier was presented to the CE in December 1999. She had no resources of her own, but an entrepreneur friend offered to pay for her HAART, after his having financially supported a recent hospitalisation. Her economic situation was judged very precarious, and a supplementary survey was asked of the social worker to ensure the "quality" of the third party's commitment. Upon his filing of a letter of commitment, the CE in January 2000 proposed the minimum monthly contribution of 20,350 CFAF, and her ARV treatment began at the end of January 2000.

–Cases no. 5 and 6: couple (42-year-old man, lumber retailer, and 33-year-old woman, unemployed), seven child dependents. Both were accepted as candidates for triple therapy with protease inhibitors by the CMT in November 1999. Aware of the minimum contribution required (21,000 CFAF), the man, although clinically less affected, wanted to be treated first, while waiting for the resources to treat his wife. In view of this situation, a supplementary social survey was requested to better evaluate their living conditions and familial resources. Their dossiers were presented once again to the CE in January 2000, following a visit to their home. The man committed to covering the cost of both treatments with the help of the maximum subsidy (the treatment came to 42,000 CFAF altogether for a declared domestic revenue of 150,000 CFAF). The man began his treatment in February 2000; his wife died before initiating treatment.

–Case no. 7: 38-year-old man, married, manager of a Crédit Mutual fund in Pikine (in the department of Dakar). Treatment was recommended by the CMT in April of 2000, and his file was presented to the CE in May. His salary was 100,000 CFAF per month and his expenses 80,000 CFAF. The validity of his social survey was called into question, particularly the information concerning his salary, which seemed disproportionate to his position. Furthermore, the patient had a 235,000 CFAF debt to a local hospital, which he was reimbursing over one year. The patient, at an advanced stage of the illness, was deemed not creditworthy and was denied enrolment. He could no longer be included in the clinical trials because of his low CD4 count (4/mm^3), and he died in July 2000.

Social Profile of ISAARV Patients

Between November 1999 and October 2001, clinical trials (ANRS 1204/IMEA 011 and ANRS 1206/IMEA 012) were conducted in ISAARV. The cohort of patients eligible for social monitoring consisted of three patient subgroups (one from each of the two trials and one other), each with certain distinguishing characteristics relating to financial participation for treatment access, previous experience with antiretroviral treatment, duration of follow-up, antiretroviral regimen, and certain immunovirological enrolment criteria. These are summarised in Table 2.

Table 2

Enrolment criteria and baseline immunovirological profile of the three subgroups of 170 eligible adults in the study

	90 patients on a two- or three-drug regimen with PI or NNRTI	**40 patients on a three-drug regimen with NNRTI Clinical trial ANRS 1204/IMEA 011 [2]**	**40 patients on a three-drug regimen with NRTI Clinical trial ANRS 1206/IMEA 012 [3]**
Sex ratio (M : F)	1	1	1.3
Mean age ± standard deviation	39 years ±9	37 years ±8	36 years ±7
Proportion of naive patients	91.1% (82/90)	100%	100%
Intent to treat regimen	–8 dual therapies with 2 NRTI (8.9%) –80 triple therapies with 2 NRTI and 1 PI (88.9%) –2 triple therapies with 2 NRTI and 1 NNRTI (2.2%)	40 triple therapies with 2 NRTI and 1 NNRTI	40 triple therapies with 2 NRTI and 1 NNRTI
Patient's financial monthly contribution for HAART at baseline	Median: 20,850 CFAF Average: 24,753 CFAF Range: 0 to 198,000 CFAF	Medication given free of charge	Medication given free of charge
Enrolment period	Aug. 1998–Feb. 2001	Jan.–May 2000	Oct. 2000–April 2001
Average duration of follow-up at the time of initial social survey (± standard deviation)	8.9 months ± 7.6 months (median: 11 months)	0.4 months ± 1.1 months (median: 0 month)	1 ± 1.09 months (median: 1 month)
Immunological and virological inclusion criteria	CD4 < 350/mm^3 VL > 10^5 copies/ml if patient is stage A VL irrelevant if patient is stage B or C	50 < CD4 < 350/mm^3 VL > 30,000 copies/ml	CD4 < 350/mm^3 VL > 30,000 copies/ml
Mean viral load at baseline ± $\log_{10}$* standard deviation (range)	4.75 ± .78 (2.7–5.9) (n = 82)	5.4 ± 0.4 (4.5–5.9)	5.54 ± 0.4
HIV type	HIV-1: 84 (93.4%) HIV-2: 4 (4.4%) HIV-1 and -2: 2 (2.2%)	HIV-1: 100%	HIV-1: 100%
Mean CD4 count at baseline ± standard deviation (range)	155 ± 144 (1–622)	163 ± 75 (48–347)	133 ± 92
Clinical stage at inclusion	Stage A: 5.5% Stage B: 30% Stage C: 64.5%	Stage A: 15% Stage B: 40% Stage C: 45%	Stage A: 0% Stage B: 47.5% Stage C: 52.5%

* $\log_{10}$ denotes, in decimal logarithmic scale, the viral load.

Participation in Social Surveys

Among the 170 patients eligible for the initial social survey (see "The Study: Patients and Methods," above), 47% were enrolled in clinical trials. In the 24 months of monitoring, 17 deaths (10%) and four withdrawals (2.3%) were recorded. Among the 90 patients enrolled outside of trials, 55 were already under treatment at the start of the study and 35 were newly enrolled — 21 of them before the price reduction effective in November 2000 and 14 after. The 80 patients in the trials mentioned above were selected and enrolled in the course of the study. Six out of the 170 eligible patients did not participate in the study: four died, one withdrew, and one refused to participate. The rate of participation for the initial survey was therefore 96.4%.

For the biannual social surveys, 150 patients, out of the 156 who were eligible, participated in a second survey (rate of participation: 96%), and 109 out of 114 participated in a third (95%). The rate of participation within the three different patient groups was greater than 92%. The 150 second surveys were conducted on average at 11 months of treatment (median eight months): 16 months on average for patients not in trials, and seven months for patients in trials. The average interval between the first two surveys was seven months. The 109 third surveys were conducted on average at 19 months of treatment (median 16 months): 24 months on average for patients not in trials and 13 months for those in trials. The average interval between the first and third survey was 14 months.

Social criteria were not supposed to interfere with the trials' patient selection process. The trials, however, offered the possibility of free treatment for 18 months and were likely to be proposed to the poorest patients. A particular interest was thus given in this study to a socioeconomic comparison of the three subgroups.

Patient Socio-Demographic Characteristics

Age, gender, nationality

Recruitment was balanced between genders for each patient category. Women were on average younger than men (six years average difference) and women enrolled in trials were younger than those who were not (four years difference on average). The majority — 94.5% — were Senegalese. Five patients were originally from other West African countries and four were from Central Africa.

Education level

A third of patients never attended modern school, while 44% of patients had access to secondary schooling or beyond (158 respondents out of 164 surveyed). There was no difference found in the review of all 158 patients in education level between genders. Certain trends distinguished those in clinical trials from those not in trials: women in trials appeared to have had more limited access to education than those enrolled outside trials (44% of those in trials did not attend school, compared to 26% of those not in trials); and, among those in trials, access to education appeared more common among men (35% of men were uneducated, versus 44% of women). The women enrolled in the ISAARV programme had had greater access to schooling than the average Senegalese

woman,[2] while male patients had an education profile similar to that of Dakar's general population [1].[3]

Marital status and number of children

Among those surveyed, 48% were married or lived in a common-law marriage, 33% led a single-parent household (following a separation, divorce, or death), and 19% were single. However, the matrimonial profile differed greatly by gender, with 62% of men married (versus 33% of women) and 51% of women leading a single-parent household (versus 15% of men). Widowhood affected the sexes most unequally: 2.5% of men were widowed, compared to 31% of women. Widowhood is more frequent among women in all age brackets of the Senegalese population, probably due to the prevalence of polygamous marriages and the marked age difference between partners.[4] In our sample, it was even more manifest, due to the impact of HIV on the family. The matrimonial profile was similar for those enrolled and not enrolled in the clinical trials. Among the 76 married patients, 29 were in a polygamous union (30% of men and 51% of women) while 47 were in a monogamous one.

Six percent of patients reported a change in their situation in the course of the repeated surveys, including four spouse deaths, two remarriages (one of which was a levirate), three divorces, and one case of separated spouses getting back together. On average, patients had three living children, but 22% had no children and 1.2% had more than ten. Widows, like those married, had between three and four children on average, while those divorced or separated had between two and three. Childcare was therefore significant for the single-parent families. Three percent of survey respondents had a change in their child situation; four births and one death were reported.

The family unit

Patients belonged to large domestic units: ten people, on average, lived under the same roof (n = 163). Among them, 1.5 people had income. Within these domestic units, which commonly included family elders or brothers and sisters, only a third of patients surveyed were heads of the family, a status granted to men more often than women: close to half of male patients (39/80) were heads of the family, compared to a quarter of female patients (21/84). This household make-up and structure reflects that of the Senegalese population.[5] The household appears to undergo frequent restructuring (reported by 43% of patients in

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[2] Enquête Sénégalaise sur les Indicateurs de Santé (Senegalese Survey of Health Indicators; ESIS) 1999. Ministère de la Santé, Direction des Etudes, de la Recherche et de la Formation, Dakar, Senegal. Groupe Serdha, services d'études et de recherche pour le développement humain en Afrique, Dakar, Senegal. June 2000. Compared to women from the Senegalese general population aged 25 to 29 (a group with a higher rate of access to education than that of older women), the women in our sample had greater access to school, particularly secondary education or higher (12.4% versus 41.2%).

[3] See [1]. A comparison of education levels between a male sample of Dakar's general population and the men in our study did not reveal a significant difference: never schooled: 35% versus 32.1%; attended primary school: 32.5% versus 20.5%; attended secondary school: 25% versus 32%; and pursued higher education: 7.5% versus 15.4% (P = .16).

[4] See [1]. In a sample of 1965 people aged 41 to 60 in Dakar's general population, 0.7% of men were widowed, compared to 22.5% of women in the same age group.

[5] ESIS 1999, idem. In urban areas, households included an average of 8.5 people, whereas in rural areas, they included an average of 10.

the course of the surveys), accompanied by a shift in the head-of-family responsibility (20% of homes undergoing a change in a 14-month period).

Place of residence and housing

Eighty percent of patients lived in Dakar, where the prescription and dispensation sites, in December 2001, were still exclusively located; one in five patients was farther than 50 kilometres from town. Patient's geographical mobility was important, pertaining to 16% of patients during the surveys. Moving, however, usually took place within the same administrative region. For lodging, patients were largely dependent on other family members: more than half (54%) stayed with family for free. Home-buying was less common for patients in clinical trials, who generally did not pay rent (see Table 3) ; patients in the trials were also more likely to live in more-basic housing (shacks, etc.).

Access to basic services (water and electricity) was better than that of the majority of Senegal's urban population,[6] as was ownership of certain commodities (telephone, television, refrigerator, car); patients' homes thus appeared to reflect a more privileged socioeconomic situation than that of most of Senegal's urban population.[7] There was no marked difference between trial and non-trial patients regarding access to basic services and goods, with the exception of televisions (see Table 3).

Generally speaking then, life is lived in a small space, according to the rules of communal living. This situation can raise problems for patients, managing their illness and treatment (mealtimes, confidentiality, personal space to store medicine) in a family environment.

Professional situation

At the time of the initial survey, 44% of 164 patients asked had no paid work (unemployed or student), and one of every three patients worked in the private informal sector. Unemployment was three times more common among women than men ($P < 0.001$).

Among the 164 patients, only 17% held jobs. Nearly one patient in three reported a change in work following the deterioration in her or his health (n = 152). The majority of patients (81%) were on medical leave or permanent leave from work.

In the successive surveys, nearly 20% of patients were affected by a change in their professional situation. In 57% of cases, the change was positive: resumption of work, training, a promotion, or improvement in results. In other cases, the new employment was more precarious or even adverse.

Patient monthly income

Professional situation determines income: 44% of patients (n = 71/161 respondents) had no revenue, and 37% earned between 4000 and 100,000 CFAF per

[6] ESIS 1999, idem. A comparison of access to basic services between the urban households surveyed in the Senegalese Survey of Health Indicators and the homes of ISAARV patients showed that the latter more commonly had electricity (72.8% versus 90.9%) and running water (65.7% versus 85.4%).

[7] ESIS 1999, idem. Ownership of certain commodities was more common in ISAARV patient homes than in those of a sample of the Senegalese urban general population surveyed in 1999; this was true for televisions (74.4% versus 50.8%), refrigerators (53.9% versus 32.1%), telephones (52.4% versus 22.9%) and cars (20.1% versus 11.1%).

month. Monthly personal income was, on average, 60,000 CFAF, with a median value of 15,000 CFAF. The highest monthly income declared was 1,000,000 CFAF. Working patients who were enrolled outside trials appeared to have higher incomes than working patients in trials, a tendency more marked among women than men. Patients in clinical trial ANRS 1206/IMEA 012 seemed to have particularly low personal income compared to patients outside trials and to those in trial ANRS 1204/IMEA 011 ($P < 0.01$) because of a higher rate of unemployment or lower-paying work (see Table 3). Men earn an average of 55,000 CFAF more than women ($P < 0.001$), due notably to a low rate of employment among women; a comparison of men and women in paid work, however, reveals no revenue gap between the sexes.

In the second survey, a third of patients reported a change in income, however the monetary amount of these fluctuations was minimal, averaging 1800 CFAF for all patients. In the third survey, 28% reported changes in revenue; income appeared to have dropped on average by 6000 CFAF in a seven-month period. Among patients monitored for one year, income did not change substantially, revealing patients' sustained fragility in a difficult job market, as well as the very relative impact of physical well-being on the capacity to generate income.

Social security (health insurance)

Among 160 respondents (of 164 surveyed), 19% benefited from a group welfare system that more or less covered their medical fees. Seventy-eight percent of patients had no social security cover (75% of men and 82% of women), and 1.8%, although affiliated with Social Security, did not have health coverage. In the 12 months of follow-up, access to welfare did not change. None of the patients was reimbursed for HAART by a third-party health organisation.

Aspects of HIV Infection

Patients' therapeutic routes

Diagnosis of HIV infection was known within 12 months prior to undergoing treatment for more than 54% of patients, and within 18 months for 64% of patients (n = 161 of 164 respondents). For the majority of patients, diagnosis was sought because of deterioration in their health or that of their partner, indicating the lateness of testing, which was usually done at the hospital. The doctor was most often the person to inform the patient of HIV infection. In the course of treatment, 20% of patients participated in research projects and multiple surveys, and participated or had participated in research projects besides those accompanying the introduction to multi-drug therapy. Experience taking HAART prior to enrolment in the ISAARV programme was rare: 8% of patients (13/164) had done so, which was 13 of the 86 patients enrolled outside of clinical trials.

Because HIV diagnosis is often obtained at a late stage of the illness, half of patients learned of their seropositivity in the year preceding their treatment, and as a result had to modify the perception of their state of health, or even reappraise certain behaviours and lifestyles, given the uncertain prognosis with its heavy implications for their private lives. Beyond the existential upheaval of seropositivity, and the difficulties of managing the illness among people close to them, patients also had to prepare for introducing and integrating a three-drug regimen into their everyday lives.

HIV infection in the family

During the initial survey, 35% of homes had, or had had, a second person with HIV (n = 147). Twenty-two people experienced the death of an HIV-infected family member (spouse, co-wife, or child), and 22% have someone close to them who is HIV-positive (spouse, co-wife, friend, child). However, the situation is probably underestimated since a third of married people don't know the serological status of their lawful sexual partner, as shown by the frequent secondary discovery of new cases: the identification of a new familial case was reported by 5% of patients in the second survey and by another 5% in the third. Those newly detected were spouses and young children.

Socio-demographic information of the three main groups is summarised in Table 3.

Discussion and Conclusion

Whereas the administrative procedures for accessing the ISAARV programme remained the same in spite of increased enrolment, ARV pricing underwent heavy modifications in the programme's first three years. Founded on the principal of social justice, ISAARV established its lowest patient fee with a maximum subsidy (from the government) of up to 96% of the medicines' cost. In November 2000, this maximum subsidy was brought to 100%. This apparently slight difference manifested itself in absolute terms by a drop of about 20,000 CFAF per month in the required minimum contribution, a considerable amount on the scale of patient resources and more than half the Senegalese minimum-wage salary. We will expand on the role that minimum pricing levels potentially played in “regulating” enrolment in the following chapter.

Due to the developments in pricing and the possibility of free treatment in clinical trials, various channels of access merged or were transformed, bringing about changes in financial accessibility to treatment in ISAARV's first three years. The social profile of enrolled patients reflects in part these changes tied to the terms of enrolment. The salient aspects of the patients' socio-demographic profile highlight their economic vulnerability resulting from their low incomes, from the precariousness of their professional situation, and from their high degree of dependence on family members (for lodging and often for all living expenses). Personal income was nonexistent for 44% of patients and low or irregular for most of the others. No significant change was recorded for patients monitored over a 12-month period. Patients belonged in general to large households within which only a third were heads of the family. In these homes, one or two people on average earned money, providing for the needs of around eight others.Care of children (three living children on average) was important for non-single patients. In households with many people, having the group schedule set by external factors can make discretion in the management of the illness and of antiretroviral treatment difficult.The severe impact of HIV infection on the family is felt in the high rate of widowhood (particularly for women), the significant number of patients out of work, and the high proportion of homes (a quarter) with more than one infected person to care for. Only one patient in five was receiving medical insurance, which is not used, in any case, to cover expenses for antiretrovirals, for fear of indiscretion. An HIV-positive diagnosis is often late, coming in half of these cases in the 12 months preceding the start of treatment.

Table 3

Socio-demographic characteristics of 164 patients monitored outside clinical trials and in each of the trials, evaluated in initial surveys from November 1999 to October 2001

	Patients outside trials (n = 86)	Trial ANRS 1204 (n = 40)	Trial ANRS 1206 (n = 38)	*P* (1 versus 2 + 3)
Sex ratio (M : F)	0.95	1	0.9	0.9:1 (n = 164)
Mean age (standard deviation)	40.4 (9)	36.4 (8)	36 (7)	$< 10^{-2}$ (n = 164)
Primary or higher education	72.3%	63.2%	56.8%	0.1 (n = 158)
Percentage unemployed	40.7%	37.5%	60.5%	0.38 (n = 164)
Percentage employed in private or public formal sector	29.1%	27.5%	13.2%	0.27 (n = 164)
Average patient income (CFAF)	72,892	70,756	19,000	0.06 (n = 161)
Patients who are heads of household	45.3%	32.5%	21.1%	0.02 (n = 164)
Patients who are widowed, separated, or divorced	31.4%	30.0%	42.1%	0.6 (n = 164)
Patients who are married	50.0%	45.0%	44.7%	0.6 (n = 164)
Average size of domestic unit (people)	9.9	10.3	9.7	0.8 (n = 163)
Patients who own their home	30.2%	10.0%	10.5%	$< 10^{-2}$ (n = 164)
Homes with electricity	93%	92.5%	84%	0.41 (n = 164)
Homes with running water	86%	87.5%	81.6%	0.96 (n = 164)
Homes with television	81.4%	72.5%	60.5%	0.03 (n = 164)
Patients with medical insurance	18.6%	22.5%	18.4%	0.91 (n = 164)
Period between diagnosis of seropositivity and start of HAART (median)	221 days	337 days	299 days	0.17 (n = 160)
Shared confidentiality	19.8%	41%	23.7%	0.09 (n = 163)
Patients with HIV-positive close friends or family members (living or deceased)	40.7%	30.0%	28.9%	0.18 (n = 164)

This rapid sequence suggests that patients, often physically distressed, must exert tremendous psychological effort to handle the pronouncement of seropositivity, and then to adapt to treatment in the familial environment.

Our sample of ISAARV patients appeared to differ from the urban Senegalese population in the following ways: women had better access to schooling, ownership of goods was more common (telephones, refrigerators, televisions, cars), and they had better access to basic services (water, electricity). These characteristics suggest a more privileged socioeconomic situation on the whole than that of the average Senegalese. We will see in Chapter I.2 that in terms of available financial resources at the domestic level, this gap does not appear.

Within our sample, two subgroups appear to have vulnerable socioeconomic situations:

–patients participating in the clinical trials, in particular those in ANRS 1206, who had lower levels of education, higher rates of unemployment, and much lower income. Lodging seemed less equipped. Most patients seemed to be in a situation of dependence (on the head of the family and for lodging);

–women, who were more likely than men to be widowed or unemployed. They were less commonly heads of domestic units and thus frequently in a position of dependence for financial resources. All decision-making, particularly tied to the start of ARV treatment, is subject to the agreement of the head of the family, possibly compromising confidentiality.

Building on the issues presented here, the following chapter will focus on the selection made, in social terms, in the various channels of inclusion, and on the microeconomic impact of the cost of HAART.

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Chapter I.2
ISAARV Financial Accessibility and Microeconomic Impact for Patients

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The high cost of antiretroviral (ARV) multi-drug therapy is one of the major obstacles to its accessibility in Africa. The first ARV pilot programmes in Africa (Uganda, Côte d'Ivoire, and Senegal), implemented in 1998, adopted different methods of financing the medications: Uganda left the full cost of treatment up to the patient, Côte d'Ivoire subsidised dual therapies and had patients cover the protease inhibitors, while Senegal moved toward sliding-scale subsidies for multi-drug therapies [1, 2].

As it turned out, the cost for patients in Uganda and Côte d'Ivoire was an obstacle to treatment access and the leading cause of its interruption. The relationship between the cost of highly active antiretroviral treatment (HAART) and patients' social profile can be readily analysed in Senegal, where treatment access channels were diverse and evolving in the first three years of ISAARV.

This chapter will assess the effects of economic criteria on treatment recruitment and follow-up. The programme's financial accessibility — the cost of treatments for patients, the impact of selection procedures on the social profile of enrolled patients, and the operational aspects of the established procedures — will be evaluated. The familial contribution to the purchase of treatment will also be explored in estimating the microeconomic impact of ARV costs.

Financial accessibility is assessed for ISAARV's first 39 months, while microeconomic information is drawn from successive social surveys carried out between November 1999 and October 2001.

Financial Accessibility of the ISAARV Programme

From 1998 to October 2001, three financial modes of HAART access existed: 1) the first patients, enrolled outside clinical trials within the initial fee structure, 2) patients enrolled in the two trials, in which payment coverage was ensured for the first 18 months, and 3) patients enrolled after November 2000 within the reduced fee structure (see Chapter I.1). We will first look at the distribution of patients within payment categories according to the mode of access.

Patient Financial Contribution Levels at Enrolment and During Treatment

Patient fees underwent a major change in November 2000 following the price cuts negotiated with pharmaceutical companies under the aegis of UNAIDS (see Chapter I.1).

As shown in Figure 3, the majority of patients enrolled in ISAARV in any given period were charged the minimum fees. Thus, until October 2000, when only a small category of patients[1] was receiving a 100% subsidy, most participants were enrolled at close to the minimum fee (21,000 CFAF per month). The same phenomenon continued after the price reductions, when the minimum fee was reduced to 5000 CFAF per month and free treatment was possible for the poorest patients. The number of 100% subsidy allocations increased (42% of patients were granted the subsidy at Day 0, up from 11%), and half of patients were enrolled at fees lower than 20,000 CFAF/month.

This substantial modification of the fee structure begs the question of whether the change in access procedures was accompanied by a change in enrolled patients' social profile.

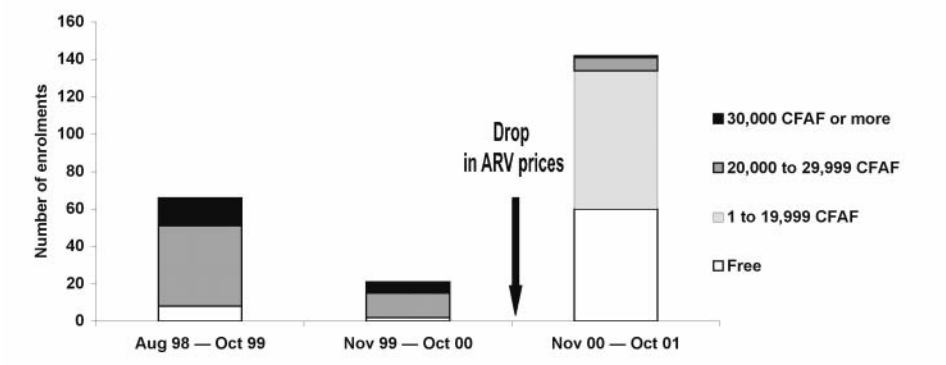

Figure 3

Change in number of enrolments in each financial-contribution category by programme period

Change in Socioeconomic Profile of Enrolled Patients

The socioeconomic profile of enrolled patients progressively changed in the course of ISAARV's operation.

Figure 4 shows that patients' personal income (mean value) appeared lower among patients enrolled with complete coverage of treatment cost (clinical trials) and among those enrolled after the fee reductions ($P < 10^{-4}$). These results indicate an opening of access to poorer people in the trials and following the price reductions. The enrolment of four subgroups took place chronologically, with the initial enrolment of well-off patients, followed by those of poorer patients.

It is likely that the initial minimum fee (21,000 CFAF, more than half the monthly Senegalese minimum wage[2]) was too high for the poorest people seeking treatment. Although the social profile of patients who were not enrolled was not studied, it seems that the doctors and social workers effected an implicit

[1] Health workers and AIDS association activists.

[2] 36,250 CFAF per month in December 2000.

selection process, upstream from the programme committees, according to patients' financial capacities and treatment opportunities for the most underprivileged. This process was not quantified but was reported by doctors, who had all experienced painful situations of refusing patient files for economic reasons in ISAARV's early months [3].[3] Aside from urgent cases, they chose then only to introduce the proposition of treatment with patients at the lowest risk for rejection, in order to avoid raising false hopes. The emergence of free or reduced-cost treatment allowed for an undeniable expansion of access among socioeconomic groups.

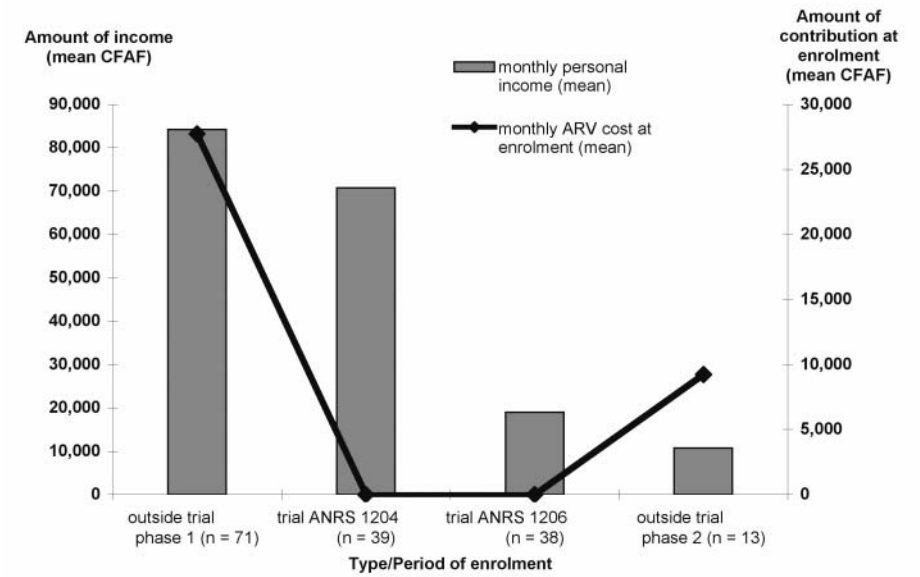

Figure 4

Profile of personal income and financial contribution at Day 0 of 161 patients, by type of enrolment and fee

Limitations of the Subsidy Allocation System

The minimum fee as key element for equitable treatment access

From November 1999 to October 2000, eight percent of prospective patients presented to the Eligibility Committee (Comité d'éligibilité; CE) were rejected because of their financial situations and some of them were directed to ANRS clinical trials. This percentage is low, given the financial resources expected of patients, and indicates the probably significant proportion of patients to whom treatment was not even proposed in this period of higher fees. Thanks to trials, and then, after November 2000, to price cuts and to more possibilities for free

[3] In ISAARV's first three months, a Fann social worker estimated that three in four candidates could not pay the required minimum amount and were therefore not enrolled for purely financial reasons (in [3]).

treatment, enrolment of poor patients could be expanded. The principle of sliding-scale financial contributions manifested itself, in practice, in the enrolment of patients judged capable of paying at least the current minimum fee. The drop of this minimum rate played a major role in reducing inequalities in treatment and promoting equity.

Arrangements for patients unable to make payments

Once under treatment, many patients (nearly a quarter) were unable to buy their medications due to an overestimation of their resources at the time of enrolment, or to the precariousness of their income during treatment.

The programme then responded case by case, often late and after a break in treatment. The procedure in case of financial difficulties was for the CE to reevaluate the financial contribution after an update and reexamination of the social dossier by the Welfare Committee (Comité technique pour les aspects sociaux; CTAS). Nearly a quarter of patients enrolled outside of trials and monitored from November 1999 to October 2001 resorted to having their initial contribution amount reduced. Other measures were implemented in rare cases: sponsorship by an individual or temporary exemption from payment.

Operational limitations of subsidy procedures

Although the subsidy mechanism in effect substantially lessened the financial burden of HAART for patients, the system came up against the five following constraints:

–The process is slow and bureaucratic. The social survey requires an approximately hour-long individual interview with a social worker and is successively reviewed by two committees (CTAS and CE) in meetings comprising 10 to 30 people. Implementation of treatment, which hinges on these meetings, can be delayed by many months.

–Collected data is intrusive and subjective in nature. The survey examines patients' individual and familial resources and expenses. Economists consider this type of survey imprecise and very subjective when it concerns, as in an African context, a large proportion of people working without salaries or in the informal sector. In addition, patients' responses were sometimes biased, some consciously or unconsciously overestimating their resources because their access to treatment appeared to depend on their creditworthiness. Furthermore, this type of survey is considered intrusive, especially in the context of access to care.

–The lack of transparency in criteria for establishing subsidy levels leads to subjectivity in the amounts granted and to beneficiaries not understanding the system. No programme directive was given to correlate social profile (drawn from survey data) and contribution level. For each case, members of the CE compared thoughts on the patient's ability to pay a hypothetical amount, and differences emerged which could cost time and create tensions. These discussions forced the actors into the roles of accountant, inquisitor, or righter of wrongs, sometimes contrary to their positions as caregivers or social workers, but they occur less frequently since the price reductions.

–The overall cost of the system is high relative to the programme's meagre gains. Among these costs are the mobilisation of a large number of actors and

the high risk of treatment irregularities, which can well lead to viral rebounds or even the emergence of a viral resistance requiring costly biological tests. Cost-recovery estimates made at different periods in ISAARV's operation were poor (approximately 10% from August 1998 to October 2000 and 5% in the 12 following months). Holding intensive inquiries with each patient, when the majority of them could not sustain even the minimum financial levy in the long term, was not cost-effective.

The following cases illustrate the subjectivity and lack of reproducibility in the allocation of contribution amounts.

–Case no.1: 33-year-old man, single, no children, jeweller's apprentice, presented to the CE in October 1999. The social worker requested the minimum contribution of 21,000 CFAF for this young patient, in training and thus earning little income. The social survey is judged inconsistent by some members of the CE because it does not include certain elements relevant to the patient's revenue and family standard of living (payslip, telephone bill, etc.) Furthermore, the patient, from a family of jewellers, is considered to be part of a wealthy milieu likely to contribute financially to treatment costs. This prejudice, as well as the questioning of survey data, were arguments for lowering the subsidy requested by the doctor and social worker and for setting the initial contribution at 47,000 CFAF. The patient began his treatment in November 1999. From the second month of treatment, he was unable to continue his treatment for lack of funds (he came up with only 20,000 CFAF). The request to reduce his contribution could only be presented to the CE in May 2000, when the minimum contribution was granted.

–Case no. 2: 27-year-old woman, widow, no children, unemployed, dependent on her parents (her father a welder and mother in "small" commerce), declared herself prepared to pay 5000 CFAF. Although having very limited means, the patient was assigned a monthly contribution of 5000 CFAF.

–Case no. 3: 27-year-old woman, single, unemployed, housed without charge by her uncle, with neither income nor financial support. A 100% subsidy was given.

Cases no. 2 and 3 were reviewed by the CE in November 2000, the two dossiers having similarities in terms of total financial dependence but resulting in two different decisions as a result of one patient's stated ability to fulfil a particular financial commitment. The interpretation of this statement sparked discussion: was it to increase her chances of receiving treatment that the young woman made this gesture of goodwill? Was it related to a real capacity to pay? did she foresee the total costs inherent in treatment? The range between the two amounts may seem small, but as a recurrent expense, 5000 CFAF per month could compromise, for the poorest patients, their ability to cover other necessary and recurrent direct costs of care (transportation, consultation, etc.).

–Responses to patients having financial difficulties are slow and frequently accompanied by a break in treatment (see Case no. 1).

Adapting Enrolment Terms to the Programme's Growing Scale

The acceleration of enrolments at the programme's Dakar sites in 2001 clearly demonstrated the limitations of the current procedures, which appeared too complex, too centralised (decisions to enrol patients should have been made at

each clinical monitoring site), and not sufficiently transparent for widespread implementation in short-staffed contexts. A simplification of the current price scale (which included six contribution levels), as well as a clear definition of subsidy-allocation criteria, are necessary to apply subsidies equitably and to relieve the system. Maintaining wide access to 100% subsidies is indispensable to patients' bearing the costs of a regular supply of medication. The role of social workers should move away from its predominant task of assessing resources, and be refocused on psychosocial monitoring of patients under treatment, particularly in regards to adherence and living with the illness. Simplification and a reduction of current fees should be considered, taking into account the financial investment of patients, and often of the family, to buy HAART, and keeping in mind that antiretroviral multi-drug therapy is not the only expense in treating HIV infection.

The Microeconomic Impact of HAART Costs

Economic studies often struggle to assess a home's resources and expenses and to identify the most impoverished. An estimate of household expenses seems like a more reliable indicator than income for assessing monetary flow in the household [7]. In the context of ISAARV, reported revenue or domestic expenses are sometimes incomplete, due to the impossibility of interrogating all adults in a household for confidentiality reasons.

Monthly Financial Resources in the Household

The financial resources of a home have two sources: income of permanent members of the household and financial assistance from people outside the household. They are often difficult to assess when many people earn income within a large family or when the person interrogated, having no earnings, does not participate in the household's financial affairs.

Total financial resources in the household was estimated for 126 homes of 164 during the initial social survey. This total amount (income + external assistance) reached on average 151,000 CFAF (median: 138,000 CFAF). Household monthly income averaged 148,000 CFAF (median: 130,000 CFAF). Eight percent of households (10/126) had no income. Revenue seemed higher for patients enrolled outside trials than for those within ($P < 10^{-2}$).

External aid supplemented family revenues in nearly 40% of cases. For 58 respondents among the 63 beneficiaries, this amounted to an average 50,000 CFAF (median: 37,000 CFAF). Residents' incomes are lower in homes receiving external assistance than in those that do not ($P < 0.01$). This assistance comes from the family in 75% of cases, acquaintances in 10% of cases, and non-governmental organisations in 5%. Familial aid came from a member of the family working abroad in 50% of cases. Patients often mention this support to substantiate their financial capacity. However, although a considerable and sometimes singular source of income, this financial support can be irregular or not easily available to the patient for the duration of treatment. It can also spawn a state of dependence likely to put stress on the personal relationship, and may involve negotiation at the potentially risky expense of confidentiality.

Monthly Available Funds per Household Individual

Available monthly financial resources per household resident was estimated by dividing the total monthly financial resources of the household (income + external aid) by the number of people living under the same roof. This assessment was possible for 126 patient homes in the initial social survey, with monthly individual resources amounting to an average 24,000 CFAF (median: 13,000 CFAF). The median, which represented the financial capacity of the majority of patients better than the average, seemed lower among patients in trials (11,500 CFAF) than among those outside trials (16,500 CFAF).

Domestic Expenses

Although difficult to estimate for those not involved in managing household finances, monthly domestic expenses were assessed for 126 homes (of 164 surveyed). Twenty-eight percent of patients did not contribute to household expenses, which were on average 144,000 CFAF (median: 95,000 CFAF, standard deviation: 150,000 CFAF). They appeared lower in homes of patients in trials than those outside trials ($P < 0.01$). Individual monthly expenses came to, on average, 23,000 CFAF (median: 11,000 CFAF) for the same households.

Primary household expenditures

Primary expenditures were documented for 72 patient homes (32 in and 40 outside trials). Of the total average expenditure of 145,500 CFAF, food counts for almost half (see Figure 5). Average monthly expense per head is 17,000 CFAF (median: 10,500 CFAF).

It was only possible to estimate monthly resources per head for 67 of 72 households: they came on average to 17,700 CFAF (median: 11,500 CFAF).

A Comparison of Socioeconomic Situations: Patients and the Senegalese General Population

In 126 of 164 homes, both the average individual monthly expenses (23,000 CFAF) and average individual monthly resources (24,000 CFAF) recorded in the initial survey indicate that 69% (based on individual resources) and 70% (based on individual expenses) of households live below the poverty line as defined by the United Nations Development Programme (less than US$1 available per person per day, or less than 21,600 CFAF [US$1 = 720 CFAF x 30 days] per person per month). The distribution of individual monthly expenses in the patient cohort appeared close to that of the Dakar population, as reported in a broad study of equity and health-care access [7]. This report, prepared with personal descriptions of expenses, is different from that outlined in Chapter I.1, which stated that the patient cohort seemed more well-off than most of the urban Senegalese population, particularly in terms of education and ownership of commodities. It is possible that the disease's impact on work (termination of employment, deaths of working people) explains this dissonance of an environment marked by both former relative wealth and weak immediate financial capacity. Accuracy of data in a domain as sensitive as resource assessment may also be questionable.

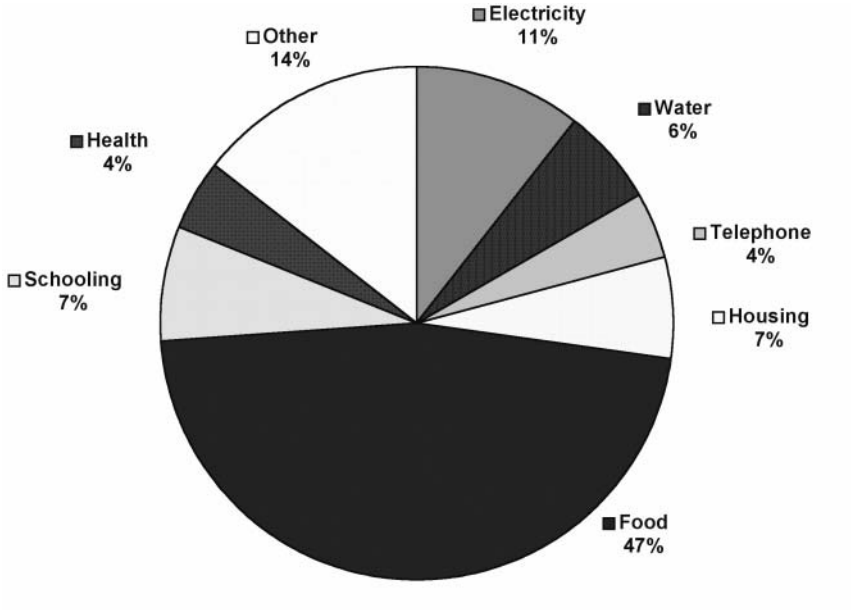

Figure 5

Allocation of domestic expenses among 72 patients receiving HAART

Impact of HAART Costs on the Family

HAART in overall household budget

Very few patients benefit from a social welfare system covering health care (see Chapter I.1). Furthermore, no one with health insurance enrolled in ISAARV has sought to make a claim on a paid amount, most often for fear of a lapse in confidentiality in the administrative process. The cost of HAART is thus deducted from the family budget and its burden has been assessed at different periods of the ISAARV programme:

–in the initial survey, among 77 patients paying for their treatment, 66 stated the amount of household income. Multi-drug therapy represented on average 32% of the domestic budget, with a median value of 16%. Antiretrovirals were thus a significant additional expense for patients, often the second largest after food;

–in the following surveys, this percentage went from 35% on average among patients within the initial pricing structure to 6% after the November 2000 price reductions.

The price cuts thus greatly eased financial pressure on the family to ensure continuity of treatment.

Mobilising funds to buy HAART

Because a large proportion of patients lack personal income or group resources (refer to the monthly available funds per household member), many turn to third

parties to finance their treatment. These supports are generally secured from individuals (most often relatives) rather than organisations or institutions.

In the initial survey, 86 of 163 patients (53%) received financial support from a third party specifically to buy ARVs and cover medical fees connected to HIV infection. Women seemed to mobilise such support most often (64% of women versus 41% of men; $P < 0.01$). In 90% of cases, the assistance came from a relative; of the 86 responding patients, 45% named a brother or sister, 15% the spouse, 12% the mother or father, and 18% another relative. Instances of support from a private organisation were rare: one patient received assistance from a non-governmental organisation (Society for Women and AIDS in Africa; SWAA) and another from the sponsorship of a private company. In both cases, the third parties covered the patient's HAART contribution (and not the cost price of treatment), a monthly amount between 21,000 and 25,000 CFAF. The amount of assistance expected or received by patients is on average 20,000 CFAF (n = 65), close to the minimum fee in effect at the time.

During the 12 months of follow-up, the percentage of patients receiving aid was between 20 and 30%, women numbering twice as many as men. Nearly a quarter of beneficiaries reported fluctuations in this assistance, most often in decreases. The financial aid of third parties seemed to be exhausted over time. The support of NGOs or companies remained anecdotal and concerned 3% of patients (two NGOs covered the contribution of three patients, and two patients received support from their firms).

Economic difficulties in paying for treatment

In the first follow-up social survey, 18% of patients (28/150) cited financial difficulties (7% in trials and 30% outside trials) due to debt, a drop in income, delays in receiving assistance or salaries, expenses for other medications to treat opportunistic infections, or priority given to other expenses.

In the second survey, 12% of patients (13/109) cited persistent difficulties covering expenses (4% in trials and 17% outside trials) in spite of the price reduction. Prescribing doctors were frequently asked for transportation costs (given patients' overall treatment expenses; see Chapter I.3), and pharmacists often advanced medicine to patients to ensure their continuous supply.

Discussion and Conclusion

Patient social surveys highlighted the weakness and precariousness of household income. The evolution of the ISAARV cohort's socioeconomic profile suggests that recruitment of economically vulnerable persons was postponed or secondary, only coming with reduced or waived fees. Financing treatment of HIV, and particularly HAART, proved to be a permanent challenge to patients, who often mobilised the resources of family members. This familial solidarity erodes over time, forcing the patient to disclose his or her infection to someone outside the family. Because of this dependence of the patient on her or his family circle, only the patient's personal income should be considered in setting an appropriate recurrent fee. Due to frequent shortcomings in patients' finances or those of their families, quick response mechanisms should exist to compensate for financial gaps before antiretroviral treatment is interrupted. The negative

influence of financial contribution on drug adherence is explored in Chapter II.1. The phenomenon is not particular to Senegal; in other countries such as Kenya, Uganda, Burkina Faso, and Côte d'Ivoire, patients' financial capacities are a major obstacle to treatment continuity [5, 6, 11].

Among the first ARV provision experiences in Africa, the Senegalese programme was unique in its concern for equity and its prices for antiretroviral triple therapy, which were the lowest in Africa. The programme's directors adapted pricing and developed subsidies quickly and pragmatically, according to the preferential prices that came with the United Nations initiative, and according to patients' financial difficulties. It was the success of these interactions that brought about the new pricing, which boldly offered minimum fees adapted to the means of the majority of HIV-infected people in Africa (the 100% subsidy, in particular). As some authors have emphasised [8, 10], the provision of ARVs at affordable prices does not resolve the issue of HIV/AIDS treatment, which must be part of an improved health-care system that can ensure optimal use of these medicines. The cost of treatment, however, inarguably remains an obstacle for patients in many Southern countries, requiring international aid to support governmental and private-sector commitments.

The treatment price for the patient is crucial to programme equity because it adapts access to the patient's financial capability [1, 9]. In a context of scarce treatment subsidies, procedures for their allocation can be a factor in regulating enrolment, as was shown in Côte d'Ivoire, where nearly a third of treatment candidates did not get prescriptions due to delays in subsidies [4]. Inequality in access to care is thus obvious. Totally subsidised HAART appears to be the missing element in the Ivorian initiative's subsidy scale, which essentially eliminates the most impoverished populations [12]. The introduction of waived fees to the Senegalese pricing scale was innovative in a health-policy context that advocated partial cost recovery in the spirit of the Bamako Initiative. ISAARV was able to compromise with this dominant model, to consider the experience of the first patients as a base for programme evaluation, and to apply certain principles held for the treatment of other endemic illnesses (tuberculosis, leprosy, etc.) to AIDS treatment, namely, guaranteed universal access.

From the operational point of view, certain aspects of ISAARV access procedures could be improved toward greater simplification, reproducibility, transparency, and cost-effectiveness. The current constraints will become increasingly burdensome with the growing decentralisation of treatment. The proportion of newly enrolled patients receiving 100% subsidies has only increased since the implementation of new fees: from nearly half in 2001 to more than 90% at the beginning of 2002. The paucity of collected amounts begs the question of whether or not the maintenance of an ARV purchase fee, which requires a non-negligible cost structure, is even relevant [13].

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Chapter I.3
Direct, Extra-ARV Medical Follow-Up Costs for Patients

A. Canestri, B. Taverne, S. Thiam, C. Laurent, A. Ndir, R. Schiemann, R. Landman

The costs of medically treating PLWA in Southern countries are most often analysed by assessing the expenses of health-care facilities [7] or the cost-effectiveness report for the health-care system, which outlines the system's various policies for prevention, treatment of opportunistic infections, and ARV treatments [1, 2].

Because of the small number of HAART access programmes in Africa, few studies have been published providing data on the price of antiretroviral molecules or laboratory reagents, or on the total per-patient cost of establishing a treatment programme. Similarly, there are practically no studies that explore patients' direct costs of ARV treatment.

Although attention is, for good reason, focused on the high prices of ARVs, the cost of medical treatment is not limited to these molecules alone. Patients have many other expenses, usually divided by economists into direct and indirect costs of care. Direct costs cover medical consultations, diagnoses, medications, hospitalisations, and transportation; indirect costs refer to the maintenance of solidarity networks, domestic care, loss of time for patients and those who take care of them, losses in productivity, etc. The influence of these costs on individual recourses, through the mobilisation of resources that they require, has been clearly demonstrated for various conditions and in many African countries [8, 13, 14].

The research programmes that accompanied ISAARV's launch presented an opportunity to quantify patients' direct costs. An initial evaluation was conducted with a questionnaire survey in which patients' stated expenses were recorded, the main results of which were presented in Chapter I.2. At the same time, we were able to evaluate, in a patient subgroup, direct costs tied to the diagnosis and treatment of opportunistic infections and intercurrent pathologies arising in patients' first nine months of treatment.

Patients and Methods

Three groups comprising 138 patients participated in this study: the first 58 patients enrolled in the ISAARV programme, 40 patients in clinical trial ANRS 1204/IMEA 011, and 40 patients in trial ANRS 1206/IMEA 012.[1]

These three groups differed in patients' immuno-clinical characteristics at the time of enrolment: 72% of patients in the ISAARV group, 52% of the ANRS 1204/IMEA 011 group, and 45% of the ANRS 1206/IMEA 012 group were at clinical stage C of the illness (CDC classification). None of the patients in the ISAARV or ANRS 1206/IMEA 012 groups, and 15% of the ANRS 1204/IMEA 011 group, were at stage A. The median CD4 count at enrolment was considerably higher for ANRS 1204/IMEA 011 patients: 185, compared to 121 (ANRS 1206/IMEA 012) and 108 (ISAARV).

Working with the assumption that medical follow-up was the same for the three groups, we estimated the costs for all 138 patients according to their clinical stage and CD4 count at enrolment. During the 18 follow-up months of ANRS 1204/IMEA 011 and ANRS 1206/IMEA 012 patients, doctors participating in the study recorded for each patient the nature and the number of pathological occurrences requiring a prescription; the name, dosage and duration of medication prescribed; supplementary tests; required consultations with specialists; and hospitalisations (duration, reasons). For the 58 patients in the ISAARV group, only the nature and number of pathological occurrences requiring prescriptions were recorded, as well as the name, dosage, and duration of prescribed treatments, although even this information was missing for four patients; information on supplementary tests, medical consultations, and hospitalisations were not recorded. Prescription costs could therefore be calculated for only 134 patients, and other direct costs could be assessed for the 80 patients in the two clinical trials.

Medicine costs were estimated using prices in effect at the Fann Teaching Hospital pharmacy — which employs preferential rates through the sale of generic medicines — and from the selling prices in a private pharmacy for those products not available at Fann[2]. The cost of chemoprophylaxis with cotrimoxazole is included; tuberculosis medications, on the other hand, were not considered, since they are provided free of charge in Senegal. Supplementary test costs were calculated from the rates used by hospital labs; the cost of immunovirological follow-up (CD4 and viral load) and that of biological tolerance of treatment (blood count and biochemistry) were not counted because they are covered in full by ISAARV. Finally, hospitalisation costs fall under patient expenses.

The resulting estimate is a theoretical figure; it does not reflect expenses actually covered by patients. Indeed, the cost of prescriptions was calculated to the pill, under the assumption that the patient strictly respects the dosage and

[1] These trials were designed to evaluate the acceptability, effectiveness, and tolerance of a three-drug regimen combining, in the first trial, didanosine, lamivudine, and efavirenz in a single daily dose, and in the second, didanosine in capsule, stavudine, and efavirenz in a twice-daily dose; see [10, 11].

[2] We are grateful to Doctor Brigitte Soarez, owner of Pharmacie Actuel, on Av. Cheikh Anta Diop in Dakar, who was kind enough to supply us with the price list for medicines sold in private pharmacies.

duration of the prescription. But in many cases, the medicines were dispensed by the prescribers, either in a trial or as a donation, and some patients could not follow certain prescribed regimens.

The analysis was performed using SPSS 11.0. The monthly individual costs were compared with the Kruskal-Wallis test between patients categorised according to their disease stage or CD4 count. Patients' distribution according to cost categories was studied between disease stage or CD4 using Chi^2 test. The Wilcoxon test for paired samples was used to compare the monthly costs over two time periods (D0–M3 and M4–M9), and the marginal homogeneity test was used to compare the distribution according to cost categories between the two time periods.

Results

Cost of Non-ARV Prescriptions

At the start of antiretroviral three-drug regimens, 4% of patients were at CDC classification stage A of the disease, 38% at stage B, and 58% at stage C. CD4 count was higher than 200/mm^3 for 33% of patients, and lower than 200/mm^3 for 67%.

In the nine-month period following the start of treatment, the median monthly cost of non-ARV prescriptions for the 134 patients was 2500 CFAF (interquartile range [IQR] 900–5500 CFAF) (Table 4).

Table 4
Monthly cost of non-ARV prescriptions during the first nine months of treatment according to clinical stage and CD4 count at enrolment (in CFAF)

	CDC stage classification			CD4 count classification		
	Stage A	**Stage B**	**Stage C**	**CD4 > 200**	**CD4 < 200**	**Total**
Patients n (%)	6 (4.5)	51 (38.0)	77 (57.5)	44 (32.8)	90 (67.2)	134 (100)
Category n (%) in CFAF:						
< 1000	5 (83.3)	17 (33.3)	13 (16.9)	16 (36.4)	19 (21.1)	35 (26.1)
1000–5000	1 (16.7)	26 (51.0)	36 (46.8)	19 (43.1)	44 (48.9)	63 (47.0)
> 5000	0 (0)	8 (15.7)	28 (36.4)	9 (20.5)	27 (30.0)	36 (26.9)
P		< 0.001			0.147	
Pathological occurrences						
median no. (IQR)	3 (2–7)	5 (4–7)	6 (4–9)	5 (3–9)	6 (4–12)	6 (4–8)
P		0.035			0.068	

The average monthly cost is significantly different ($P < 0.0001$) according to the disease stage (CDC classification) at enrolment. For patients at stage A, the median is 600 CFAF per month (IQR: 300–1200); for patients at stage B, 1900 CFAF per month (IQR: 900–3200), and for those at stage C, 3500 CFAF per month (IQR: 1300–7500). Maximum expense was 2400 CFAF per month for stage A patients, 13,000 CFAF/month for those at stage B, and 27,500 CFAF/month for those at stage C (Figure 6).

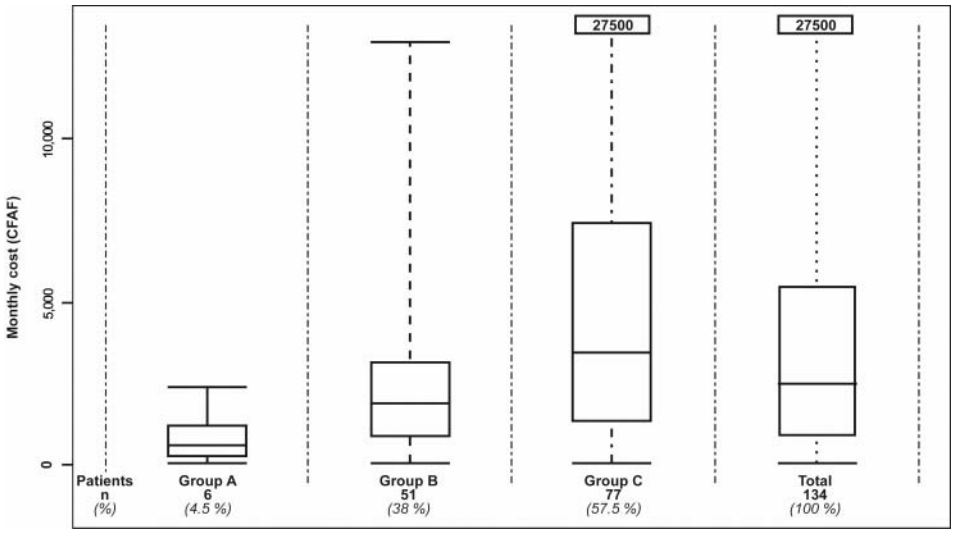

Figure 6

Average monthly costs, according to disease stage (CDC classification), over the first nine months of ARV triple therapy (in CFAF)

Similarly, the average monthly cost appears significantly different ($P < 0.001$) according to CD4 count at the initiation of treatment: average monthly cost for patients with greater than 200 CD4/mm^3 is 1800 CFAF per month (IQR: 800–4100), while it is 2900 CFAF/month (IQR: 1100–6100) for patients with lower CD4 counts. Maximum expense was 19,000 CFAF for patients with CD4 counts above 200/mm^3 and 27,500 for patients with less than 200/mm^3 (Figure 7).

For 83% of stage A patients, average monthly costs were less than 1000 CFAF, while for 17%, 51%, and 47% of patients at stage A, B, and C, respectively, costs were between 1000 and 5000 CFAF. None of the patients at stage A, 16% at stage B, and 36% at stage C spent more than 5000 CFAF/month. Distribution by cost category differs significantly between the three stages ($P < 0.001$).

The difference observed in costs according to disease clinical stage also emerges in the frequency of pathological occurrences: stage A patients had three per month (median value, IQR: 2–7), stage B patients had 5 (median, IQR: 4–7), and stage C patients had 6 (median, IQR: 4–9) ($P = 0.035$). Conversely, the difference is not significant ($P = 0.068$) in comparing CD4 counts.

Cost Variations between the First Three Months and the Second Six Months of Treatment

Costs tied to medical prescriptions significantly decreases between the first three and next six months of treatment ($P < 0.0001$). The median drops from 2800 CFAF per month (IQR: 1000–7500) in the first period to 1100 CFAF/month in the second (IQR: 1000–7500) (Figure 8).

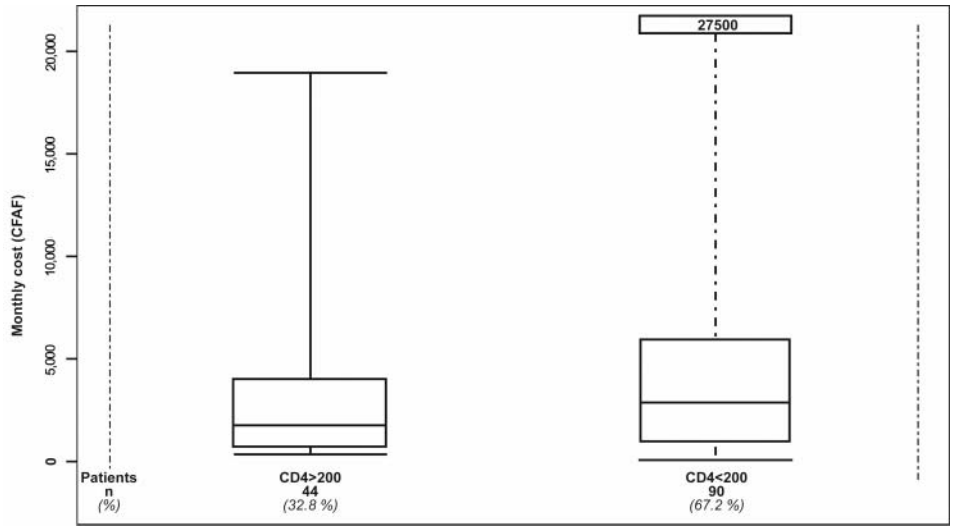

Figure 7

Average monthly costs, according CD4 count at enrolment, over the first nine months of ARV triple therapy (in CFAF)

The percentage of patients spending less than 1000 CFAF per month went from 22 to 48%, those spending between 1000 and 5000 CFAF went from 38 to 29%, and those spending more than 5000 CFAF/month, from 40 to 23%. This reduction in costs was accompanied by an insignificant drop in the number of pathological occurrences (Table 5).

The reduction of pathological occurrences included mainly a drop in opportunistic infections (Table 6). There were only two episodes of genital candidiasis (reported in a three-month period) over the second follow-up period, compared to 13 in the first period; two cases of genital herpes in the second period, compared to seven in the first; and four cases of oral candidiasis, compared to 21 in the first.

Table 5

Variations in monthly costs and frequency of pathological occurrences between the first three months and second six months of treatment for all patients (in CFAF)

		D0–M3	M4–M9	*P*
Distribution by categories of monthly costs for non-ARV prescriptions n (%)	< 1000 CFAF	30 (22.4)	62 (48.0)	0.203*
	1000 to 5000 CFAF	51 (38.0)	37 (28.7)	
	> 5000 CFAF	53 (39.6)	30 (23.3)	
Frequency of pathological occurrences per patient: median no. (IQR)		3 (2–5)	3 (2–4)	0.123

* test of homogeneity

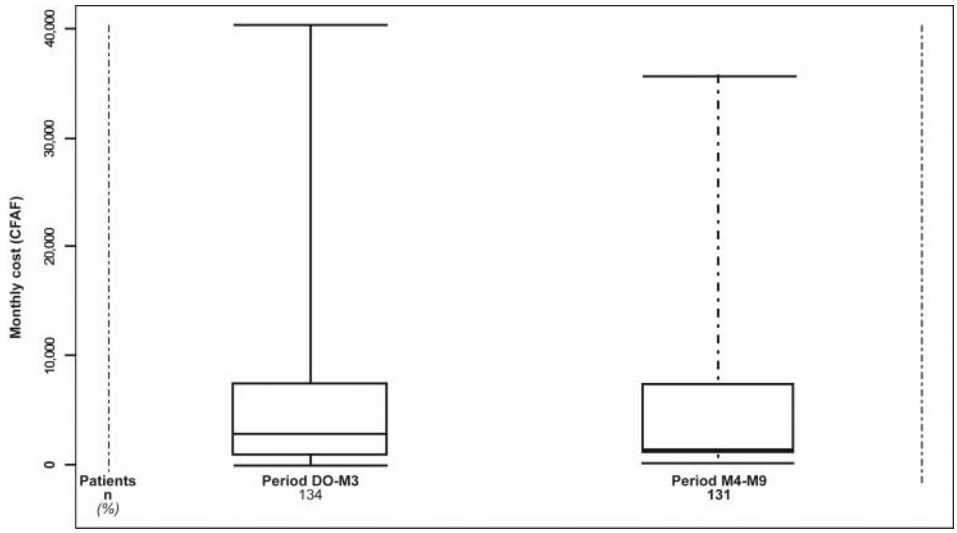

Figure 8.

Average monthly costs, in periods D0–M3 and M4–M9 of antiretroviral triple therapy (in CFAF)

Costs of Tests, Consultations, and Hospitalisations

The costs of biological tests, consultations with specialists, and hospitalisations are not very high if we consider the group of patients in clinical trials during the nine months of follow-up: 2000 CFAF per patient per month (Table 7). Average values are not very representative given the low number of occurrences. Only 17 patients were hospitalised (nine in the first trial and eight in the second). Estimating hospitalisation costs is practically impossible due to the gross differences in fees between hospitals (1000–5000 CFAF a day at Fann, compared to 15,000–22,000 CFAF a day at Principal Hospital; *see* Table 8). The costs for patients were high (up to 252,000 CFAF for 16 days). Similarly, for an episode of acute diarrhoea with fever, a patient could spend up to 10,000 CFAF for the biological tests (stool culture, stool examination for parasites, blood smear and blood films to check for plasmodia and blood count; see Table 8).

Discussion

The information used in our retrospective study was initially collected from a clinical perspective, to analyse and interpret the effectiveness and bioclinical tolerance of treatments, and not for socioeconomic analysis. Also, some information was not recorded precisely enough to allow for an economic evaluation; for example, data on hospitalisations and biological tests for the 58 ISAARV patients could not be found. In addition, it is possible that the recorded information on biological tests and on treatment of opportunistic infections is not exhaustive; omissions of information could have resulted in underestimated costs.

In addition, we assumed that medical follow-up was equivalent in quantity and in quality for the three subgroups participating in the study. The first 58 ISAARV

Table 6

Average number of pathological occurrences (x 100) per patient by period (D0–M3 and M4–M9) reported in a standard 3-month interval

Condition	D0–M3 n (x100)	M4–M9 n (x100)
Cutaneous reactions	7	1
Pruritis	13	4
Superinfections, impetiginised abscess	13	6
Dermatomycosis	7	5
Scabies	1	0
Herpes Zoster	5	2
Seborrhoeic dermatitis	3	1
Onyxis	1	1
Dermatology total	**50**	**20**
Genital candidiasis	13	2
Genital herpes	7	2
Cervicitis	7	4
Genital ulceration	2	0
Anal ulceration	1	1
Gynaecology total	**30**	**9**
Bronchitis and pneumonia	33	15
Oral candidiasis	21	4
Diarrhoea and intestinal parasites	19	8
Malarial syndrome	14	13
Anaemia	15	6
Neuropathy	11	10
Pharyngitis, otitis, sinusitis	5	2
Adjuvant tuberculosis treatment	4	0
Headache, vertigo	4	1
Flu-like syndrome	7	7
Kaposi’s sarcoma	0	1
Atypical mycobacteria	1	0
Pneumocystis	1	0
Cryptococcus	1	0
Fatigue, anxiety	7	1
Other	13	8
Total	**236**	**105**

patients were monitored at three different sites, by multiple and varying clinicians, whereas the patients in the two other groups were monitored at two of these sites, and always by the same three clinicians. Medical follow-up in clinical trials is normally better than that in standard consultations, due to the patients' investment, more standardised protocols, more frequent tests, and doctors' different workloads. However, in the particular context of ISAARV's beginnings, patient follow-up terms and conditions tended to be close to those of the trials. Indeed, the first 58 ISAARV patients, like those in the trials, had great confidence in their medical follow-up, some seeing it as the opportunity of

a lifetime. The clinicians were also for the most part very invested in patient follow-up, and the Medical Committee's frequent meetings allowed for the homogenisation of patient follow-up. For the three groups, monthly medical consultations were free, and the clinicians themselves supplied patients with many medications for opportunistic infections, taken from donations.

Table 7
Costs of biological tests, specialised consultations, and hospitalisations for the 80 patients in clinical trials over the nine months of follow-up (in CFAF)

	Total expense over nine months	Number of patients having at least one pathological occurrences	Monthly expense for patients with occurrences	Monthly expense for the 80 patients
Biological tests and specialised consultations	658,800	56	1300	900
Hospitalisations	816,200	17	5300	1100
Total	1,475,000	–	–	2000

Table 8
Costs of principal supplementary tests (in CFAF)

Medical Imaging		Bacteriology/Parasitology	
Abdominal CT scan	41,000	Stool examination for parasites	1500
Abdominal or pelvic ultrasound	10,000	Mycobacterial culture	2000
Electrocardiogram	5000	Blood smear & blood films	1500
Spinal X-ray	5000	Urinalysis	3000
Chest X-ray	3000	Stool culture	3000
Biological tests		**Hospitalisation**	
Biochemistry	3000	Fann Teaching Hospital (per day)	1000–2500
Full blood count	2500	Principal Hospital (per day)	15,800–21,800
Pregnancy test	2000	Specialised consultations	2000–15,000

Some choices of patent drugs were adapted to the available medicines in stock. The medicines chosen, therefore, were not necessarily the least expensive, or generic. One would think that this favourable context would increase the demand for care and thus the number of prescriptions, thus leading to an overestimation of costs. But, on the contrary, this easy access probably facilitated early diagnoses for some serious conditions, whose treatment cost was thus ultimately reduced. We cannot assess the extent of these ambiguities.

This study is limited to the estimation of patients' costs; it does not examine the costs of care for the health-care system. Moreover, we were not able to assess transportation costs — too difficult to estimate in Dakar due to the diversity of modes (public transport, taxis) and to the substantial range of fares — nor the totality of indirect costs.

This study shows that during the first nine months of HAART, patients must cope with costs, outside of ARV purchase, of between 5000 and 10,000 CFAF per month (6800 CFAF per month for the first three months; 5200 CFAF per month on average over the nine months). These costs should be considered average minimum costs payable by patients; they include costs of diagnoses and treatment of opportunistic infections, with medication for the latter comprising around 80% of these costs.

Biological tests do not make up a substantial proportion of this cost estimate because for many conditions, clinical diagnoses are not confirmed by biological tests (laboratory or medical imaging), which are too costly, inaccessible in the country, or for exceptional use. The lack of access to some medical services thus leads to, in effect, a reduction of costs.

To date, we only know of one other study conducted in Africa exploring patients' direct costs: it focused on the direct cost of treatment in the first year of life of children with HIV, born of seropositive mothers, in Abidjan in 1996 and 1997 [12]. The direct monthly cost (not including transportation) was estimated at 12,600 CFAF per child. Although this value is close to our estimates, we cannot draw any conclusions from a comparison as the populations are too dissimilar.

The impact of opportunistic infections on the direct cost of treatment, and the correlation between the progressive stage of disease and costs of medicines were described in various studies in Northern countries [4, 5]. In our inquiry, the cost differences observed are due to the number and type of opportunistic infections or intercurrent pathologies. Costs below 1000 CFAF per month covered prophylactic treatment with generic cotrimoxazole (990 CFAF per month) or treatment of genital candidiasis with Nystatine® suppositories (700 CFAF per month). More than half of costs in the 1000–5000 CFAF per month range were for treatment of oral candidiasis by Triflucan® tablets. Treatment of herpes, germ-resistant pneumonia, or rarer opportunistic infections (atypical mycobacteria or Kaposi's sarcoma) are among the most costly (Table 9). The increase in costs proportional to the illness's aggravation confirms that patients must be treated before immune deficiency becomes major — while respecting the CD4 limits recommended for undergoing HAART — in order to prevent opportunistic infections arising and to thus reduce the illness's direct and indirect costs.

Some of the pathologies affecting patients are tied to the African epidemiological context. Thus, malaria, digestive parasitosis, and some bacterial diarrhoeas are not necessarily tied to HIV, but are specific to the local epidemiological context. We chose not to exclude these illnesses from our cost calculations. In some cases, these pathologies are opportunistic infections specific to Africa, even if it is difficult to precisely diagnose them (diarrhoea). Moreover, recent studies show close interactions between HIV and other parasitic infections that are not normally considered opportunistic infections, such as malaria; the risk of serious malaria is doubled for HIV-positive patients [3, 9]. Finally, even if these pathologies are not directly linked to HIV, they should be taken into consideration because they impact on patients' health and adherence.

The cost of treatments for opportunistic infections is less than that of HAART,[3] representing 7% in our study. Although this is exact in some situations,

[3] See The National Alliance of State and Territorial AIDS Directors, Annual Report – April 2002. www.atdn.org/access/adap.

particularly when generic medicines can be used, this assertion cannot be generalised. Some medications specifically designed for opportunistic infections are almost as costly as ARV (Table 8), and some of these are not even available in Africa. Improvements in ARV accessibility does not mean that the issue of accessibility to these medicines can be ignored: price-reduction strategies for these medications must also be developed.

Table 9
Costs of the 12 most expensive prescriptions (in CFAF)

Medicine	Prescription	Package price	Treatment price	Indication
Triflucan® 50	1 tb/day x 8 days	18,476	21,115	oral candidiasis
Zovirax® 200	6 tb /day x 10 days	15,800	37,920	genital herpes
Bléomycine® 15	–	15,000	–	Kaposi's sarcoma
Nizoral® 200	1 tb /day x 10 days	11,500	11,500	oral candidiasis
Augmentin® 500	3 tb /day x 10 days	9371	23,428	pneumonia
Clarytine®	1 tb /day x 16 days	5648	6025	cutaneous reactions
Lamisil® cream	2 tubes	4600	9200	dermatomycosis
Mucomyst®	3 pkt/day x 7 days	4595	3217	pneumonia
Quinine® 500	3 tb /day x 3 days	3142	9426	malaria
Erythro® 500	2 tb /day x 10 days	3087	5145	pneumonia
Vitamins	3 tb /day x 30 days	2952	5314	asthenia
Bactrim Forte®	1 tb /day x 30 days	2543	7629	prophylaxis

To reduce the impact of these costs on patients' adherence and on the effectiveness of triple therapy, their integration with ARV costs in the framework of subsidised medical treatment should be considered.

Patients' direct costs could be deemed low, even negligible, compared to the prices of ARV or to the total cost of treatment for the health-care system. To appreciate how they can impact on patients, however, they must be seen in relation to patient resources. In the Dakar region, 60% of the population have no fixed employment or regular income, 60% of people spend less than 15,500 CFAF each per month to secure all their needs (lodging, clothing, food, health, etc.), and 83% of the population do not have social welfare coverage that would cover or subsidise medical expenses [6]. With regard to the population's standard of living, many patients may struggle to meet all their treatment costs, not to mention the fact that treatment exists within an individual history, which may have begun several years prior, punctuated with health problems, multiple medical consultations, medication purchases, and thus many expenses.[4] Finally, the indefinite duration of treatment expenses is also a source of long-term instability that can adversely affect an individual's capacity to respect the prescriptions and medical advice s/he receives and limit her or his access to health-care facilities.

[4] This, in most cases, well before HIV-infection diagnostics were established.

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Chapter I.4
The Antiretroviral Medicine Supply and Financing System

M. Ciss, P. Vinard, K. Diop

Health authorities in many African countries question the amount of financing necessary to treat people with HIV/AIDS (PLWA). How to manage these funds and integrate them in the organisation of health services are also growing concerns. Simultaneous to the microeconomic analysis of patient strategies, this assessment of ISAARV focused on the overall economy of the project to determine its place in the country's health policy.

An information system was thus established to monitor antiretroviral (ARV) supplies and all obtained financing. Various aspects of the Initiative's management were integrated into a number of health structures, and so it is useful to demarcate the distribution of roles. The analysis of this overall organisation is essential at a time when treatment in Senegal is moving toward decentralisation and when other similar projects in Africa are taking shape. It is also interesting to identify, through Senegal's case, the concrete impact of international developments, particularly in the global ARV market.

A Changing and Integrated System

In three years of operation, ISAARV's supply system and financing mechanisms underwent significant change due to the launch of new activities, the expansion of treatment, and new external constraints. Figure 9 illustrates the organisation of the ARV system and its financial flow in December 2001.

This structure was developed in a very pragmatic way, while keeping certain organisational aspects intact. All supplies continued to be centralised at Fann Hospital pharmacy using the same inventory cards as for other products. This fixed routing allowed for better control of supply to many facilities (Social Hygiene Institute [IHS], Albert Royer Children's Hospital [HEAR], etc.) and programmes (prevention of mother-to-child transmission [PMCT], accidental blood exposure [ABE]). The Fann pharmacy has also, since November 2001, supplied the Kaolack regional hospital within the decentralised programme. If all of these supplies are valued at current prices, their respective amounts are very different (Figure 10).

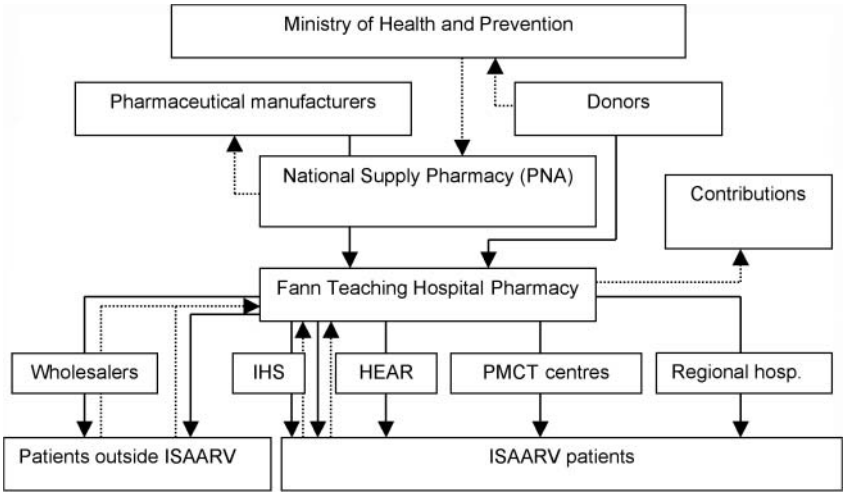

Figure 9

Organisation of ARV routing and financial flows

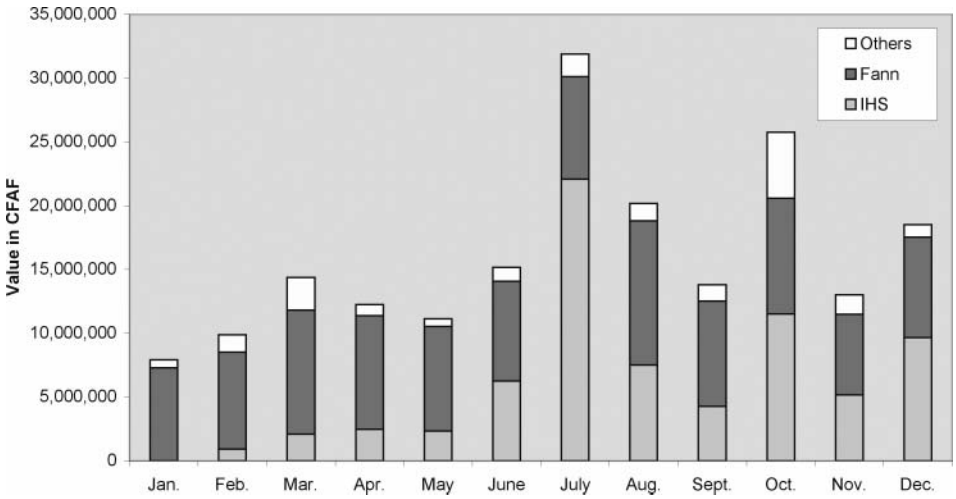

Figure 10

Value of ARV provisions in 2001

The majority of medications (52% of the total value of 2001) are dispensed directly to patients by Fann Hospital. Distribution was also entrusted to the Social Hygiene Institute (IHS) in February 2001, and was expanded in July 2001 (36% for 2001). The IHS is run as an annex of the Fann pharmacy, stocking almost as many ARVs as Fann pharmacy and treating more than 60 patients. Monthly variations result from stockpiling in these various structures and programmes. Other dispensation sites account for 12% of the 2001 total (Figure 11).

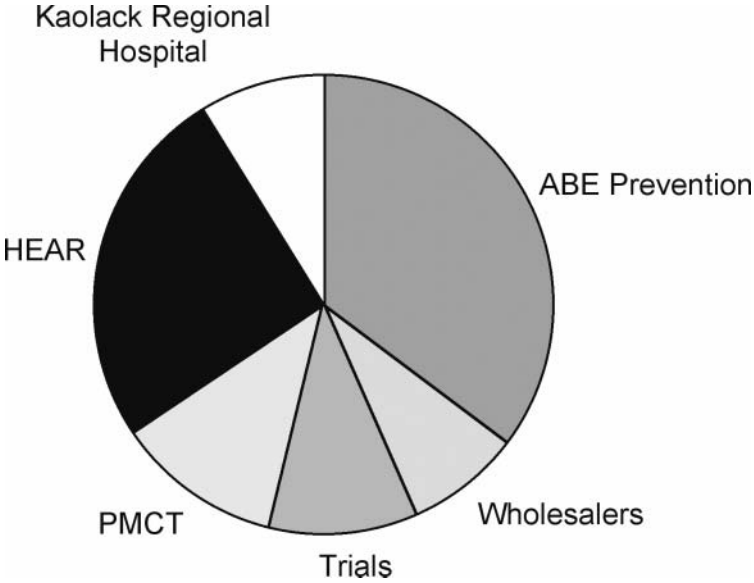

Figure 11

Distribution of ARV stocks among dispensation sites other than Fann pharmacy in 2001

Albert Royer Children's Hospital (HEAR) receives three percent of drug supplies for ten children. A similar percentage is received for treatment of ABE. The PMCT programme currently gets less than one percent of the total ARVs for a few dozen women. The clinical trials (ANRS 1204/IMEA 011 and ANRS 1206/IMEA 012) receive ARVs directly from the pharmaceutical manufacturers and are under separate management.[1]

A few wholesalers sell ARVs to a very limited number of patients who receive treatment in the private sector — outside the programme but under the survey of ISAARV, which records quantities distributed to wholesalers. After the October 2000 ARV price reductions, Fann pharmacy played a larger role in the distribution system, supplying wholesalers with ARVs so that all patients could benefit from the reduced prices. The price cuts were therefore passed on right away, and ISAARV compensated for the financial losses of old stocks with the sale of additional quantities. From July 2001, wholesale sales significantly decreased, and more and more “off-programme” patients were supplied directly by Fann pharmacy.

All financial transactions, as well, went through Fann pharmacy, where they underwent a separate accounting process. The receipts came from three sources (IHS, Fann programme, and off programme) because the other dispensations were free. The funds collected were periodically transferred to an ISAARV bank account.

All transactions — of products and money — are recorded (see Table 10).

[1] The same is true for the "Care Program" trial (Pharma Access International), which began in 2002.

Table 10
Forms for recording ARV and monetary transactions

Form	Contents	Use
1. Prescriptions	Prescriptions	Written by doctors; copies kept by pharmacist. ISAARV only.
2. Moderating fee	Patient fee established by social survey and Eligibility Committee decision	Base payment to pharmacy. ISAARV only.
3. Patient file	Assembled prescriptions and moderating fee	Prescription monitoring. ISAARV only.
4. Delivery log	Date, patient number, prescription, amount paid, start and end of treatment	ISAARV only.
5. Adherence log	One page per patient and duplicate	ISAARV only. Duplicate sent to research project.
6. Agenda	Patient appointments	ISAARV only.
7. Summary of National Supply Pharmacy (PNA) bills	Date, items, and amount of bills	All pharmacy.
8. Product inventory card	Receipt, dispensation, stock, expiry date	All pharmacy.
9. Weekly receipts record	Date, patient number, amount paid	Copy of receipts record submitted to bank with deposit. All pharmacy.
10. Monthly bank statement		ISAARV only.
11. End-of-month stock inventory	Products, stock at beginning of month, distribution by dispensation site, stock at end of the month	All pharmacy.
12. Survey of ARVs dispensed "off programme"	Date, product, patient, amount paid	ISAARV only.

Certain documents were common to other Fann hospital services. Others were created specifically for the Initiative. The system is rather difficult to keep up-to-date, but it facilitates effective monitoring of activities. Records (of stock transactions and receipts, in particular) must match. This process is being simplified as ISAARV develops.

Medicine Supply

The National Supply Pharmacy's (PNA) purchase of ARVs from the pharmaceutical manufacturers is negotiated by the management of the National AIDS

Control Programme (PNLS). These decisions are not subject to the rules normally applied by the PNA to invitations to tenders. Only supply management within Senegal is analysed here, but orders from abroad almost always tally with bills from the PNA to Fann pharmacy.

Total PNA purchases come to 732 million CFAF since the start of the Initiative in August 1998. This amount only covers ARVs and about 18 million CFAF in fluconazole orders (Figure 12).

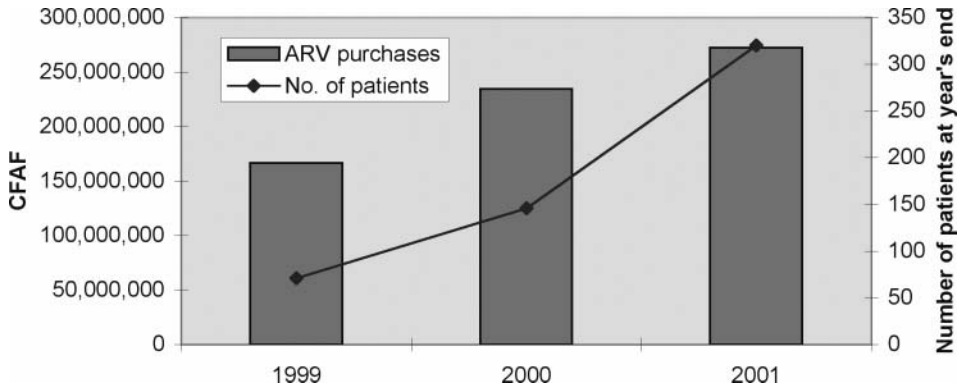

Figure 12

Value of ARV purchases by Fann pharmacy (1999–2001)

ARV purchases rose thus to 166 million CFAF in 1999, 234 million CFAF in 2000, and 272 million CFAF in 2001, although the increase slowed down (+40% in 2000, +16% in 2001). The drop in ARV prices was thus a bit more than compensated for by the increased volume of purchases. Sustained financial aid allowed for a rapid increase in the number of patients, which more than doubled each year.

Orders are frequent (two or three per month) and their amounts variable (maximum 117 million CFAF, minimum 128,000 CFAF). Fann and the PNA keep fewer medicines in stock since sizeable purchases in this context of low prices would not be judicious. Nevertheless, budgetary constraints of what is essentially public financing often explain significant year-end purchases. A system of more-regular orders is progressively being set up. For these three years, no break in stock was reported, in part because regular meetings were held to monitor medicine requirements and examine stock inventory (see form no.10, Table 10).

The PNA invoices the ISAARV account in full for the purchase price paid to suppliers. Changes in product prices can therefore be analysed with the invoices received by Fann pharmacy (Figures 13 and 14).

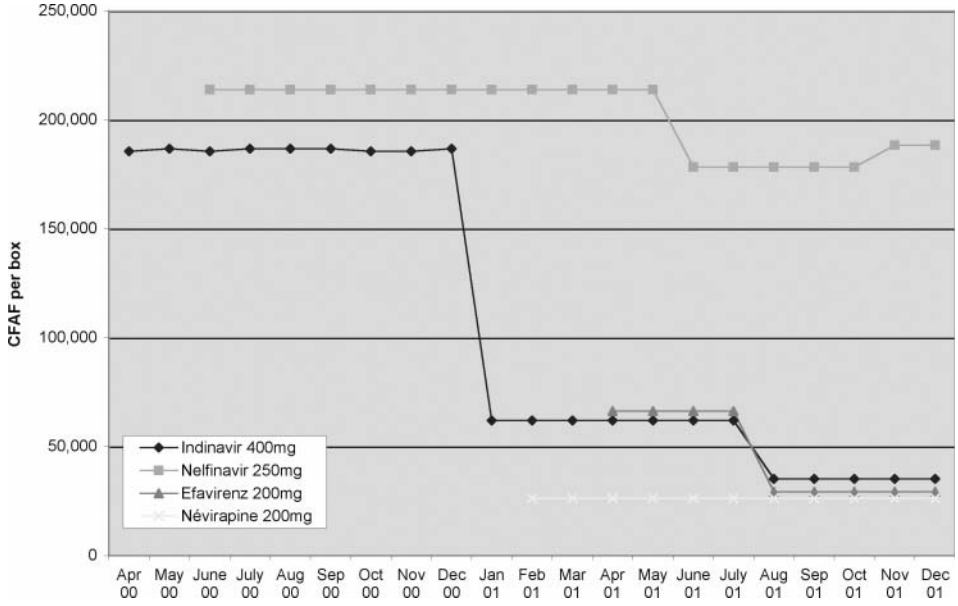

Figure 13

Change in unit prices invoiced by the PNA, non-nucleoside reverse transcriptase inhibitors (NNRTI) and protease inhibitors (PI)

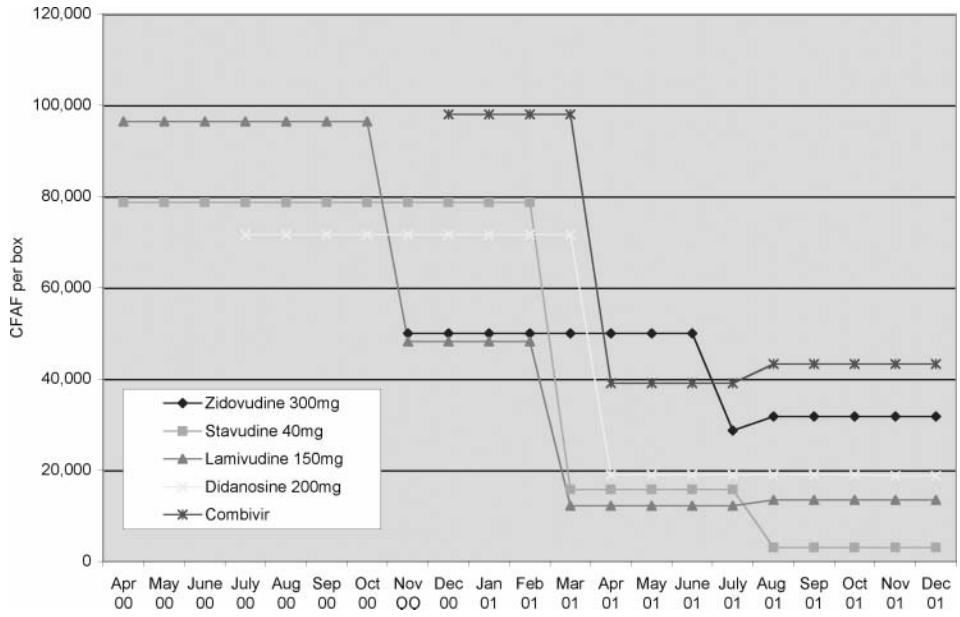

Figure 14

Change in unit prices invoiced by the PNA, nucleoside reverse transcriptase inhibitors (NRTI)

From the start of the project, ARVs were supplied at preferential prices, and thus the impact of price reductions appeared less marked. The principal price cuts announced by the pharmaceutical industry in May 2000 and negotiated with the Senegalese authorities in October 2000 only actually appeared in March and April 2001, although patient prices were adjusted in November 2000.

Price cuts were almost always made in many stages beginning in October 2000; some were reduced again in August 2001. They were in some cases relatively modest, and some prices even increased slightly because of variations in the exchange rate. The biggest price reductions applied to NRTI, whose prices on average fell 60% in two months. From April 2001, they stabilised at between 31,800 CFAF and 3000 CFAF per box. The range between prices of different products therefore remained substantial. For NNRTI and PI, which could be significantly more expensive, the ranges were even greater. Some, such as nelfinavir, did not see such a marked price drop: it still costs nearly 190,000 CFAF while prices of other drugs have stabilised at around 30,000 CFAF per box.

The effect of the price reductions varies according to the extent to which each drug is used. Thirty combinations were analysed (Table 11).

Treatment costs are appreciable for certain products that were lowered very little or not at all. The prices were set by box, with each box corresponding to about one month of treatment. The changes in monthly costs of seven treatment protocols (chosen with the widest range of costs) were thereby estimated using the varying prices (Figure 15).

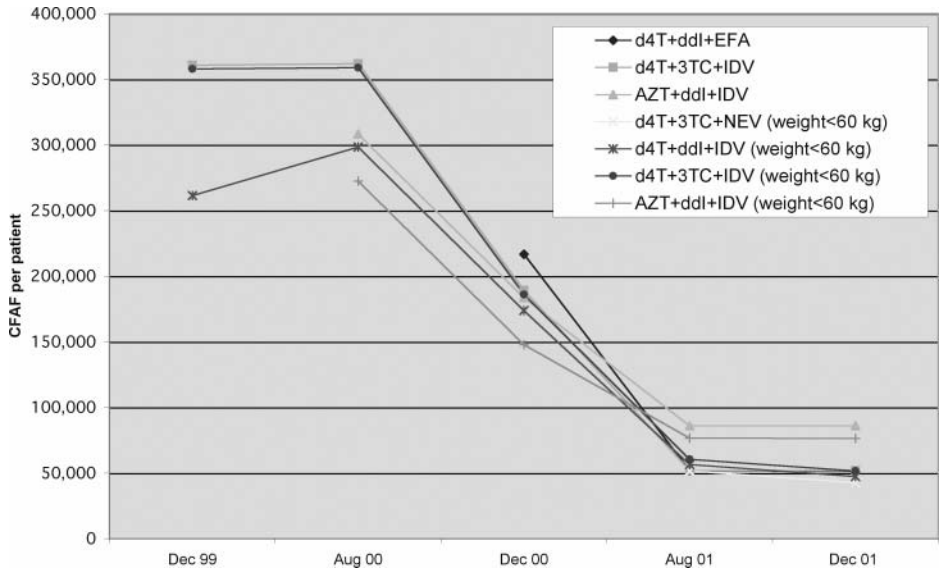

Figure 15

Monthly costs of seven treatment protocols between December 1999 and December 2001

Table 11
Costs of 30 treatment protocols (December 2001)

	Patients over 60 kg	Total CFAF		Patients under 60 kg	Total CFAF
1	Stavudine 40 + Lamivudine + Efavirenz	**45,946**	**16**	Stavudine 30 + Didanosine + Nevirapine	**47,921**
2	Stavudine 40 + Didanosine + Efavirenz	**51,240**	**17**	Stavudine 30 + Lamivudine + Nevirapine	**42,627**
3	Stavudine 40 + Lamivudine + Nevirapine	**42,996**	**18**	Stavudine 30 + Didanosine + Efavirenz	**50,871**
4	Stavudine 40 + Didanosine + Nevirapine	**48,290**	**19**	Stavudine 30 + Lamivudine + Efavirenz	**45,577**
5	Stavudine 40 + Lamivudine + Indinavir	**51,846**	**20**	Stavudine 30 + Didanosine + Indinavir	**47,374**
6	Stavudine 40 + Didanosine + Indinavir	**57,140**	**21**	Stavudine 30 + Lamivudine + Indinavir	**51,477**
7	Didanosine + Lamivudine + Efavirenz	**61,644**	**22**	Didanosine + Lamivudine + Efavirenz	**52,247**
8	Lamivudine + Zidovudine + Didanosine	**62,094**	**23**	Lamivudine + Zidovudine + Didanosine	**52,697**
9	Lamivudine + Zidovudine + Nevirapine	**69,700**	**24**	Lamivudine + Zidovudine + Nevirapine	**69,700**
10	Lamivudine + Zidovudine + Efavirenz	**72,650**	**25**	Lamivudine + Zidovudine + Efavirenz	**72,650**
11	Lamivudine + Zidovudine + Indinavir	**78,550**	**26**	Lamivudine + Zidovudine + Indinavir	**78,550**
12	Zidovudine + Didanosine + Nevirapine	**76,994**	**27**	Zidovudine + Didanosine + Nevirapine	**67,597**
13	Zidovudine + Didanosine + Efavirenz	**79,944**	**28**	Zidovudine + Didanosine + Efavirenz	**70,547**
14	Zidovudine + Lamivudine + Indinavir	**80,550**	**29**	Zidovudine + Didanosine + Indinavir	**76,447**
15	Zidovudine + Didanosine + Indinavir	**85,844**	**30**	Zidovudine + Lamivudine + Indinavir	**80,550**

The average monthly treatment costs greatly decreased (326,000 CFAF in December 1999 to 175,000 CFAF in December 2000 to 62,000 CFAF in December 2001). The range of costs according to treatment protocol remains substantial. In the same period, the least expensive treatment went from 261,430 CFAF to 42,627 CFAF, and the most expensive from 360,730 CFAF to 85,844 CFAF. More than half of treatments still cost in excess of 60,000 CFAF. Product classification according to cost changes with price variations, and so making choices based on economic criteria becomes more difficult.

Financing

A description and analysis of patient financial contributions established at treatment initiation were presented in Chapter I.2. With the amounts actually disbursed that are examined here, payment difficulties can be taken into account and the resources that were finally collected by the programme can be measured. The majority of patients receive their medication once a month, but some pay for two months at a time (especially “off-programme” patients). Detailed data could only be gathered beginning in November 2000, when a flat-fee system was established (Figure 16).

Prior to March 2001, receipts from ARV sales were relatively stable and rarely exceeded 500,000 CFAF per month. They then rapidly progressed to more than

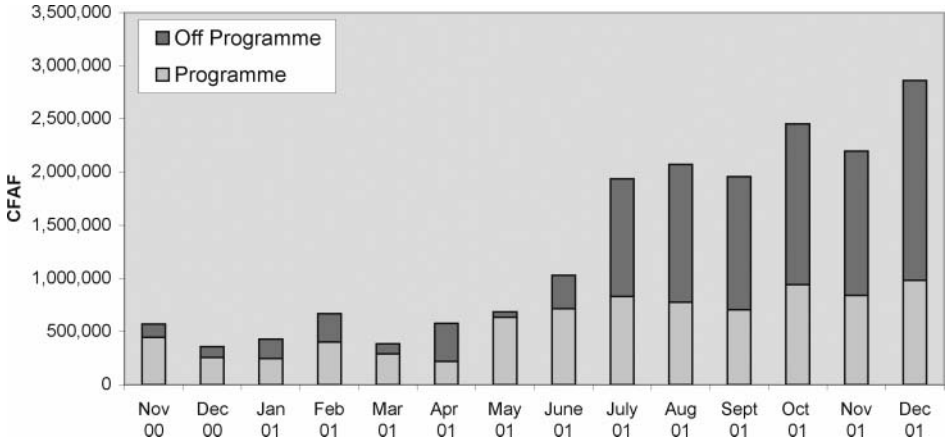

Figure 16

ARV receipts recorded at Fann pharmacy from November 2000 to December 2001

2 million CFAF per month beginning in July 2001. Altogether, since the Initiative began, nearly 51 million CFAF has been collected.

This amount has been kept in a bank account and was never used. The problem of appropriating these funds will grow with the programme's expansion and decentralisation. This amount only actually corresponds to two months of ISAARV's current ARV supply.

Receipts from Programme Patients

Since the beginning of 2001, receipts from programme patient contributions have increased, following the increase in patient enrolment. These receipts have stabilised since July 2001 at less than one million CFAF per month, whereas the number of payments continue to increase. The average payment amount dropped from 6500 CFAF to 4500 CFAF at the end of 2001: 42% of ARVs were dispensed without charge, 44% of payments were in the fixed 5000 CFAF category, and only 7% were in the 10,000 CFAF category. Only a few payments, often irregular, were of more than 20,000 CFAF. In practice, the sliding-scale principle is less and less operational due to most patients' poor financial situation.

The Increase in "Off-Programme" Sales

The growth of total receipts was above all the result of increased "off-programme" sales, which brought in, from July 2001, two times more monthly receipts than did the programme itself. The cumulative total "off-programme" payments in 2001 came to 9.2 million CFAF, and the number of "off-programme" payments also increased very quickly, to reach 23 on average over the last six months. The average payment amounts stabilised, after having greatly varied (Figure 17).

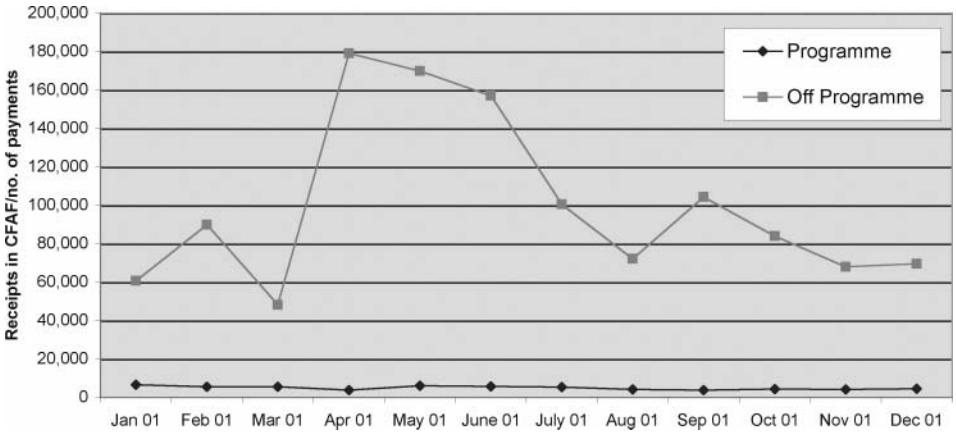

Figure 17

Average payments for ARV purchases recorded by Fann pharmacy

High payments, which actually correspond to multiple treatment months, became rare. In December 2001, the off-programme payment average was 69,500 CFAF, which remains 15 times higher than the average programme payment.

By eliminating partial payments or payments made for multiple months of treatment, the incidence of various protocols, whose costs were previously assessed, can be estimated (Figure 18).

The least expensive combinations are not the most frequently prescribed by doctors, even for patients paying for their medicines in full. Financial monitoring is not designed to measure "off-programme" patient adherence or to check if these patients manage to maintain this investment level for the duration of treatment.

A two-tier system thus progressively developed: a nearly free service offered within the programmes, and another, with private follow-up, limited to the more well-off. So far, the two services have been managed and financially supported by the government. In the future it will be necessary to determine more precisely the roles of the private sector and of Fann pharmacy within the system.

Limited Donations and Essentially Public Financing

Donations in kind are sometimes made by institutions and private individuals. They are few in number and their amounts are small; they are often products of limited use or near their expiry date. Free nevirapine provision is being progressively set up within the PMCT programme. Estimated using PNA prices, these donations have amounted to 12.6 million CFAF since the programme's outset

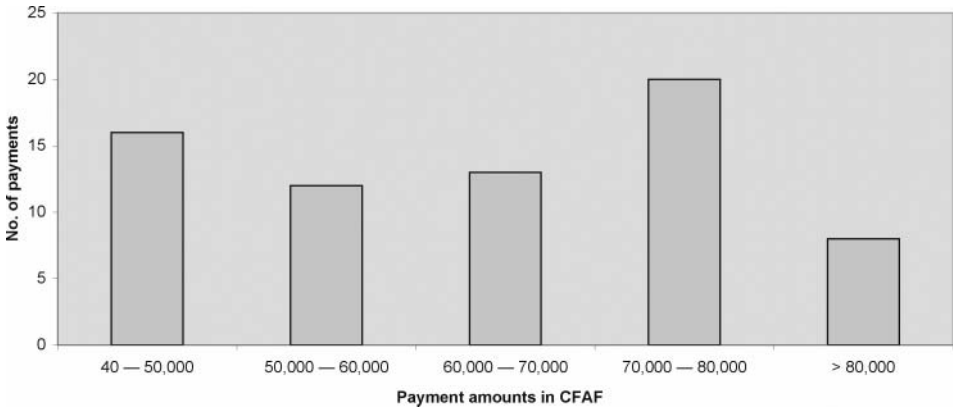

Figure 18
Number of "off-programme" payments in 2001 by amounts paid

(1.7% of provisions). On the other hand, ARV supplies for the clinical trials are substantial (on the order of 100 million CFAF for the two ANRS-IMEA trials). Most of these patients are subsequently treated within the main ISAARV programme. International aid, which goes through the state budget, could not be separately quantified here.

Some financing from bilateral institutions was paid directly to the PNA. Some pharmaceutical laboratories also financed orders via a subsidy to this account. Table 12 details how the PNA account is credited for the PNLS.

Table 12
Breakdown of National Supply Pharmacy account from 1998 to 2001 (in CFAF)

	State budget	Other backers
1998	200,000,000	
1999	316,865,000	
2000	253,809,000	4,493,000
2001	585,102,000	10,706,000

This backing will go to the PNLS as a whole and thus will cover not only Fann pharmacy supplies but also PNA ARV stocks (valued at 81.9 million CFAF in December 2001), laboratory products, and some medicines for opportunistic infections.

The state is thus ISAARV's principal financier for medications as well as for salaries and operating expenses, which come under the Ministry budget. In the commitments for 2002, the public budget remained stable and backers are expected to renew promises to increase funding for the treatment of PLWA.

Conclusion

Only ARV financing was analysed in this study. Treatment of HIV/AIDS also involves other costs, which require the mobilisation of other public resources and which create expenses for patients and their families. Nevertheless, the increase in ARV total costs was brought under control while the number of patients increased sharply. This was made possible less by a large contribution of the population than by a drop in unit prices, the judicious choice of treatment protocols, and the maintaining of public financing.

The Senegalese Initiative also developed a management system that will continue to evolve with new demands. ARV supply could be integrated into existing public facilities which could provide an opportunity to improve the management of services for PLWA and even for all patients. The monitoring of ISAARV programme patient receipts confirms the limitations of regular fees for serious and long illnesses. HIV/AIDS treatment could thus contribute to adapting the health-financing systems that have been in place in Africa for over a decade.

Chapter I.5
Family Solidarity in Patient Treatment: Realities, Myths and Limits

K. Sow, A. Desclaux

To support the high cost of highly active antiretroviral treatment (HAART), treatment access programmes in Africa depend on patients' — and their families' — financial contributions. Recourse to family solidarity was already recommended as a partial or a total response to the needs of patients living with HIV/AIDS (PLWA), well before antiretroviral (ARV) treatment was even mentioned. In 1994, obstacles to AIDS treatment led the World Health Organization (WHO) to suggest that "the family, whose ties are based on love, confidence, support, and openness, is best placed to protect its members from infection and to bring compassion, care, and support to those infected by HIV or ill with AIDS" [5]. Community care from then on became the buzzword in the rhetoric of international organisations, who described families as "human resources" without which the HIV epidemic could never be managed.

In Senegal, the financial and social constraints connected with HAART access led some patients to seek help from their families to be enrolled in the ISAARV programme. Treatment requires making adjustments and looking to the family circle for support. Seeking help from the family for an expensive treatment can have serious consequences when everyone is struggling, and when the problem is a stigmatising illness.

The purpose of this work is to analyse the nature, the function, and the impact of "family solidarity" in accessing ARV treatment and its follow-up. What kinds of support do families provide for patients to have access to treatment? What are the social norms that determine solidarity? Is help given for nothing, or is something expected in return? Who gets involved to help a patient undergoing treatment? What impact does a patient's treatment access have on family solidarity?

Family Solidarity in Africa

Solidarity, understood as both material and moral support to the people concerned, implies a link between people who have common interests, family relationships, or a feeling of belonging together. Traditional African societies have been recognised for their community solidarity, or even collectivism, which has been regarded as a form of "natural socialism." This solidarity now seems to be challenged for economic reasons, while "The African reality of today ... faced with the crisis, ... is characterised by community solidarities becoming increasingly precarious and problematic, in a climate of contradiction and heightened

tension..." ([3], p. 53). Do African families still have sufficient means to practise solidarity? If solidarity in the form of economic support has limits, can other kinds of solidarity survive in the face of the crisis?

Another factor contributing to the erosion of traditional solidarity is the process of individualisation currently in progress in Africa, concomitant with the development of the modern state and the extension of capitalism and fuelled by various social factors [3].[1] African situations today are not marked by an alternative between individualism and collectivism, but rather by compromises between these two trends, which can assume very different forms. Particularly in the health field, modern institutions assign value to solidarity, especially family solidarity, and seek to promote it. Will sick people continue to seek help from their families, or will they try to manage their illnesses alone?

The idea of solidarity is a complex one, which can include or exclude reciprocal exchange between partners; the term has two connotations: solidarity as altruism (a favour without anything expected in return), and solidarity as a reciprocal action or a strategic act (favour and return favour). Following M. Mauss, ethnologists have shown that an offering is invariably followed in due course by a return offering, similar or otherwise, and that such a cycle of exchange is one of the constitutive elements of social order in traditional societies [4]. These customs observed at the macro-social level are not always systematically followed at the micro-social level, where examples of refusal, self-exclusion, or exclusion can be found, and where an individual may receive no support from the people around her or him.

In the health field, the question of solidarity arises when the family becomes aware that the health of one of its members is altered, and that looking after him or her requires a group investment. To declare an illness is a presumably legitimate way to seek help from the family. To obtain it, the person seeking help cannot be regarded as at fault for her or his illness and must be willing to accept "sick" status [1]. Taking on this status is a social process, based in particular on giving up work and on family members' recognition of symptoms. It implies inability to fulfil the usual family and social obligations, and carries with it varying rights and benefits, according to different societies and social groups.

The important role that relatives and their representatives play in recognising the illness and in developing a scheme for caring for and treating the patient has been described by Janzen, who calls the concerned group a "therapy managing group" [2]. The intervention of this group, however, has more often been analysed in terms of resources, or even power dynamics, than in terms of solidarity, which suggests that conditions for support and the question of reciprocity have hardly been considered. In addition, the work of ethnologists on the provision of family care for people with illnesses in Africa has been mainly concerned with acute illnesses, or with chronic pathologies or handicaps that cannot be treated, implying that the possibility of solidarity becoming exhausted has not been considered, nor have aspects related to maintaining one's diseased status, which is important in the case of AIDS.

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[1] A. Marie cites the domination of "written logic" over the oral tradition, which contributes to the emergence of a critical mindset; urbanisation, which gives rise to cosmopolitanism and individual opportunities; the development of the media, which short-circuits traditional methods of communication, etc. ([3], p. 85)

The extended family is traditionally esteemed in Senegal. A. Sylla shows that the social philosophy of the Wolof, the majority ethnic group, is guided by the persistent concern to keep the family both "large and united" [6]. Such values are nowadays challenged by poverty and the development of nuclear households.[2] Seeking help from the family for HAART falls under this tension between group values and the material constraints that run counter to them.

The Survey

To explore these questions, we conducted intensive semi-directive interviews, group interviews, and participatory observations in health-care services, homes, and discussion groups with 26 HIV-positive patients from July 1999 to July 2001. This immersion in patients' living conditions and the drafting of family trees and solidarity-network diagrams enabled us to analyse various aspects of family care. In continuing these conversations over two years, we followed the changes in the lives of those in our study. The subjects we explored were: patients' personal histories, the development of the illness, the history of relations with the family circle, confidentiality management, financial questions, various forms of support, social relationships, the therapeutic context of HAART prescription, and factors related to adherence. It was not possible for us, due to reasons tied to ISAARV enrolment terms, to meet patients not enrolled in the programme, which would have allowed for a comparative analysis of results. Individual characteristics of the people questioned are listed in Table 13.

Types of Patients Support

All the people we studied had been supported by their families during periods of illness while they were under treatment. This aid included material support, in financial or other forms (food and shelter), help in obtaining access to care, moral and psychological support, and/or support with adherence and care. Adherence support is discussed in Chapter II.3.

Material Support

When ISAARV was instituted in 1998, a financial contribution was required, based on patients' incomes and commitments from their family and friends. Only 11 out of the 26 patients were able to persuade their families to make regular financial contributions specifically for the ARV treatment. Financial support for these patients was used for their contributions for HAART, the purchase of

[2] In the Dakar region, the average number of people in a household has gone down from 9.2 people in 1991 to 7 people in 2001. This decline in the size of households seems related to the precariousness of living conditions. Poverty has increased; the proportion of people living below the minimum level in Senegal has increased from 46.4% in 1991 to 50.7% in 2001. Poverty increases the more numerous the household: the incidence of poverty went up from 28.1% for households with fewer than 4 people to 57.5% in households of 5 to 9 people. Direction de la Prévision et de la statistique, Ministère de l'Économie, des Finances et du Plan, 1991. Enquête sur les Priorités (E. Gomes do Santo, 2000). Étude sur l'équité dans l'accès aux soins de santé et les déterminants socio-économiques des recours de soins dans la région de Dakar. Ministère de la Santé, UNICEF, Service de Coopération et d'Action Culturelle de Dakar, décembre 2000.

Table 13
Principal social characteristics of study participants

	Age	Sex	Marital Status	Profession	Residence	Shared Information with:	Material Support
Bachir	44	M	polygamous	senior manager	own house	spouse	self-sufficient
Awa	40	F	widowed	secretary	family	family	brothers and sisters (4)
Ndeye	38	F	married	housewife	family	spouse	spouse (1)
Sophie	30	F	unmarried	transit agent	family	no one	self-sufficient
Amie	28	F	unmarried	small trader	family	no one	would not ask help
Astou	28	F	married	small trader	rented room	family and spouse	spouse and brothers-in-law (3)
David	27	F	unmarried	unemployed	family	family and friends	would not ask family
Kiné	32	F	married	housewife	own house	spouse	spouse (1)
Salif	30	M	unmarried	unemployed	rented room	doctor cousin	half-brothers (3)
Eladj	46	M	divorced	driver	rented room	no one	would not ask
François	27	M	divorced	trader	family	family	half-brothers (2)
Laye	43	M	polygamous	unemployed	family	uncle	half-brother, wife, and sons (3)
Pape	48	M	married	unemployed	rented flat	brother-in-law	brother-in-law
Anna	36	F	widowed	housewife	rented room	family	elder sister, brothers (2)
Jérôme	39	M	widowed	teacher	own house	spouse	wife
Chérif	31	M	unmarried	unemployed	family	family	elder sisters (3)
Oumy	43	F	widowed	unemployed	family	family	no one
Oumar	43	M	divorced	labourer	family	no one	self-sufficient
Marie	32	F	divorced	unemployed	family	friend	sister, brothers-in-law (2)
Ibra	45	M	married	unemployed	family	friends	father
Sophie	26	F	married	unemployed	family	spouse	mother, father-in-law (2)
Fifi	26	F	married	trader	rented room	husband	spouse
Djeïnaba	27	F	married	unemployed	family	husband	mother, sisters, and brothers-in-law (5)
Charles	49	M	married	unemployed	family	family and friends	spouse
Hamet	45	M	married	tailor	rented room	spouse	brothers (2)

medicines for opportunistic infections, health checks payable by patients, transport costs, etc. Most of the other patients asked their families for occasional help to meet their health expenses. The number of family members involved in giving this help varied between one and five. Most of the patients were living in precarious socioeconomic conditions, after having been forced to stop working due to the deterioration of their health.[3] The possibility of welfare benefits in cases of illness or unemployment is extremely limited, and most of these patients were completely financially dependent on their family circle.

Other forms of material support included temporary or long-term accommodation to facilitate hospital visits; food; clothing; repayment of debts that patients had incurred; leisure activities; and contributions towards family or religious ceremonies. Solidarity could also include the family's covering patients' social responsibilities: food and lodging, school fees, or health care. These expenses, formerly paid for by PLWA, were for their children, spouses, relatives, or other dependents. Six patients out of the 26 did not receive any material support from their families, either because they were well-off, had been rejected by the family, or had not asked.

Support for Health-Care Access

The family accompanies and supports the patient in his or her search for treatment. Family members or close friends seek out traditional healers or religious figures, who might comfort, heal, or protect the patient against a tragedy curse. All patients we spoke to had turned to some kind of traditional or religious medicine: brews, charms, sacrifices, or prayers for protection. The cost of these could be very high, and some patients admitted having spent millions of francs on traditional healers, particularly during periods when their illness became severe. This line of action was often followed before access to HAART. Although most patients expressed reservations about the effectiveness of these remedies against HIV infection, they continued taking them to protect themselves, to increase their chances of being cured, or to have a child.

Patients' family members exploited their connections in the medical world to facilitate inclusion in the ISAARV programme. They accompanied the patient on hospital visits, and tried to make use of people they knew there in case of problems or long waits. Using recommendations based on family connections could be helpful during trips to the hospital.

Psychological and Moral Support

Moral solidarity implies accepting the patient's status and respecting his or her confidentiality. Patients regard not being stigmatised, rejected, or morally condemned as signs of solidarity. This kind of support is especially welcome by those who feel "blameworthy" for their infection or excluded, as is often the case with immigrants and young, single women.

The family is thus involved in supporting the patient in many ways, whether related to health or not. Support for treatment generally fits into PLWA's pre-

[3] Thirty percent of patients had no income, and the incomes of the other two-thirds left them below the poverty line (cf. Chapter I.1).

existing relationships of dependency on their families. Different kinds of support are often combined. Economic support is generally linked to other kinds of support, but these various types of support can have conditions attached, as we shall see below. Some patients can receive a considerable amount of material support, but still feel that they are being morally rejected. Others do not receive any material help, but enjoy remarkable moral solidarity.

People Involved in Support

The Spouse

When patients live together as a couple, the spouse is the first to be called on, assuming that the HIV diagnosis has been shared.[4] Seventeen of the 26 people we met were living or had lived together as couples. Only 11 of them had shared the information with their partner, for reasons we will analyse below. In such cases, the couple preferred to manage treatment on a conjugal basis, except where they had insufficient resources; couples seemed particularly reluctant to involve their families in managing their illness. Patients insisted on how beneficial it was to have the moral support of their spouse, to whom they felt linked by AIDS.

Close Family Members

The next to be asked for help are close family members (parents, brothers, and sisters). The younger patients in a family are given help more readily than their elders, who find greater difficulty in asking the family for help, without "losing face." An older patient in a family of 40 brothers and sisters who found it difficult to mobilise support said that "obtaining support depends on your position within the family. I'm the one who is supposed to set an example, who is meant to be a success, so that I can help my younger brothers. An elder brother is not meant to ask for help. Beyond a certain age, your parents are no longer supposed to take care of you, but rather the contrary. It's up to you to look after them." The same situation was shown to exist in Abidjan, where family solidarity towards PLWA seemed to be easier to organise for the benefit of the younger members of the family [7].

The Extended Family

In some cases, help is provided by members of the extended family. This was the case of Salif, who was seriously ill before he began HAART. His mother had to sell a family possession in order to pay for his medical expenses. He was included in the ISAARV programme, thanks to the support of a cousin who was a doctor. He was the only person with whom he shared the information of his seropositivity. This doctor played the role of intermediary with other family members, and asked for their help without revealing that the patient was seropositive — justifying this with the principle of medical confidentiality which he was bound to observe. Salif's mother, who lived outside Dakar, sent him a little

[4] The term "sharing information" is used in "international AIDS culture" to mean the announcement by the PLWA that s/he is HIV-positive.

money to pay for his lunch and transport costs. He was lodged in a rented room by his cousin. He took his meals (breakfast and dinner) with another cousin. The cost of HAART was met by his half-brothers. Friends also helped him from time to time with such expenses as clothing, pocket money, leisure activities, etc.

Other People Involved

Other people who contributed help were mainly friends and acquaintances in the neighbourhood. Six of the 26 patients to whom we spoke said they had asked friends for some material support. These were usually patients who did not share the information with their families. These requests were still made only rarely and then only in cases of real difficulty. Some patients, particularly those who lived in rented rooms, were sometimes given some financial help by their neighbours, to help pay for food or transport costs. This kind of help was limited by the need for confidentiality.

The Conditions for Asking for Support

All the patients we monitored experienced a decline in their health serious enough to justify HAART. But not all of them sought help, because certain conditions had to be met before they could hope to obtain it.

Revealing Seropositivity

Being supported by one's spouse or family implies that they are very much aware of the state of health of the person they are helping. One of the patients told us: "I can't ask anyone to help me without explaining why." It is hard for patients to ask for help. Fourteen patients out of the 26 had not yet talked to their families about their illness before they were included in the ISAARV programme. Those who had shared the information, either deliberately or otherwise, recalled the conflicts that followed the disclosure: accusations from one patient's spouse that she had infected him, destabilised relationships, or risks of separation. Most of the patients had not experienced open rejection, but they had to put up with their family circle speaking in a hostile fashion about AIDS. Every day, they feared having to face situations where they were implicitly or openly condemned, rejected, or avoided by those close to them. To most of the people we met, having to appeal to solidarity thus seemed to be an additional burden on social relations that were already complicated, if not conflictual. When patients had any choice in the matter, i.e. they had the money to pay for their own treatment, they usually preferred not to involve their families. Disclosing HIV status does not guarantee support, and if refused, patients feel even more disgraced for having revealed her or his secret without getting any support — or worse still, when totally rejected. For this reason, patients did not readily ask their families for help.

The fear of being rejected was generally exaggerated, although it was sometimes justified. Only one patient out of the 26 had been categorically rejected by his family, who refused to meet any of the costs of his treatment and threw him out of the house. This was a young man who had no occupation, whose father had died, and who had been taken in by his paternal aunt after various periods

of ill health. During this period, the family was not aware that the young man was HIV-positive. He disclosed this and asked for the family's help to meet the costs of HAART.

Having Relatives with Resources

All patients received help from their families at some point during the history of their illness. But it was hard for some of them to go on receiving help from the family for buying ARVs. Either the family did not have enough resources, or refused to continue giving help, or the patient did not want to ask for help any more. The patients themselves estimated the financial resources of the family before they decided whether a request for help had a chance of being met. In drawing up a list of advantages and risks, they also had to consider the fact that making such a request, which had to be accompanied by admitting their seropositivity, might impose a moral burden on the family, whatever response it decided to give. Altruistic support could more readily be provided for younger members of the family or for patients who had no resources.

Not Being Regarded as Blameworthy for the Illness

Patients who were regarded by their families as having been infected because they had transgressed moral rules found it harder to get help than those who were regarded as "innocent," or as "victims." Married women, whose husbands were strongly suspected of being responsible for their illness, were in most cases regarded as "victims," which enabled them to obtain support from the family.

Being Able to Provide Help in Return

Solidarity based on the principle of reciprocity was more likely to be seen among patients with above-average socioeconomic means. Young men seemed particularly involved in this kind of solidarity. A lot of patients feared not being able to repay a debt, whether a moral or a financial one, because of the uncertain future that faced them. Those who had a high economic and social status, before they found their earning capacity reduced, also found it hard to ask their families for help, because this showed that they had lost their previous high status.

Having Already Provided Help

Family support towards treatment costs was sometimes linked to repaying a debt previously contracted with the patient or with someone close to him or her. Salif's treatment, for example, was at first paid for by his half-brothers, who had the same mother, in acknowledgement of what they had received from their stepfather. The father of these half-brothers had died when they were very young. Their mother had remarried with Salif's father, who had brought up Salif's half-brothers and supported them. Helping Salif was thus an opportunity for them to express gratitude to their stepfather. In other cases, patients regarded getting support as a matter of "returning the favour," after they themselves had given help to the family by providing lodging or financial help or by giving a recommendation for a job.

Patients who readily obtained help from their families tended to be married women, those who had themselves contributed to family solidarity by helping other members of the family, patients with money, those who were ill, and those who enjoyed harmonious relations with the head of the family. Those who found it hardest to get help were unmarried women, those who had had a "high" socioeconomic position before their illness, those who were in extreme poverty, those who were suspected of being infected by not observing the rules of moral conduct, those who were suspected of having infected their wives, or those who had never accepted family obligations.

Returning the Favor

Getting help from family members left patients exposed to possible demands in return.

Talking About One's Illness

Sharing information about the illness was a precondition for getting help. It was also the "price that had to be paid" when the help was actually obtained. When patients made their disclosures, they often had to explain at the same time how they had become infected. They were afterwards obliged to keep those who helped them informed about the progress of their illness and the cost of treatment. It was not easy to make these explanations. In addition to the fear of being rejected, patients wanted to preserve confidentiality about their private lives. They wanted to spare their family circle the blow of such a diagnosis and also feared that if it their seropositivity was known, the criticism they would receive as AIDS patients, would be extended to their family. On the other hand, to keep quiet about the diagnosis did nothing to alleviate their distress and added the extra burden of lying.

Sometimes, even if the family suspected that the patient was HIV-positive, they preferred that the problem remain tacit, for fear of the financial and moral burden that open knowledge of the patient's illness would bring. Some of them thought it was not necessary to share the information, as long as the patient did not display obvious clinical signs of the illness, such as extreme weight loss. Whatever the circumstances for sharing the information, most patients preferred to do it themselves to control what would be said. Disclosures made to others by health professionals or by friends were regarded by patients as a breach of confidentiality. For some patients, on the other hand, the chance to access HAART made it easier to disclose their HIV status.

Meeting Family Expectations

The unexpressed price to pay for family support is dependency. When s/he can no longer take part in the cycle of exchange within the family, the patient has to keep to the social place expected of her or him or adopt a position of humility or even contrition. This happened in the case of Awa, a young widow, supported by her brothers and sisters. As soon as the members of her family learnt that she was HIV-positive, they decided that she had to leave her late husband's home and return to her family home. Everything was provided there for her and

her children: food, clothing, lodging, the children's school fees, money for leisure activities and the cost of her HAART. For a whole year, her brothers and sisters bought the ARVs in France, at a cost of 6000 French francs (about US$900) a month, paid from a collective bank loan they had taken out together solely for this purpose. Thanks to their connections with health professionals, she was one of the first patients to be enrolled in the ISAARV programme. Awa submitted to all family decisions. Her brothers were in regular contact with her doctors and with her employer, who was informed that she was HIV-positive. They "watched over" her to make sure she adhered to her treatment. A few months after she had recovered her health, her lack of independence began to weigh on her. She admitted that living in the family home "had never been a pleasure. You weren't free there. It was like an old people's home." But she did not have the courage to gainsay her family, who felt she should live in the family home for her own support. She dare not disagree with this conclusion, for fear of seeming ungrateful to those who had helped her.

A young patient, who was married to a labourer without regular employment, was obliged to turn to her family to pay the 20,000 CFAF asked of her as a contribution towards her HAART. Her father insisted that she divorce as a precondition for financial support. This patient regarded her submission to this demand as a condition of solidarity. She experienced double guilt: for becoming infected with HIV and for not being independent.

There was often a heavy price to be paid in terms of self-respect. A 50-year-old married patient, an unemployed manager, was mainly supported by his family. He paid all his treatment expenses, explaining: "You don't live as you ought to do and you can't make both ends meet. You can't say what you want. You have to accept whatever you are given. I am clearly aware that many of the people I went to for help disliked me."

Reciprocity of Material Support

The requirement for reciprocal support is rarely made explicit. The story of Laye reveals the economic limits of solidarity and shows how the patient himself is constrained by this requirement. Laye, a tailor from Abidjan, returned to Senegal after being chronically ill for several years. He was polygamous, and one of his wives lived in Senegal in the family house, while the other lived in Abidjan. His savings were soon exhausted by the cost of the biomedical and traditional remedies that he took. He lived in the family house with his first wife's children. His brothers and half-brothers, who also lived in the family house, looked after them. To be included in the Initiative, he asked for a monthly contribution of 20,000 CFAF from the members of his family who were living in Abidjan, without disclosing to them that he was HIV-positive. His brother, who had taken over Laye's tailor shop, his second wife, who was a market trader, and his eldest son, who was an apprentice tailor, undertook to help him. Laye adhered strictly to his treatment, and a clear improvement was observed in his bio-clinical condition. After several months, however, his brother withdrew his help, because of his own family expenses. Laye still got by, with the help of his other brothers. He cut back his prescribed daily dosage of HAART, in order to make the drugs last longer and thus space out the payments. A few months later, he decided to stop his treatment altogether because of his financial problems. He was ashamed to

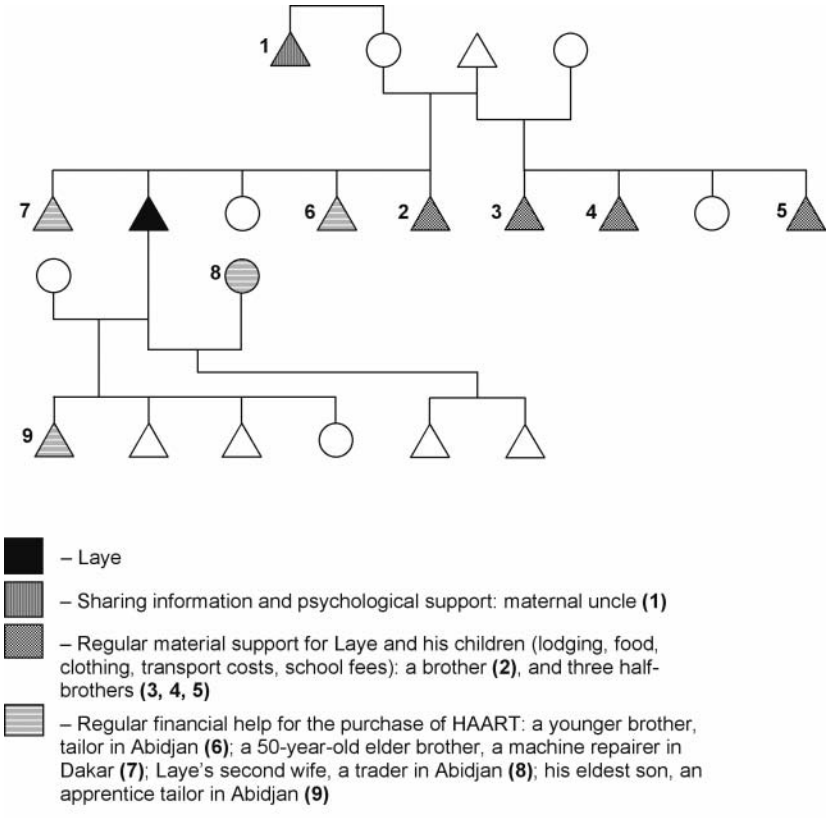

Figure 19
Family solidarity: Laye's case

have to rely on family solidarity, when he seemed to be in good health, and when he had nothing to offer in return. He was even more upset that his brothers and half-brothers were paying all the expenses of his own family.

Laye's professional future as a tailor seemed in doubt, because his sight had deteriorated and he did not have the means to work on his own account. Certain rules of honour had to be followed when turning to family solidarity: failing to return the help was dishonourable. He also felt constrained by the fear of becoming such a burden that he would endanger all those contributing family members.

At the start of his illness, the support of Laye's family seemed legitimate, because during the time he had lived and worked in Abidjan, he had regularly helped his family. But the precariousness of his own professional future compromised his ability to return the support of his family. Family solidarity is generally in keeping with an exchange system: financial help is balanced by a revelation of one's private life, submission to the family, and/or repayment of the moral and financial debt that one has incurred.

Duration of Support

Long-term Strategies

Some families have worked out various strategies to enable patients to access treatment and adhere to it: monthly contributions by senior family members, the organisation of tontines, approaches to programme doctors. In Anna's case, her seropositivity was discovered after repeated abortions. She had just remarried, after her first husband had died, following a long illness whose diagnosis was not revealed by her doctors. As she was convinced that her first husband had been responsible for infecting her with HIV, she had no difficulty telling her close family that she was HIV-positive. Her sister, who was a nurse, approached health professionals to help her be admitted to the ISAARV programme. After she had started her HAART, her brothers and sisters organised a tontine over several months, to provide a financial reserve, in case those who had agreed to support her ran out of money. They then agreed to monthly contributions to cover her medicines.

The Impact of Solidarity on Treatment Adherence

Organising collective resources, whether financial, moral, or in-kind, reduces the individual cost of AIDS and the suffering of those infected with HIV. It provides an aspect of liberation for the patient who is accustomed to sharing his problems. Some patients have been able to enjoy a remarkable amount of help from their families in order to access HAART. This help can result in all treatment costs being met, changing meal times to fit in with the prescription of treatment, being accompanied on hospital visits, psychological support, and mediation in case of non-adherence or an interruption in treatment. In some cases, even the initiation of HAART has resulted more from family decisions than from the patient's. This solidarity can go so far as to establish close family supervision of treatment adherence. It should be noted that this exceptional measure of support has usually occurred in well-off families. Family support is more present when family ties are close and when the family resources are sufficient.

The Solidarity of Confidentiality

Patients' spouses, older relatives, and brothers and sisters manage to keep secret the private details of their close relatives. They are careful that the information not be divulged, in order to avoid additional difficulties for the patients, which could also rebound on themselves. In case close family and friends are unable to provide sufficient material support, the choice is to look to those most likely to support the patient while maintaining discretion: maternal uncles, cousins, friends, etc.

The Limits of Family Solidarity

Exhaustion of Resources

Making regular demands on the family for moral, physical, or financial support for HAART is not something that can continue forever. It is limited if the sick per-

son no longer has the status of an invalid or if the patient wishes to rejoin normal life, and also if family funds run out, either because there is nothing left or because other events have led to new demands on family solidarity.

Losing the Status of a Sick Person

A return to health and the recovery of physical ability means that patients lose "sick" status. The patient once again has to meet his or her social obligations: help the family, be ready (in the case of women) for marriage or for motherhood, and start work again. When the patient is ill, s/he is in a position to receive, and her or his family under the obligation to give. Once s/he is well again, the roles are reversed. The social reinsertion of the patient means that dependency on those around him or her should come to an end. Whatever determination and will the families have shown in support of the patients, once they recover their health, the patients regard this state of dependency as a humiliation which reduces even further their social position. Support of this kind is no longer appropriate for the patient, who now appears to be like everyone else. Some people find it hard to accept that they are obliged to appeal to family solidarity for their basic needs, such as food and lodging and the cost of health care. The wish of the patients is to rediscover a socio-professional status, so that they can be independent and can once again take up their social obligations and repay the help they have received.

Recourse to Other Forms of Solidarity

To be infected with HIV and follow HAART means for most patients having to adopt new priorities in their life. Maintaining a proper state of health — following proper rules of hygiene, eating proper food, and following the rules for treatment — becomes their main preoccupation. They naturally turn toward people who have the same priorities.

Some patients, through self-help groups or associations, have formed friendships with others who are living with HIV. Besides comparing their experiences, patients undergoing HAART find increasing mutual support. This network of mutual help gives patients various possibilities in case of economic or psychological difficulties or of changes in their state of health. The patients tend to replace asking their families for help with asking for help from their peers.

Conclusion

Family solidarity as a way of looking after patients infected with HIV is a reality and enables them to reduce the social consequences of the lack of resources. This help can take many forms and can combine material help, economic help, psychological assistance, and also support for treatment. This help is, however, subject to conditions, which vary according to the socioeconomic status of those involved, their state of health, and their relations with their family circle. It has its limits, due notably to the financial capacity of the family. Community solidarity is limited by debt obligation. Patients who are made vulnerable by being HIV-positive try to avoid turning too readily to family solidarity, because of fears that they may not be able to return the help they receive.

Disclosing HIV status is a condition of obtaining support for treatment. But sharing information is avoided as much as possible, or made selectively if absolutely necessary, and is regarded as a constraint because of the risk of being stigmatised or of the family intruding into the patient's private life. Financial independence is the main factor that enables individuals to free themselves at least partially from family supervision of their illness and their health regime, and to avoid the heavy burden of moral indebtedness.

Family solidarity is not endless nor is it something that, once acquired, is never lost. Recovered health can provoke or revive old conflicts, because the logic of those who help may diverge from the logic of those who receive. Patients, who above all want to recover their independence and their social position, often consider that help from the family is insufficient or inappropriate or that it implies an unduly high expectation of compensation in return.

Thus, families are capable of raising significant psychological, financial, and physical resources to support those living with HIV and to enable them to access care and treatment. Such help often obliges patients to pay a heavy compensation in return, to accept a state of dependency — particularly material and financial — which prevents them from regaining their former social position. Moreover, this help cannot continue indefinitely. Many people are unable to obtain financial support from their families — because the family is too poor to provide it or because the PLWA does not wish to disclose his or her seropositivity. In this context, turning to family solidarity as a way of meeting the costs of care for PLWA cannot be regarded as an equitable arrangement.

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Part II
Antiretroviral Treatment Adherence and Its Determinants

Chapter II.1
Antiretroviral Treatment Adherence and Its Determinants: A Quantitative Analysis

I. Lanièce, A. Desclaux, M. Ciss, K. Diop, B. Ndiaye

Patients' capacity to adhere to highly active antiretroviral treatment (HAART) in African health and social contexts has not yet been widely researched, despite the establishment of the first African antiretroviral (ARV) access programmes in 1998. Recent publications about cohorts monitored in Northern countries revealed a high incidence of non-adherence and demonstrated that only a high level of adherence can produce optimal effectiveness of the antiretroviral multi-drug therapies and slow the illness's progression [1, 17, 18]. In addition, evaluating adherence, a parameter with a changing nature and no reference quantifying method, poses some methodological challenges [15].

In November 1999, sixteen months into the Senegalese programme's operation, a treatment follow-up research project was implemented to assess adult patients' adherence and identify the duration and causes of treatment interruptions. This project took place over a 24-month period, during which ISAARV underwent profound changes: a quadrupling of the enrolment rate following patient ARV price reductions in November 2000; a diversification of molecules (the introduction of non-nucleoside reverse transcriptase inhibitors [NNRTI] and a second protease inhibitor [PI]); research of simplified drug regimens (clinical trials ANRS 1204/IMEA 011 and ANRS 1206/IMEA 012); and the revision of treatment initiation recommendations, with triple therapy as the reference treatment. This period coincided with ISAARV's transition phase, as it progressively developed from a pilot project to a generalised ARV access programme, moving towards decentralisation of care.

The adherence research project combined a quantitative study of descriptive and analytical epidemiology, presented here, and a qualitative socio-anthropological study, the results of which are outlined in Chapter II.2. Results included in this chapter relate to adherence level and its primary causes, with an emphasis on non-behavioural institutional factors — indicators for the strategic choices that African ARV access programmes must make in their implementation.

Study Enrolment and Methodology

Any patient belonging to the first 180 adult patients enrolled in ISAARV and having been medically monitored in the programme for at least 30 days of the 24 months of observation (November 1999 to October 2001) was eligible to volunteer in this study. Eligible patients belonged to two groups: 80 patients receiving treatment in clinical trials (40 in trial ANRS 1204 and 40 in trial ANRS 1206) and others enrolled in the main access programme. These two groups differed mainly by enrolment date, clinical stage at enrolment, previous experience with antiretrovirals, type of treatment regimen, and financial contribution towards HAART (see Chapter I.1, Table 2). Patients were monitored in three Dakar health-care facilities (Internal Medicine Unit at Principal Hospital and the Infectious Diseases Unit and Ambulatory Treatment Centre of Fann Teaching Hospital) and collected their medications at a single dispensation site.

This long-term study of an observational cohort was carried out in successive monthly surveys completed at the pharmacy. All patients followed the same dispensation procedures and had access to a number of adherence-support measures (pharmacist counselling, free access to group discussion and information sessions, personal contact in case of a missed appointment, and financial support in case of prolonged inability to pay for treatment).

While no reference method exists to quantify adherence, the choices in Africa are limited anyway due to resource limitations: plasma drug assays or electronic pill dispensers are unavailable, and high illiteracy rules out the use of self-rating questionnaires [4]. Our collection of adherence data is based primarily on information gathered by the pharmacist, who, when filling prescriptions, conducted monthly individual interviews based on a questionnaire of mostly closed questions. He also counted the returned pills in the patient's presence, which could prompt a reevaluation of the patient's declared intake.

Quantitative adherence estimates were based on patients' stated number of missed pills over the preceding month and were expressed in percentages — the number of pills declared taken out of the total number prescribed. Declared adherences for each drug in a multi-drug therapy were averaged.[1] Treatment interruptions for medical reasons were not considered breaches of adherence. The prescribing doctor or social workers were sometimes able to collect missing information from patients if their trips to the pharmacy were irregular. Those patients whose surveys indicated difficulties with adherence were brought to the attention of the Welfare Committee (Comité pour les aspects sociaux; CTAS). Measures adapted to each individual's situation were implemented by the social worker and treating doctor.

Data was captured with Epi Info 6.04cfr software, and analyses conducted with Epi Info 6.04 or Stata 6.0. Adherence between different subgroups of the cohort at given times in follow-up was compared with the Kruskal-Wallis test for quantitative variables. Adherence between two points in time was compared with the Wilcoxon test for paired data.

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[1] For example, a patient enrolled in a clinical trial who reported having missed a dose of three ARVs in the preceding month will have an estimated adherence of 97% (all medication was taken 29 out of 30 days). A patient monitored outside the trial, on a triple therapy of 2 NRTI and indinavir (IDV), reporting one missed noontime dose of IDV, will have an overall estimated adherence of 99% ([100% + 100% + 99%] / 3).

Results

The Patients

A total of 167 patients met the eligibility criteria. Two patients refused to participate and one withdrew from treatment, yielding a 98% rate of participation. This cohort was quite dynamic and tripled in the 24 months of observation. Patients in the study represented 100% of adults enrolled in ISAARV in November 1999 and 52% of those enrolled in October 2001. Fifteen deaths (9% of patients) and three drop-outs (2%) occurred during the study. Follow-up of the 164 patients in the study's 24 months produced 2775 patient-months of observation, and adherence data were available for 2389 patient-months (86%). The total treatment period was 2501 patient-months. The median length of follow-up within ISAARV was 10 months for the 164 patients. The results finally involved 158 patients (80 of whom participated in clinical trials) because data were unavailable for six of the 164 patients initially enrolled.

Initial socio-demographic, biological, and clinical characteristics

The study population consisted of 84 men and 74 women (M:F sex ratio 1.1:1) with a mean age of 38. Forty-four percent of patients were married and 15% widowed, with an average of 2.6 children per person. Thirty-two percent of patients had never been to school, and 41% were not in paid employment. The median monthly income was 15,000 CFAF. The CDC disease stage distribution of the 155 patients at the outset of antiretroviral treatment in ISAARV was as follows: 6% stage A, 39% stage B, and 55% stage C. The infection was due to HIV-1 in 97% of cases, HIV-2 in 1% of cases, and HIV-1 and -2 in 2% of cases. At enrolment, the mean viral load (log_{10}) was 5.34 copies/ml (n = 154); the mean CD4 cell count was 156/ml (n = 154); and 93% of patients were antiretroviral-naïve.

Treatment regimens at initiation and in the course of treatment

The intent-to-treat regimens were triple therapies in 96% of cases, including two nucleoside reverse transcriptase inhibitors (NRTI) and one protease inhibitor (PI) for 43% of patients, and two NRTI and one non-nucleoside reverse transcriptase inhibitor (NNRTI) for 53% of patients. The intent-to-treat regimen prescribed to patients in the clinical trials consisted of two NRTI and one NNRTI (efavirenz [EFZ]). Intent-to-treat regimens were dual therapies for 4% of patients.

Most antiretroviral treatments prescribed in the 24-month study period were the following three-drug regimens: stavudine (d4T)/didanosine (ddI)/indinavir (IDV) (26.2%) and lamivudine (3TC)/ddI/EFZ (30.6%).

Dual therapies (d4T/ddI, 3TC/zidovudine [AZT], or ddI/IDV) were used in 8.2% of documented patient-months of observation. In most cases, this regimen was consistent with the intent-to-treat regimen; in other cases, it was prescribed due to concomitant tuberculosis treatment, side effects requiring a temporary break from a molecule, or, rarely, the temporary unavailability of a low-dose formulation of stavudine (Zerit® 15 or 20 mg). Viracept® was rarely prescribed because of its high cost relative to Crixivan® or the NNRTI (Stocrin®, Viramune®). No stock shortage of antiretroviral products occurred in the dispensing pharmacy, aside from occasional unavailability of low-dose forms of Zerit® (15 or 20 mg). Donations sometimes supplemented programme stocks.

From November 1999 to October 2001, 13 patients (8%) temporarily discontinued a product on the advice of their doctors: in four cases because of concomitant tuberculosis treatment and in nine cases because of adverse side effects (six cases of peripheral polyneuropathies attributed to d4T, one case of glucose intolerance, and two cases of vomiting attributed to IDV). The d4T dosage was reduced for four patients with peripheral polyneuropathies, and substitutions were prescribed for 16 patients (10%): NRTI was replaced in seven cases; IDV was substituted with nelfinavir (NFV) in five cases for adverse side effects (vomiting, renal colic, and hepatitis); IDV was replaced with EFZ in one case of vomiting; and EFZ was replaced with nevirapine (NVP) for three pregnant patients.

Adherence

Mean adherence rate

During the 24-month study period, the mean monthly adherence among the 158 patients, according to their own statements, was 91% (median 100%, interquartile range [IQR] 97–100%). Patients declared having taken their entire monthly doses in nearly 70% of the months covered by the study period.

Changes in adherence during the study period

Mean adherence was 90% during the first year (median 100%, IQR 97–100%) and 92% in the second year (median 100%, IQR 98–100%). Mean adherence always remained above 80%, oscillating between 83 and 95% depending on the month. Adherence tended to be better, with a smaller dispersion of values, among the 80 patients in the trials than among the other 78 patients (97% versus 87%). This difference diminished with time (Figure 20), being statistically significant every month during 17 of the 24 study months.

Adherence improved between October 2000 and April 2001 among patients not included in clinical trials ($P = 0.02$) and declined between October 2000 and October 2001 among patients in trial ANRS 1204 ($P = 0.03$).

Main Determinants of Adherence

This analysis of factors influencing adherence focused on treatment-related factors: duration of antiretroviral treatment, patient contribution towards treatment cost, and type of combination therapy. This choice, particularly in terms of treatment pricing and combination, was guided by the strategic decisions to be taken in the process of generalising ARV access in Senegal.

Treatment duration

Aside from the differences in adherence between patients in trials and others (statistically significant differences at Month 6, M12, and M18), overall trends were difficult to identify due to low study population size in some months of the study period and different follow-up periods for the three patient subpopulations (see Figure 21). Among patients monitored outside trials, the only trend statistically confirmed was the increase in adherence between M18 and M30 ($P = 0.03$). For patients in ANRS 1206/IMEA 012, no trends appeared in the first

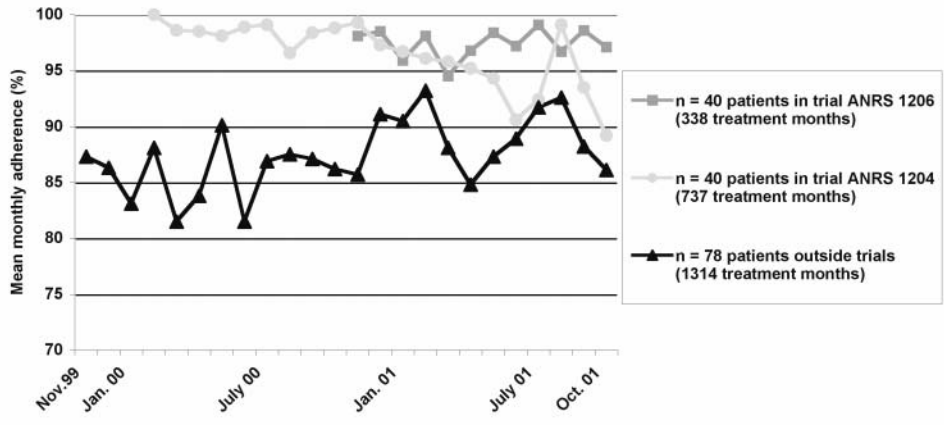

Figure 20
Changes in mean monthly adherence from November 1999 to October 2001 by patient category

nine months. For those in ANRS 1204/IMEA 011, adherence dropped from M9 with a difference close to statistical significance ($P = 0.09$) when adherence at M1 is compared with that at M12.

Patient financial contribution

Patients enrolled in the two clinical trials were treated free of charge, whereas other patients paid monthly between 0 and 198,000 CFAF, depending on their subsidy, towards the cost of their treatment. Mean adherence among patients receiving d4T/ddI/IDV outside clinical trials decreased as their financial contribution increased. The trend was noted during the first year of the study (November 1999 to October 2000) and to a lesser extent in the second year (November 2000 to October 2001; see Figure 22). In the first year, most patients made a substantial minimum monthly payment of around 21,000 CFAF, while the legal minimum wage in Senegal was 36,250 CFAF. Thus, a large proportion of patients encountered financial difficulties (see Chapter I.2). Following the antiretroviral drug price reduction of November 2000, the mean patient contribution was cut fourfold, and the required minimum contribution was cancelled. This decrease in contribution amounts for patients not participating in clinical trials probably contributed to the improvement of adherence in the second year (mean value: 90%, up from 83% in Year 1).

Treatment regimen

Adherence to different molecules should be considered in the initial treatment choice. IDV was the most widely prescribed PI in our cohort, being the only low-cost PI available in Africa, and EFZ the most widely prescribed NNRTI. Adherence to each among patients receiving their treatment free of charge differed by eight points — 89% and 97%, respectively — over the study's 24 months. The differences at M6, M12, M18 were close to statistical significance ($P = 0.09$, $P = 0.17$, and $P = 0.05$ at M6, M12, and M18, respectively).

No difference in mean adherence levels appeared among the three NRTI used in the clinical trials (ddI, d4T, and 3TC). Among patients outside trials, adherence to 3TC was four points higher than to AZT, ddI, and d4T. Patients tended to tolerate EFZ better than IDV, and 3TC or AZT better than ddI or d4T, according to the incidence of side effects reported to the pharmacist and attributed by the patient or pharmacist to the drugs.

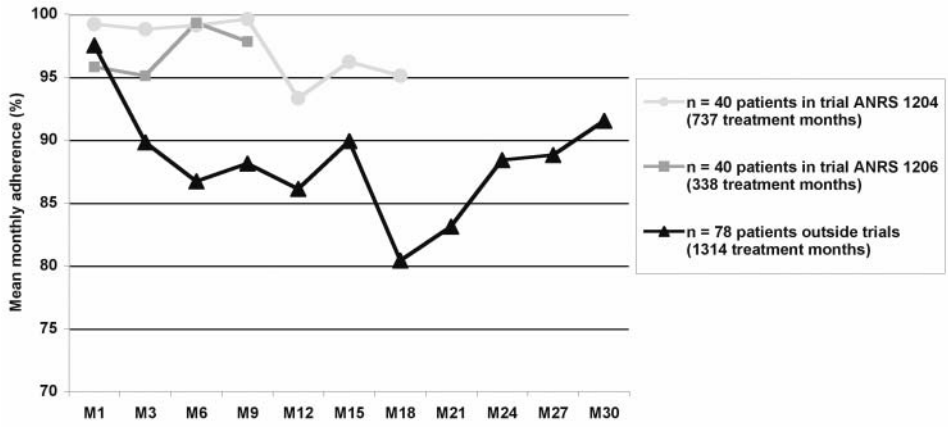

Figure 21

Change in mean adherence, according to treatment duration from M1 to M30, by patient category

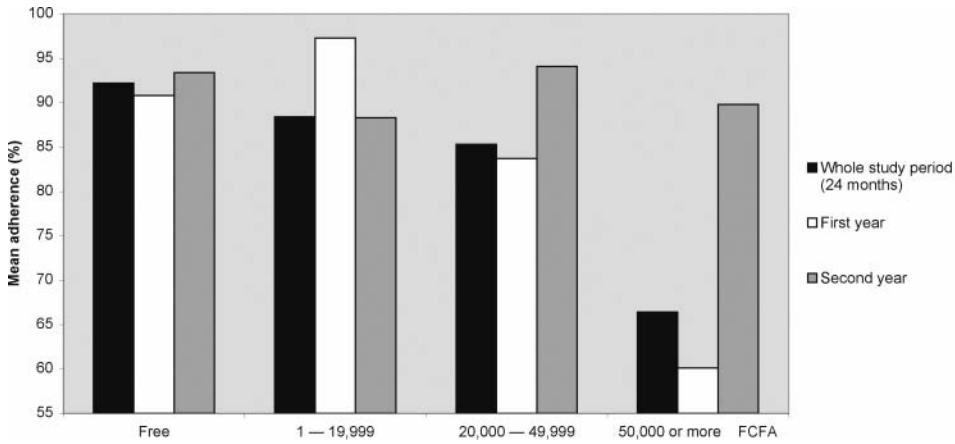

Figure 22

Mean adherence according to patient monthly financial contribution

Main Reasons for Non-Adherence

In the 24 months of study, 143 out of 158 patients (90.5%) reported a month of treatment when pills were missed. Incomplete doses occurred in 30% of treatment months. Of these 727 months of non-adherence, 693 were documented. The six main stated causes were:

- an absence due to either travel or a special social event (26% of cases)
- a health problem, side effect or other (17%)
- financial difficulties (13%)
- forgetfulness (13%)
- sleep (8%)
- difficulties filling prescription: patient availability did not overlap with that of health workers (clinicians, pharmacist) (7%)

Financial difficulties, the leading cause of treatment interruption in the first year among patients outside trials, dropped to the fifth-leading cause in the second year due to the price reduction.

Relationship Between Adherence and Virological Efficacy

At months 6, 12, 18, and 24, adherence in the previous month was compared to contemporary viral load values (logarithmic scale). In a group of patients not participating in clinical trials and receiving a PI-containing three-drug regimen, viral load mean values were compared: those with stated adherence of 90% or more and those with poorer adherence. A relationship between viral load and adherence emerged: viral load was higher in the less adherent patients, with statistically significant mean differences of 1.7 and 1.8 $\log_{10}$ copies/ml at M18 and M24, respectively.

Discussion

Methodological Considerations

The method and the unit period (30 days) used to assess adherence in this study require discussion.

In this African setting, it seems reasonable to estimate adherence on the basis of stated drug intakes and/or unused pill counts, as these parameters are simple, inexpensive, and accessible. Assessment by interview, however, is limited; the system is time-consuming for the patient and the pharmacist, requiring 15 to 30 minutes, and the adherence indicator (based on the patient's statements) is subjective and tends towards overestimation [22]. Counts of unused tablets help to refine this estimate, however, and so, the combination of the two methods (based on both subjective and objective indicators) yields a more accurate figure [16]. The unavoidable approximations inherent in all procedures used to assess adherence, given the lack of a reference tool, have been widely described in the literature [3, 4, 13]. Three elements reinforce the validity of the data collected in this study: 1) the correlation between adherence and virological response (although this relationship is not systematically observed, it tends to validate the adherence assessment of patients taking their first antiretroviral

treatment [4, 9, 13, 17–19]); 2) the good immunovirological efficacy observed in this cohort [10–12]; and 3) consistency between adherence data gathered from the patient by the pharmacist (in this study) and those gathered by the prescribing doctor (see Chapter III.1).

The period of time for patient recall was relatively long in this study (30 days). Stated adherence over the last three days of each one-month period, also measured in this study, tended to be slightly lower than the corresponding 30-day estimate (89% versus 91% over the 24-month study period). However, we felt that the use of a 30-day unit assessment period would more likely reflect the distribution of causes for non-adherence, notably illness and travel. This approach may have led to gaps in information, due to a weaker memory of adherence lapses prior to the seven preceding days. However, in quantitative terms, this bias appears to have been insignificant.

Adherence data were unavailable for 386 patient months of follow-up (14%). In nearly half of these cases the patients received their drugs, but the corresponding datasheet had not been filled out (either the patient or pharmacist was unavailable, or more than one month of medication was dispensed). In these cases we postulated that the treatment had not been taken differently than in the documented months. For the remaining months (7% of all months of follow-up), the patients had not received the drugs from the pharmacy but may have had sufficient personal stocks.

Results

The main result of this study is the high stated level of adherence in each patient category; patients declared that they had taken, on average, 91% of their dose during each month of follow-up, and their entire dose for nearly 70% of those months. These results are similar to those obtained in follow-up cohorts in industrialised countries; for example, in self-rating questionnaires, 73.3% of respondents in the "Aproco" ANRS EP11 cohort stated that they had taken their entire dose during the previous four days at M4, and 67% of respondents in the "Ciel Bleu" trial stated in questionnaires that they had taken 100% of their doses [2, 20].

Compared to studies in Northern countries, however, our results revealed a major difference [18]: a weakening of adherence in later periods of treatment was not observed; on the contrary, lapses in adherence were most marked in the first 18 months. Improved adherence beyond M18 is probably due in part to the price reductions made during the study.

In addition, the most frequently reported reason for non-adherence is travel, which may suggest that, where treatment is only available at a few sites, strategies based on the patient's contact with the health-care system, such as DOTS (directly observed treatment strategy), proposed in other Southern countries, may hinder adherence [8].

Patient fees had a major impact on adherence. Treatment interruptions because of financial problems were reported in other African studies [6, 7, 14]. In Dakar, financial obstacles led to lengthy treatment discontinuations until a more appropriate pricing structure was adopted.

Finally, regarding prescribed treatment regimens, adherence tended to be better

with EFZ- than with IDV-containing regimens, and experience in Northern countries suggests that this difference will persist beyond trials. EFZ's facility (no food restrictions, one dose per day) and better tolerance contributes without a doubt to its wider acceptability [21].

Conclusion

Adherence was consistently high in this Dakar patient cohort, which may be explained by different factors: the experimental nature of the programme (a pilot initiative and development of clinical trials which resulted in the specialised organisation and attention of health professionals); recent inclusions in a small cohort; and the fact that most of the patients had never previously taken HAART and were very motivated (many were symptomatic) [5]. These results provide evidence of high adherence capacities in PLWA in Africa.

Two main factors were found to influence adherence: the cost of treatment and the type of drug combination. As in Northern countries, simplified treatments (especially with NNRTI) appear to be better managed and better accepted. The pricing of treatment must be adapted to patients' financial resources (which are often nil) if the continuity of treatment is to be assured. These two points, along with the measures set up to support adherence (see Chapter II.2), should receive particular attention in the design of future ARV access programmes in Africa.

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Chapter II.2
Antiretroviral Treatment Adherence and Its Determinants: A Qualitative Analysis

K. Sow, A. Desclaux

The quantitative study presented in Chapter II.1 identified some of the causes for poor adherence based on the reasons given by ISAARV patients. Some of these reasons — forgetfulness, sleep, health problems, and side effects — are also reported by patients in Northern countries; others — absence for travel or a special occasion, financial difficulties, and difficulty in obtaining drugs — are particular to the African context. To understand the role of these determining factors and to analyse the specificities of adherence in an African context, we must examine these reasons within a comprehensive analysis.

Adherence is the product of a dynamic concerning a number of diverse and distinct factors that are in constant interaction. Many models have been put forth to analyse adherence that grant more or less importance to psychological, cognitive, or social aspects; to patient-related factors; or to support measures (see [1] especially). We will suppose that, though not an exhaustive list, adherence results from the following:

– treatment factors: volume, number, and organoleptic nature of the medications, treatment regimen, constraints associated with treatment, side effects, etc. (see Chapters II.1 and II.4);

– patient factors: confidence in treatment, cognitive factors, perceptions of side effects (see Chapter II.4), ability to integrate treatment into daily life, social support and attitudes of family circle, etc. (see Chapter III.2);

– disease-related factors: seriousness, persistence of symptoms, acute or chronic nature, etc.;

– factors related to care relationships: prescribing doctors' attitudes, relationship between prescriber and patient, information given to the patient, terms of patient follow-up, etc. (see Chapter II.3);

– factors related to the prescription context: perception of the programme and the health-care system, presence of adherence-support measures (see Chapter II.3), accessibility to treatment (see Chapters I.1, I.2), accessibility of health professionals, etc.

In this chapter, we will explore causes for adherence relating to the integration of treatment into daily life; care relationships; and the prescription context in analysing the conditions and dynamics of adherence.

Adherence Conditions

ISAARV patients[1] must set up the practical conditions for taking their medication in the proper dosages, according to strict schedules, and with respect for food precautions. But adherence is not limited to simply taking the medicines: it also depends on monthly access to treatment. In Senegal, as in other contexts where medicines are not systematically available to patients, adherence involves the whole "treatment" — including its cost and monthly attendance at health facilities for prescription and dispensation consultations.

For optimal adherence, patients must work to integrate treatment into their daily lives, which requires a balance between following the medical recommendations and maintaining as "normal" a life as possible. Certain social rules must be respected for social acceptance of the patient's treatment, which may mean compromises with his or her family circle to avoid increasing difficulties for adherence, which are major at the start of treatment and permanent.

Many studies have shown that patients cannot be classified *a priori* as definitively adherent or non-adherent. The quantitative survey presented in Chapter II.1 indicates as much: adherence is a dynamic phenomenon, which depends more on the patient's and his or her family's abilities to adapt than on pre-established socioeconomic characteristics. After the treatment integration phase, patients must work on maintaining adherence, as the nature of pressures and difficulties continually changes.

Stages of Adherence

Integrating treatment into daily life involves two distinct stages: acceptance, followed by appropriation [2]. This distinction is not exclusively psychological: the acceptance phase includes a series of more or less verbal and formal negotiations and involves talking about treatment with one or more people. The appropriation phase entails familiarisation with treatment and mastering the conditions for and restrictions on taking the medications.

Treatment Integration: The Acceptance Phase

Almost all patients offered treatment within the ISAARV programme accepted. Patients' faith in treatment was reinforced by numerous factors analysed in Chapter II.4, and those who were accepted into the ISAARV programme had already passed through a selection process requiring real determination. But for treatment to be easily integrated into life, it must also be accepted by the family. To obtain and follow antiretroviral treatment requires medication "socialisation": it entails talking about the disease. Many patients cannot openly take their medication and struggle to adhere to the regimen because they don't dare disclose their illness to their family and professional circle.

Acceptance of treatment implies acceptance of HIV infection, and the treatment integration phase often involves revealing one's diagnosis. The majority of patients that we met (21 of 26) had disclosed their HIV status to a family mem-

[1] The survey population and methodology were outlined in Chapter I.5.

ber or friend. Nine of them did so after enrolment in the ISAARV programme. The need for psycho-emotional support and for financial assistance toward treatment were the main reasons for revealing their status. Chapter I.5 outlined the diversity of choices made by PLWA in talking about their status, which ranged from total silence to selective revelations to family members, depending on the social, psychological, or financial benefits of such a disclosure. Patients choose confidants by the quality of the pre-existing relationship and by their presumed capacity to accept the information and be supportive. Educated, skilled "intellectuals" are generally perceived to be most suitable because, according to one patient, "they understand, are familiar with the disease and how it is transmitted, and know that there is no reason to shun us." For some patients, their illness was an argument in advocating for financial aid.

Many patients who feel responsible for or even guilty of their infection may not disclose their status, preferring to run the risk that their treatment will be discovered and raise questions. This was the case of a young woman, Amie. Single and unemployed, living with her brother, she refused to reveal her HIV status. Despite total economic dependence on her family, she chose to manage her antiretroviral treatment alone, using subterfuge to ensure payment for her medications and adhere to treatment. But during a hospitalisation, her medications were discovered without her knowing it. She refused to talk about it with her family, despite the doctor's encouragement, and preferred to interrupt her ARV treatment, explaining that she was ashamed of having contracted HIV during pre-marital sex. She felt guilty of this "disappointment" that she anticipated from her family, who "wished that she had saved herself for marriage."

Some patients do not plainly reveal their seropositivity but give partial information about their illness — that it is serious, chronic, or incurable. They take advantage of AIDS information media broadcasts to demonstrate fervent support for PLWA. These partial revelations justify the continued taking of medications and prepare the family for possible, more complete revelations or for accidental leaks of confidentiality. In this way, these patients test their families' ability to come to terms with their seropositivity.

Treatment Integration: The Appropriation Phase

Patients report that integrating treatment into daily life is difficult; the adaptation can only be gradual. For one patient, "taking medication is like going to Koranic school: once you know, you forget all the suffering you went through." Patients describe how, with time, they internalise the restrictions and develop a "reflex" for adherence. Learning the guidelines for taking the medications and accepting the side effects facilitate treatment integration. Taking the drugs under the proper conditions gradually becomes automatic with the help of various markers: prayer times, meals, waking up, etc., and an equilibrium is reached despite the restrictions. "It's like food," said one patient after having gone through a difficult adaptation period.

Integrating treatment restrictions into daily life is even more delicate here since the economic and social context is not conducive to them. Patients report difficulties in respecting the dosage times, for one. Lipidic restrictions run counter to the traditional diet, which is rich in fat, but medicines should also not be taken on an empty stomach. Antiretroviral treatment (ART) that can be taken at any

time were appreciated by most people we met, who struggled to abide by the time intervals between meals and ART doses. To fix the hour of a group meal would require informing the whole family about the treatment and having them integrate its restrictions into home life. On the other hand, eating a meal alone, away from the common plate, would be difficult to justify and could result in stigmatisation. Some people are not in a position to request “special treatment” because they do not contribute to rent or family expenses. This issue is indicative of the many difficult decisions that patients face: reveal his or her status in order to adjust meals and mealtimes and risk stigmatisation, or hide his or her treatment and risk breaking medical recommendations.

Maintaining treatment confidentiality requires vigilance; concealing the illness from the uninformed family day in and day out is a veritable job. Patients employ strategies of legitimisation, circumvention, or avoidance to follow their treatment without too many questions. Some explain the continual medications by chronic conditions such as asthma, “liver problems,” “effects of smoking on the lungs,” etc. They may tear up the medication packaging and instructions at the hospital, use anonymous packaging, or bring back empty boxes after use. At home, patients carefully lock up the medication in an armoire, taking them as discreetly as possible. Maintaining confidentiality often entails secretiveness that can distance the patient from the family. Some patients moved into rented rooms so they could take their medicines without this pressure.

On the other end of the spectrum, the family can help the patient integrate treatment into their lives. Some patients found their partner to be a major support to adherence. Generally, in couples taking treatment, the one who believes most in the treatment's benefits supports the other. In some cases, s/he also serves as mediator with the health professionals. This was the case of Fifi, who gradually convinced her spouse that they should transcend their mutual accusations of transmitting the virus and adopt a united and motivated attitude. She set up reminders for pill times, and, as an active member of PLWA associations, she related her experiences in support groups to her husband. “Since I had faith in the effectiveness of our medicines, and he didn't, I had to support him. Usually we ate at 11 in the morning, but I made it so that the meal was ready at 8. I give him his medication at ten. I will have already prepared them and put the Videx® in water. After rinsing the glass I return the medicines in the chest and close it…. I'm impatient for the support group to come so I can talk about it with the others, to say what's in my heart, to listen to what's in theirs, and feel better. When I go home, I'll help my husband benefit from what I've heard since he refuses to go.” For people not yet taking ART, the best encouragement is the treatment's efficacy on their partner. One partner's weight gain or disappearance of opportunistic infections can have a major effect on the other's faith in the treatment.

Managing confidentiality applies equally to relationships between patients and health professionals. A patient's family could deduce seropositivity from his or her regular visits to health facilities, and so patients on ART try to space out or cut down on their hospital visits. Most of the people we met go alone to the hospital, some not informing their family, even when they are hospitalised. Picking up medications is a dreaded moment. The pharmacist at Fann Hospital set up a personalised dispensation system with a consultation space, but this is potentially stigmatised insofar as it is only used by patients on ART.

Maintaining Adherence

After the integration phase, maintaining adherence requires the continued negotiation of economic, social, medical, and institutional constraints. In cases of adherence difficulties, the pharmacist or doctor adjusts the schedules, correcting errors. Few patients, though, read the notices, which they consider too complicated. More than anything else, contact with others who struggle with adherence, in support groups or in other interactions, enables patients to re-establish adherence. Participation in support groups allows patients to break their isolation in a context where HIV visibility is low, and discuss their common difficulties. For patients, the words of one who "practices" sometimes mean more than those of the "theoretical" doctor.

Adherence over time is never linear, but evolves with periods of doubt, uncertainty, suffering, and reassessment. Feeling healthy, though, and especially putting on weight, reinforces the patient's commitment to ART and encourages his or her adherence, all while facilitating his or her social reintegration. Maintaining adherence depends also in large part on relationships with the medical team and with associations.

Relationships with the Health-Care System

Living with treatment involves regular contact with health professionals. Clinical doctors, social workers, and pharmacists primarily ensure patients' medical, social, and therapeutic care. The particularity of such a system is that it requires continual monthly medical and social follow-up. In ISAARV's first year, personal relationships were established between clinicians, social workers in charge of social surveys for enrolment and welfare, the dispensing pharmacist, and patients. In the enrolment process, the different actors spoke to patients about the treatment constraints and the necessity for adherence.

Relationships with Doctors

The relationship between patients on ART and doctors is complex, marked simultaneously by a closeness maintained by monthly meetings, submission to medical authority, and, for some patients, by a form of negotiation. Patients' receptivity to medical discussion on adherence is variable and unpredictable, and patients reinterpret medical information according to their expectations, perceptions, and experience. Medical discussion is based on the seriousness of the illness, difficulties in treatment, and the strictness of follow-up necessary for optimal efficacy. Doctors seek to develop patients' abilities to be "good patients," deserving of the ARV treatment opportunity. When patients enrol in the ISAARV programme and sign their consent, doctors stress the importance of abiding by the "terms of the contract," with returned health as the payoff.

Patients often perceive discussion on adherence as a reprimand for recalcitrants. This penalty is internalised by patients in the form of anxiety: they fear being "crossed off the list." Anna, for example, wished to stop her treatment because of intolerable side effects, but she felt "a sort of discomfort with her doctor," and the fear of being perceived as voluntarily non-adherent gave rise to guilt. Some sensed authoritarianism, verging on coercion, in discussions on

adherence. One patient told a programme interviewer, “I am more afraid of my relations with you than of the disease.”

The doctor-patient relationship is also the foundation of a continual negotiation[2] in which the patient gradually becomes the central actor in his or her treatment. It appears that, with time, the patient becomes more and more demanding towards the doctor. Indeed, ISAARV patients are increasingly active in managing their treatment. Informed by the media, patients ask to know the results of their biological exams — their viral load, for example — that until then had been revealed exclusively to those in the system. Some patients research the latest information on AIDS and treatments to see if it jibes with that of ISAARV. Others are innovative with their research: Pape stopped his ART to take a “treatment vacation,” having come across news of this practice in the North; he then informed his doctor, who had not heard of it.

Monthly medical follow-up and the regular biological tests are interpreted in different ways. Some patients feel they are unnecessary and are carried out for “requirements” or “statistics.” Time spent at the hospital and the pace of consultations are deemed excessive or as conflicting with their professional obligations. Others see them as a sign that doctors lack expertise or even fear the effects of ART. Eladj recalled his fear at the start of his antiretroviral treatment: “The effect of treatment, in the beginning it did something to me, it changed me, because when someone tells me, 'take the medicines and come back in a week,' I figured I'm right to be afraid or suspicious of this medicine. If you take this medication and in one week you come back so they can see its effect, then I thought, 'They're not sure what they're doing, nothing's sure.' ” In any case, patients were reassured by the regular biological tests, and generally, the perception that health professionals had confidence in ART was testimony, in the eyes of the patients, to the treatments' efficacy. This faith in the treatment, held by caregiver and patient, could contribute to adherence within ISAARV.

The submission dynamic between patient and medical authority, mentioned in conversations about adherence, does not sum up the treatment relationship. Health professionals may defuse patients' feelings of guilt and help them accept their illness by bringing up fate or religion: “This is God's will.” The majority of people we spoke to felt that the doctors, pharmacists, and social workers were available, understanding, and competent, and some had even established fraternal relationships with them. Patients gave testimonies of health professionals supporting them financially and psychologically and advising them in various domains, including the most intimate. Because most patients did not want to involve their family in handling their illness, health workers were greatly called upon for medical, psychosocial, and financial support. Some doctors were overwhelmingly popular with patients for their supportiveness and ability to listen. In a place where AIDS remains stigmatised, patients were especially grateful to be treated with dignity, which became, in turn, a form of social rehabilitation.

Relationships with the Pharmacist

Problems with adherence are more easily raised at the pharmacy than with the clinicians. Despite the public nature of the pharmacy, which dispenses medi-

[2] In the sense used by Strauss [3].

cines for various hospital units, each patient on ART is seen individually. Although patients appreciate the attention, some fear that this positive discrimination could reveal their HIV status since only patients on ART benefit from it; this is especially so since the premises was reconfigured in 2002 to protect confidentiality. Regardless, the majority of patients appreciate this space outside the doctor's offices for discussing their difficulties.

Relationships with the Social Workers

The social workers play a decisive role as much by their social proximity to patients as by their capacity to serve as mediators with health workers or with patients' families. They were able to enter into patients' personal lives in conducting the social surveys at enrolment, and were later frequently called upon for various reasons: financial difficulties, supplementary information on ART, requests for family mediation in case of conflicts, etc. Social worker interventions give ISAARV treatment a more global dimension and create a listening and support space for the patient. But it is also possible for social workers, by directly and informally intervening in patients' social and private lives, to overstep the boundaries of their job and find themselves taking a moralising stance that can make the patient feel guilty. Social workers also organise regular discussion and information groups for PLWA, which serve as networks of support, exchange, and camaraderie and which were overwhelmingly popular with the patients we met.

Relationships with Associations

Most patients expressed reservations about or even mistrust of the PLWA associations that existed in ISAARV's first phase. This suspicion, combined with pejorative perceptions of association members as being marginalized or on welfare, as taking advantage of their serological status to derive their livelihood, is perpetuated by ignorance about these associations. Doctors and social workers do not encourage patients to join them and generally do not know of what help they could be to patients, while patients fear disclosure of their HIV status if they get involved. Moreover, members of the National Network of PLWA (Réseau national de personnes vivant avec le VIH; RNP) felt that social workers "send over those patients who are beyond them, whom they can't handle. For example, all the people referred to us were drug addicts…. But the patient who listens to them and does what they want is not sent over." Doctors as well as social workers seem to be responsible for referring this apparent selection of "bad patients" and social misfits to PLWA organisations, perpetuating pejorative representations of PLWA in Senegal and testifying to the lack of real collaboration between health professionals and associations in ISAARV's first phase. The creation of new PLWA organisations in 2001 aimed to change this.

Conclusion

The high level of adherence observed in ISAARV does not in any way mean that antiretrovirals are easier to take in Dakar than elsewhere. Patients must set up conditions for obtaining treatment, develop sometimes complex strategies, and make difficult choices to integrate treatment into their daily lives. ISAARV support measures are thus useful, according to patients, for ensuring treatment accessibility and for integrating ART into their family life.

The relative effectiveness of the system is probably due in large part to the exceptional nature of its pilot programme. Many patients express their satisfaction with the medical team's support. The staff's availability and capacity to intervene when problems arose — whether they be with adherence, side effects, or the illness itself — were contributing factors to patients' adherence and commitment to ART.

But at the same time, the burdensome procedures, and especially the increased social surveys, consultations, and biological tests, are perceived in different ways. For the majority of patients, it testifies to the seriousness of treatment, proportional to the gravity of the disease. But the obligatory monthly follow-up — requiring frequent and long visits to the hospital that are incompatible with some patients' professional schedules — seemed counterproductive to patients. At the start of treatment, they accepted the personalised follow-up, but soon thought it unnecessary when they saw their health improving. Follow-up can thus change from a factor contributing to adherence to one limiting it, as attested by the most frequently named reason for non-adherence.[3] From an operational perspective, it seems necessary to adapt adherence-support measures and follow-up procedures to the adherence "period": after personalised and reinforced support in the treatment's acceptance and appropriation phases, access to treatment should be facilitated and social follow-up should be made less systematic in the adherence-maintenance phase. The terms of social follow-up could be redefined, granting more importance, in this phase, to association interventions and to patients' own voluntary steps, all while creating an articulation with medical and psychological follow-up. Such adaptation is indispensable to support a treatment that must be maintained for life.

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[3] "Patient absence at monthly appointments due to travel or special events." See Chapter II.1.

Chapter II.3
The ISAARV Adherence-Support System

A. Desclaux, O. Sylla, I. Lanièce, F. Mbodj, M. Ciss, K. Diop

Antiretroviral treatments have the peculiarity of demanding a very high level of adherence for therapy regimens that are very restrictive. The rate of adherence achieved in clinical settings in Northern countries generally does not even yield optimal results in terms of effectiveness [14].[1] This category of medicines acutely poses an "old problem" in public health that is one of the principal obstacles to treatment effectiveness in both the North and the South.

Though not well documented by quantitative surveys, adherence is generally considered to be a major problem in Southern countries, whatever the pathology. In Africa, illnesses marked by their chronicity or their stigmatisation (leprosy, tuberculosis, sexually transmitted infections) were considered most at risk for non-adherence. Ensuring sufficient adherence for HIV treatment — in a pathology that is both a chronic and stigmatised — is thus particularly difficult, and ordinary medical follow-up may not suffice.

In Northern countries, numerous adherence-support measures were established pragmatically or were submitted to operational research [10]. Educational materials were provided for patients, adherence consultations were set up, medical psychosocial follow-up protocols were established, and treatment education programmes were created [15].[2] African health-care systems, with their limited resources, can rarely offer such services. Systems instituted in the South for long-term treatment of other chronic illnesses — such as DOTS (Directly Observed Treatment Strategy) [11][3] — are also not directly applicable to HAART because they do not allow for optimal confidentiality and they require supplementary personnel who cannot be easily mobilised within the current health-care structures. Moreover, the effectiveness of DOTS was being debated even before it was proposed for antiretroviral treatments, with some studies showing that the strategy's effectiveness resulted from a combination of measures, particularly organisational, rather than from health workers' direct observation of patients' treatment [16].

Adherence-support measures can centre on the treatment regimen, the patient, or the pharmacist [14],[4] and can be developed by the health-care system or by associations. In Dakar, the weak initial mobilisation of the association sector, combined with reluctance to set up costly systems that could not be maintained beyond the pilot stage, led to the development of measures involving primarily the health-care system.

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[1] Treatment of patients (outside clinical trials) detectably reduced viral load in only 40 to 50% of patients [14].

[2] See [15] for more on this adherence-support approach.

[3] See [11] for more on this strategy.

[4] "Regimen-focused, patient-focused, clinical care and provider-focused" [14].

A description and analysis of these measures are presented here to shed light on the results of adherence within ISAARV, and to discuss, from a public-health perspective, the feasibility, impact, and limitations of support measures established in Senegal — a potential model for recent World Health Organization (WHO) recommendations calling for "innovative techniques to improve HAART adherence" [12].

The ISAARV Adherence-Support System

A treatment-access and adherence-support system was defined and established in ISAARV's second year. The system was then adapted practically, according to the feasibility and effectiveness of the initial measures, and according to the results of studies carried out in the operational research programme.

The adherence-support system essentially comprises six measures: financial-participation terms, adapted to patients' finances, are established to ensure continued access to treatment; the pharmacist dispenses monthly treatments; counselling on HAART is provided; patient discussion groups are set up; follow-up committees review files in case of adherence difficulties; and patients who miss a pharmacy appointment or a medical consultation are contacted.

Sustaining Financial Accessibility

The initial programme access terms and procedures established to ensure financial accessibility were presented and discussed in Chapter I.1. Economic accessibility to treatment remains a major factor of short- and medium-term non-adherence, indicating that adherence depends firstly on sustained accessibility. Many cases of patients exhausting their resources prompted the revision of contribution amounts — either the fee was reduced or the initially fixed monthly amount was maintained when it would normally have been increased (due to a change in treatment regime or in dosage, for example). Patients could report financial difficulties to the doctor, social worker, or pharmacist when s/he picked up her or his medication. After an examination and update of the social dossier, the request for a fee revision is reviewed by the Welfare Committee (CTAS) and then presented to the Eligibility Committee (CE). At this point, the request is most often accepted, although the amount set is not always that recommended by the CTAS. Twelve cases were thus reconsidered between November 1999 and October 2000, and 11 cases between November 2000 and October 2001.[5]

Other special financial aid mechanisms were implemented for isolated cases: sponsorship by individuals for limited periods (two cases), sponsorship by NGOs (two adult cases[6]), advance dispensation of one week of treatment by the pharmacy pending payment for monthly treatment, and credit or even donations by the pharmacists towards treatment costs.

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[5] The affected patients belonged to all contribution categories. The 12 patients in 1999–2000 were granted an average reduction of 24,000 CFAF and the 11 patients in 2000–2001, 16,500 CFAF on average.

[6] All children treated in the ISAARV programme were sponsored by NGOs before the creation of the International Therapeutic Solidarity Fund (Fonds de solidarité thérapeutique internationale; FSTI programme).

The contribution-revision measure is relatively accessible since patients can discuss their financial problems with the mediator of their choice. It also turned out to be the fairest — since it was least subject to variations in health workers' or patients' abilities to mobilise a sponsorship or an NGO — and the most sustainable. The system's response, however, was inadequate, with significant delays between the notification of the social worker or other ISAARV actors (pharmacist, clinician), the conducting of a new social survey, and the case's submission to the CE. The patient's situation was generally adjusted only after treatment had already been interrupted. These "emergency " measures resolved a few exceptional cases, but remain palliative, insufficient to effectively solve the problem of patients' financial problems, and cannot serve as a standard procedure.

Pharmacist Dispensation and Follow-up

Adherence requires both the continuity of medicine supply and their regular dispensation, and the pharmacist was charged with managing both. Of course, this comes within the pharmacist's ordinary duties. In the ISAARV programme, a system of patient follow-up and of medicine stock supply and management was established specifically for antiretroviral treatments. Management forms were provided to the pharmacist and are regularly updated (see Table 10, Chapter I.4). Monitoring is not computerised at Fann pharmacy, the first dispensation site opened in 1998, nor at the Institute for Social Hygiene (Institut d'hygiène sociale; IHS) pharmacy, the second site, opened in 2001.

The pharmacist is responsible for checking prescriptions against international recommendations. By reading prescriptions and consulting individual dossiers, the pharmacist can assess treatment changes and drug combinations. A telephone line was installed so that s/he could easily reach prescribing doctors in case of possible prescription revisions. A delivery log and diary allows the pharmacist to ensure regular dispensations and to identify patients who do not come or who come late to pick up their medication [5].[7] Inventory cards, completed every month for product and stock quantities, prevent adherence breaches due to shortages of medication.

These measures allow staff to control the regularity of patient visits, and thus of dispensation, while ensuring that no patients lack medicines at the end of the month. Non-negotiable difficulties may arise when the scheduled dispensation date coincides with a holiday or with a prescribing doctor's absence, for example. Follow-up by one or more pharmacists in charge of HAART management at each site appears to be essential to adherence support. The system is limited, however, by the capacity of the staff (and the premises) to integrate patient follow-up into the pharmacy's everyday business. This arrangement is also taxing for the pharmacist, who must not only acquire specific expertise but also keep it continually up-to-date, which is particularly demanding considering the frequency with which new drugs and therapeutic protocols appear.

[7] For more on the role of the pharmacist in ISAARV, see [5].

Counselling at Medical Follow-Up and Dispensation

Counselling for treatment, and more specifically HAART, could be conducted by any number of association or programme actors. The decision in ISAARV was to involve the doctor, the pharmacist, and, to a lesser extent, the social worker in this counselling, given the associations' previously minor involvement in treatment follow-up. This choice had the advantage of placing counselling on a technical level, which facilitated informing the patient about treatment regimens, side effects, etc.— information that other non-specialised contributors could not provide. HAART management demands expertise in the drugs, which means that doctors must be able to solicit the pharmacist for a specialised opinion. Medical consultations include a period reserved for counselling; any issues are noted on the follow-up form at that time. The patient meets the doctor many times during pre-enrolment and enrolment, and then once (at Day 14) during the first month; additional medical consultations were not established for adherence support, as was recommended in Northern countries [14]. Later, the pace of medical follow-up (monthly for the first three years of ISAARV) became less frequent (bimonthly) due to the increase in patients and in response to patient requests. The monthly appointments were too restrictive for some patients on treatment for many months; and besides, patient absence at appointments due to travel is the first reason for adherence interruption (in order of frequency, as reported by patients; see Chapter II.1).

The disadvantage of counselling by the doctor, and then by the pharmacist, is that it restricts conversation of social and relational aspects of treatment; patients see the counselling as purely medical, and sometimes even authoritarian. Any questions regarding adherence cannot be dealt with there. This led to the distinction of two types of counselling: one technical, given by the pharmacist and based on his proficiency, and the other social, which could be carried out by the social workers or association volunteers who had acquired knowledge complementary to their personal experience.

Moreover, counselling requires that confidentiality be ensured at the dispensation site, which can require adjusting schedules and the premises themselves as well as establishing special management procedures. There again, the number of patients that can be seen depends on the pharmacist's available time. The pharmacist must also have the means to respond to patients who encounter difficulties, which can be financial.

Support and Information Groups

In Dakar, information and discussion groups were established at the Ambulatory Treatment Centre (Centre de traitement ambulatoire), one of the initial prescription sites. These groups were not created on very precisely defined methodological bases, and their coordinators were not specifically trained in group organisation or adherence education. The informational parts of these sessions, sometimes led by doctors, sometimes by social workers, seem more important than their intended purposes of providing a forum for patients to share their experiences and offering psychological support. Patients appreciate these groups, not only for their informational content but also because contacts established among patients are pursued outside meetings. Interviews with patients revealed that group members discussed adherence difficulties, managing treatment, or the wish to have children on their own time.

However, the groups set up in Dakar are not yet frequent or regular enough and do not involve sufficient numbers of patients for us to analyse their impact on adherence. The training of support group leaders proposed by CTAS was not yet realised as of the end of 2001.

Case Reviews in Monthly Follow-Up Committees

Enrolment procedures involve the review of each dossier by the Medical Committee and then by the CE. When any adherence problems are suspected or recorded, patients' files may be re-examined by the CE.

The reasons for case discussions were diverse: a patient's departure from the country, change in social status or organisation of the home, exhaustion of resources, disengagement of friends or family members, or a new need for antiretroviral treatment in the household.

The main limitation of this measure is the complexity of procedures, which results in slow responses (each committee meets monthly) and thus a long delay before a decision is reached. In addition, new patient enrolment takes precedence over case reviews of enrolled patients. That said, many proposals resulted in solutions to patients' social and medical issues.

Contacting Tardy Patients

When a patient misses an appointment, or when s/he reports a break in treatment, the social coordinator, pharmacist, or social worker must contact her or him to try to identify the problem. This procedure was difficult to set up since it requires good staff coordination for the intervention to be swift, money (if only for telephone access), and time. Distance, for patients who live far from the dispensation site, as well as confidentiality — which can limit communication possibilities or rule out contacting patients' friends or family members — are also obstacles to this intervention. About 120 people, though, ultimately benefited from phone calls, meetings at the hospital or elsewhere, and in some cases, visits to the home.

The Support System's Impact on Adherence

ISAARV's adherence-support system is part and parcel of its overall framework. Adherence recorded in Dakar during the study period is directly related to the organisation of the health-care system that provided the antiretroviral treatment. To create pertinent proposals for national programmes, beyond pilot projects, it is therefore indispensable to view these measures in their context and to compare them with those set up in other HAART access programmes in the South.

Institutional Factors of Adherence

Establishing tools for management and patient follow-up at the pharmacy appears to be essential for consistent and continuous treatment. These management tools cannot be directly modelled on those used in tuberculosis programmes due to the complexity and diversity of HAART regimens and to the frequent emergence of new molecules and new galenic forms. ARV access

programmes are thus pioneering new ways to monitor chronic illness, which require establishing specific tools that may in turn help to modernise the way pharmacies practice.

In addition, the pilot project was sustained by a bio-clinical research project demanding rigorous medical follow-up, based on forms for data collection and supported by a clinical studies observer (MEC). This monitoring clearly contributed to the regularity and quality of medical follow-up, with the MEC's supervision maximally reducing the number of missing data. The monitoring-assessment of programmes, recommended internationally (see [2] especially), is thus in the patients' individual and collective interest: the quality of intervention improves with the development of knowledge and experience. These aspects of the health-care system's basic functioning are rarely mentioned as contributing factors to adherence, probably because they go without saying in Northern countries.

Programme Scope

In its two first years, the ISAARV programme remained a small-scale pilot project, with the patient enrolment rate limited by the number of prescribing doctors and, in the initial stages, by the poor accessibility of testing in Senegal. Case discussions by the CE testify to the fact that doctors, meeting their patients monthly, know them well and fought to have their assigned financial contribution reduced as much as possible. This rapport, deeper than the usual doctor-patient relationship, probably contributes to improved adherence, as has been shown in other contexts [6].[8] Doctors' confidence in the ISAARV approach likely encouraged patients' faith in treatments, as well [8].[9]

These non-technical aspects of adherence support are not easily planned and are therefore fragile. The increase in the number of patients seen by each health worker, the growing infrequency of medical follow-up, as well as the replacement of some prescribers who had worked in ISAARV since its beginnings, risk reducing the doctor's involvement in each treatment relationship. On the other hand, limits in the number of patients seen by each prescriber and pharmacist and in the number of cases reviewed by committees, the relocation of follow-up committees, and the increased number of dispensation sites to accommodate increased patient enrolment could indirectly contribute to adherence. In addition, maintaining small teams coordinated by site or by committee favours exchange between actors and thus the consistency of information given to the patient regarding his or her treatment.

Distribution of Roles: Medical, Social, and Associational

The distribution of roles in adherence support is similar to that of counselling in HIV screening. Counselling on ARV, as in screening, comes a priori under the doctor's duties. But s/he may not always have the time for counselling, and is

[8] The quality of the relationship between the dispensing person and the patient could, more than the technique of directly observing daily treatment intake, be at the root of the high adherence levels described by P. Farmer et al. in Haiti [6].

[9] See [8] for more on the impact of doctor confidence and of doctor-patient interaction on adherence.

not the best placed to respond to questions regarding the integration of treatment into patients' daily lives. As in HIV testing situations, health professionals tend to delegate counselling to social workers. Similarly, associations were invited to provide counselling within certain health services. HAART follow-up counselling requires, however, greater technical proficiency than that needed for screening. Because of this factor — and of PLWA associations' lesser investment in this domain — adherence counselling and support was established within the health facilities, and then by the intervention of two patient associations led by a hospital social worker,[10] rather than within associations independent of medical services, as is the case in Burkina Faso [13].

The accounts of patients who participated in support groups and in association activities showed that adherence counselling must not be limited to pre-defined topics and confined by an informative and directive approach. Rather, discussion around managing confidentiality, how it feels to be HIV-positive, intra-familial relationships, etc. should be organised. Other forms of support were established within other ARV access programmes, such as the treatment education programme set up in Morocco [9], the Adherence Club in Mali [4], and mediator support in a programme for vulnerable populations in France [1]. They extend along a continuum that ranges from the technical approach, based on the transmission of treatment information, to the psychosocial approach, based on psychological support and on discussion of living with the illness.

In Dakar, roles were distributed among the doctor and pharmacist, which ensured informative technical counselling, and among the social workers and association members at the Ambulatory Treatment Centre, who instituted counselling that was more informed by experience but that maintained a directive approach. A juxtaposition of approaches, founded on professional expertise and/or patient experience, was thus established. This evolution was in keeping with the dynamics of close relationships between associations and health-care services; these associations claim a new, legitimised intervention in the health-care system, comparable to the professionalisation of association counsellors who participate in the UNAIDS Initiative in Abidjan [3].

Roles in adherence support cannot be distributed a priori between the medical, associational, and social sectors, nor assigned without coordination (by way of committees or a reference multidisciplinary team). Some authors criticised the purely individual nature of the adherence approach developed in Northern countries [7], and proposed public health actions around at-risk communities sharing the same difficulties in adherence. Without assuming the validity of the "community" concept in this case, we can see that associations, more than the health services, have the capacity to implement group interventions aimed at particular categories of the population.

[10] ASSAFSA, and then “Bok Jëf.”

Conclusion

An evaluation of ISAARV cannot explicitly identify which measures effectively influence adherence. It can neither specify their overall impact nor measure the respective importance of each. It does, however, yield certain findings related to the feasibility, prerequisites, and limitations of some of the measures that were instituted and adapted pragmatically in Dakar. These findings, though, must be viewed in the framework of a pilot project that only involved, between 1998 and 2001, a small number of patients.

Adherence support identified within ISAARV included, in addition to the guarantee of economic accessibility to treatment: simplified access procedures, dispensation supervision (trained personnel, tools for monitoring treatment continuity, management of stocks, counselling), counselling by professionals from the health, social, and/or associational sectors, interventions for "missing" patients, the establishment of adherence monitoring-evaluation, and coordination among staff.

The ISAARV experience shows that the behavioural dimension of adherence, often given priority in analyses, is in reality just part of the picture. Adherence firstly depends on treatment accessibility over a long period, and then on institutional structure: the organisation of health services, the size and consistency of programmes, and the definition of contributors' roles.

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Chapter II.4
Confidence in HAART

K. Sow, A. Desclaux

The requirement for high adherence to HAART raised questions about patients' confidence in treatment and about the relationship between that confidence and adherence. Whereas adherence entails compatibility of treatment intake with the medical indications [7],[1] confidence in treatment corresponds to the consistency between the patient's and doctor's perceptions of the treatment's value [1, 10].[2] The concept of adherence implies practice. The concept of confidence is more subjective, and refers to individual and group perceptions of treatment. Many studies identified confidence as a determining factor of HAART adherence [13]. PLWA's perceptions of HAART are formed by information received from the doctor and the pharmacist, and from less formal communication about treatment, which extends beyond the medical system and comes particularly from the media and associations. These elements are compared with cultural models of the body, the illness, and the medicine, and are reinterpreted in dynamic relationships between individuals, the health-care system, and society.

Our intention in this chapter is to analyse confidence in antiretroviral treatment within ISAARV. A priori confidence in treatment, which corresponds to social perceptions, must first be discerned. After starting treatment, this confidence is contextualized in patients' perceptions of the body, which are developed from cultural interpretations of treatment. We will examine how patients define effectiveness and the treatment's unpleasant effects. Do social perceptions of HAART have a positive or negative effect on confidence? What clinical effects of HAART are the most valued or least accepted? In what way does the perception of these effects influence adherence? Do health professionals and family contribute to confidence?

Whereas many studies only consider a priori confidence in treatment, the methodology that we adopted, presented in Chapter I.5, based on repeated interviews over a 24-month period, allowed us to study the impact of taking treatment on ISAARV patients' perceptions of HAART — both individually, in close relation to perceptions of the body, and as a group.

[1] This definition of adherence corresponds to the sense commonly used among doctors and epidemiologists, as defined in a reference article [7].

[2] See [1, 10] for a definition of confidence and the distinction between adherence (i.e., “observance” in French), compliance, and confidence (i.e., “adhésion” in French).

A Priori Confidence

Patients' perceptions of HAART are formed firstly from the doctors' introduction to antiretrovirals in the pre-enrolment stage, and then from the pharmacist's comments in monthly consultations. This initial introduction incorporates the usual counselling informational topics, while emphasising HAART's positive effects, the opportunity to benefit from the treatment, and adherence constraints more than on the possible side effects, which are just touched on. Media are another supplier of information about HAART.

An Effective, State-of-the-Art Treatment

Information from the media on the positive results of HAART in Northern countries reinforced its positive representation, and overestimated its beneficial effects to such an extent that most people we met expected an immediate improvement in their health from the start of treatment. Most had little knowledge about possible side effects. They expected above all to be back in good health, with no more pathological symptoms, and to have their appearance and physical capabilities restored.

Perceptions such as those held in African-American populations in the U.S. [11] that were so negative and loaded with suspicion that some PLWA refused treatment, were unusual among ISAARV patients. Observations here are similar to those made in Abidjan, where representations of HAART were generally positive among patients familiar with the medications [2].

The majority of people we met described HAART as “white people's treatment.” Some patients were convinced of the effectiveness of the treatment after having heard accounts from the North: “They told me the medicine was tried there in France and treatment there had positive results.” Television reports reinforced these impressions: “I saw a white person who was saying that he takes these medicines, and he praised their effects. I started to feel reassured then.” Senegalese patients respond as well to the treatment's Northern origin: in Africa, AIDS was identified early in the epidemic as “the white person’s disease.” For some, agreement between the origin of treatment and that of the disease is a guarantee of effectiveness, according to a logic often observed in the context of other pathologies [6].

ARVs were above all considered technically state-of-the-art in the biomedical sphere. Costly, imported treatments that were allocated selectively, they were among medical innovations to which only a small number of Senegalese had regular access. The treatment's scientific nature manifests itself in the requisites for taking the medication, the constraints of medical and biological follow-up, and the regular supplementary tests. This notion of technicality, along with innovation and privilege — all notions associated with modernity — supported confidence in treatment. Eladj, reluctant to take treatment because the observance requirements seemed overwhelming, tried to overcome his apprehension: “I told myself, 'but you're an idiot, why refuse to take them? The details are scary, but that's science, you don't live in the 10th century…. You drive vehicles of how many tonnes of electronic machines and yet you refuse progress. You have to go with the science.' ” These impressions are also shared by “traditional” healers: Bachir said that his marabout advised him to “take these white people's medicines.”

Treatment As Privilege

In the pre-enrolment phase, the doctor's approach influences patient perceptions: doctors introduce access to ARVs as a privilege, subject to physical and economic selection criteria and not available to just anyone. The ISAARV enrolment process, which requires a number of biological tests, a social survey and review by various committees, and, at ISAARV's outset, a relatively high amount of financial participation, contributed to HAART's "elitist" image. A feeling of privilege relative to those without access facilitated acceptance of the medications' constraints and reinforced confidence among patients. Doctors contributed by stressing the real cost of HAART and the amount covered by the government; they presented adherence as the price of this privilege. Patients are then embarrassed, both with the doctors and in considering those who have no treatment access, by breaking adherence. Some patients bring back unused medications "for others."

At the same time, patients know that the sustainability of ISAARV, and thus of treatment, are not guaranteed. The programme was described in the media as the fruit of a political initiative, and patients fear that a reversal of priorities will result in its termination. This insecurity, expressed by many patients in the course of the pilot-project phase, was felt by Eladj: "It was a real concern for me. […] I thought, the day the money runs out or the government stops subsidising the programme, what will become of us?" Although this fear probably faded with ISAARV's expansion and installation, it may have contributed to patients' confidence in treatments they received in the first few years.

The November 2000 ISAARV price reductions facilitated access for patients, who viewed it from then on as less of a privilege. At the start of the Initiative, the people we met took the position, dominant among biomedical practitioners, that only a selection of patients should get treatment; this was no longer the case in 2001. Improved economic accessibility fostered a more assertive position demanding the generalisation of HAART to all HIV-infected people. Until then, the cost of HAART appeared so high to patients that requests only concerned isolated cases. Once a privilege, HAART began to be seen as a common right. The impact of this evolution on patient confidence, however, is not clear.

Ambivalence in Confidence

None of the people we asked thought that HAART cured AIDS. It is something to be taken "until something else is found." For patients, HAART attenuates the illness, lessens its force, and blocks "the disease's children from reproducing" by "blocking it somewhere, stockpiling it." This treatment is only an opportunity, a "respite" that they'll make do with until the research yields a definitive cure, a "vaccine." Some patients are sceptical about the ability of HAART to fight AIDS, still considered a deadly disease. Similar perceptions were observed in France, where patients remain ambivalent, even though ARV treatments are generally considered effective [3, 9].[3] This apparent ambivalence explains why, despite very favourable a priori confidence, some patients have a range of psychopathological responses to HAART.

[3] Eighty-nine percent of people on treatment thought that ARVs had a positive effect on their lives [3].

Positive Effects: Treatment Efficacy

Treatment effectiveness must be physical and social. It depends on the compatibility between the individual and treatment, and on the strength of the medication.

Physical Efficacy: Elimination of Symptoms

The end of pathological manifestations and the restoration of physical abilities testified to HAART's effectiveness among the people we met. The ability to make everyday movements, do housework, and go to the hospital alone are the first indicators of treatment effectiveness. When patients return to work and social activities, they emerge from their isolation and "sick" status. But perceived treatment effectiveness must be confirmed by doctors for patients to feel reassured. Blood tests are seen as tests for "monitoring the strength" of the disease, and patients wish that doctors would give them the results. Some doctors present CD4 as "the body's soldiers" and the viral load as showing the presence of "the disease's child."[4] When doctors announce favourable biological test results, patients' impressions of treatment efficacy are confirmed, and confidence in HAART is reinforced. However, physical manifestations of HAART effectiveness, and their confirmation by doctors, only take on their full meaning for patients when accompanied by social effectiveness.

Social Efficacy: Eliminating the Signs

The normalisation of PLWA's social status depends on the restoration of a normal external appearance, i.e., the disappearance of socially significant clinical signs. According to those questioned, weight loss is perceived by the family as the principal manifestation of AIDS. In Senegal, AIDS is strongly associated with weight loss and death [12]. In this context, the disease's physical aspect assumes a key role: PLWA see weight loss as revealing the degeneration of their health. All visible symptoms likely to suggest AIDS are dreaded — dermatological lesions or "spots," weight loss, or diarrhoea. Worrying about these marks of the disease — in a context in which family suspicion of HIV status is a risk — is one of patients' main preoccupations, and so persistent physical signs of the illness could threaten confidence in HAART. Such was the case for Amie, who interrupted her treatment in part because her "spots" did not disappear.

Those patients who had been thin recount the fear and sometimes rejection that it elicited from their family circle. Family members advised them against or forbid them from going out, for fear of raising or confirming neighbours' suspicions. Change in weight and appetite, biomedical indicators, are pertinent elements in patients' and families' assessment of treatment effectiveness. Marie, a young divorcee, had been sick for many years and had lost 20 kilos before receiving HAART. A few months after starting treatment, she gained 30 kilos and resumed her household and professional work. Her friends asked for her forgiveness "for having thought that she was affected by the bad disease." Very vigilant, Marie regularly monitored the effectiveness of her treatment through her weight. "I know that the medication works well because I gained one kilo since last

[4] "domou jangoroo" in Wolof.

month, and if the medication's strength had decreased, I would have lost weight. I know that as soon as I start to lose weight, the strength is wearing off." Regaining their original appearance or exceeding their normal weight are signs of patients' good health in the eyes of their family, and tend to "erase" the social mark of the disease.

Conditions of Efficacy: Compatibility

Most patients think that the body's capacities should "go with"[5] treatment for them to be able to "bear"[6] it: for HAART to be effective, the body must be compatible with the medicines. Agreement of the individual with the medication and the perception of efficacy both entail "luck," which involves aspects of social and medical history. This compatibility means that the patient is both seriously affected by the illness and yet strong enough to withstand the treatment. Ousmane felt that: "not just anybody can take these medicines. There are people who want to take treatment but their bodies can't handle it." This was also the opinion of Anna, who decided to stop her HAART because "the medications didn't agree with me; my body couldn't withstand them, they were too heavy for me." Some patients try to strengthen their body's ability to "accompany" HAART; they improve the quality and the quantity of their diet by buying fruits and taking extra meals. Their bodies must adapt to HAART's "strength" to guarantee its efficacy. In these cases, patients felt that the treatment was "good for them."[7] This idea of compatibility between the individual and the medicine was described, in different ways, in respiratory infection treatment in the Philippines [5], Hausa pharmacopeia in northern Nigeria [4], and drug treatments in Sri Lanka [8]. In each case, this concept was a way to interpret treatment failures, perceived *a posteriori* as consequences of patient-medicine incompatibility, which bypassed questioning the medication's intrinsic effectiveness.

The "Strength" of AIDS Medicines

The "force" of AIDS is frequently mentioned by PLWA. The disease is perceived as being endowed with exceptional "strength"[8] capable of physical and psychological damage to the point of dehumanizing those affected. People who have experienced episodes of serious deterioration in their health say that the illness crushes their vitality. Marie, who was bedridden for two years, recounts this experience: "It was as if there were eggs, the illness continued to produce new eggs that wipe out your strength. And no matter what illness strikes, you're bedridden. Even if you have a cold, you lie down, your body is always hot. Everything you have, you lie down, all your strength is completely exhausted. The disease is very strong, very strong because it takes you, you change completely, you lose weight and you no longer resemble a human being…." Patients perceive the strength of the medication to be adapted to that of the disease: for a medicine to be efficacious against an illness that serious, it must be "strong." Some patients prepare psychologically for the strength of these effects before

[5] "and" in Wolof.
[6] "attan" in Wolof.
[7] "jigg" in Wolof.
[8] "dole" in Wolof.

beginning HAART. Eladj expected “new sensations,” manifestations of the medicines' strength, but was “pleasantly surprised to not feel anything serious.” The idea that the medications must be “strong” to fight a powerful disease facilitates the acceptance of HAART's unpleasant side effects.

Side Effects

Patients' perceptions of HAART's negative effects include the treatment's toxicity, exhaustion of effectiveness, and side effects. Moreover, some clinical improvements are experienced as annoying symptoms.

Toxicity

ARV “strength” is interpreted as a condition for their efficacy. Yet this strength is accompanied by negative effects that are perceived as consequences of HAART's toxicity. Patients worry in particular about harmful effects on their fertility. The fear of sterility or a decrease in virility resulting from HAART is regularly expressed by almost all patients. Some complain of frequent erections and repeated nocturnal emissions, which they interpret as signs of sexual dysfunction caused by the drugs' toxicity: the ejaculated liquid is thought to come from the transformation of Videx®, whose pills have a milky appearance, while the repeated nocturnal emissions are thought to reduce their virility. These speculations stem from an ethno-physiology of sexuality among the Wolof, who see sperm concentration as assuring masculine fertility and who believe that virility can dwindle with too many ejaculations.

Women's perceptions of HAART's toxic effects on their fertility derive from reinterpretations of information received from doctors. Astou, married for several years, had no children. She followed HAART for one year and was worried about the effects of treatment on her fertility, wondering if the treatment didn't *“upset* something in my stomach. Since it controls the disease, it could also prevent me from having a child.” Astou reinterprets the medical discourse, which forbids women on HAART from having a child for fear of iatrogenic effects. In the clinical trials, in which 8 of the 13 women we spoke to participated, women were required to sign a form of consent to this effect at the start of the trial. During the trial, some doctors specifically insisted that women on HAART use contraceptives for fear of negative effects on herself or the foetus in case of pregnancy. Pregnancy was, moreover, a criterion for non-acceptance in therapeutic trials and in the ISAARV programme.

Some patients wondered about the underlying motives of this potential effect of treatment on their fertility. Fifi, for example, was married for four years, had a two-year-old child, and wanted to have more. Her in-laws also pressured her to have a second child. Her husband had taken HAART for one year, and for several months they had had unprotected sex. She dreaded the consequences of ARVs on her husband's fertility and feared that they were instruments of a policy designed to sterilize PLWA while restoring their health: “Do the antiretrovirals have a negative effect on the reproductive cells? Do the medicines have consequences for the male reproductive cells? Is the medication a contraceptive for women? […] Is the strength of the medicine, the dose, so powerful that it can block life, because I noticed that when I have sex with my husband, the sperm

isn't the same. I thought it was thick before, but now it's fluid — I think the medication is doing that. I told him that the medicines ruin his sperm, it's less thick, there's more of it, he doesn't have erections anymore…. People say that HIV-positive women shouldn't have children, that's why they've put sterilizers in the medicine. Do these medicines make us sterile? Have you ever seen women on medication get pregnant?" Thus, the fear of a social sanction emerges in the fear of HAART's toxic effect on fertility, and the implicit trade-off for PLWA's improved health would be their sterilization. In 1998, the perceptions of treatment toxicity led members of PLWA associations to "discourage" potential HAART users, ironically saying, "They give you these medications to kill you."[9]

It is probably not insignificant, considering the social perceptions of HIV transmission and the guilt associated with it, that perceived HAART toxicity is expressed in the realms of sexuality and fertility. Without over-interpreting this focus, we can at least see it as a testament to the importance of sexuality and, to an even greater degree, procreation in the treatment experience.

Diminished Treatment Effects

Since antiretroviral treatments must be taken continuously, patients fear an accumulation of the medicines in the body: the saturation of these medications in the body would reduce their effectiveness over time, it is thought, due to the dwindling of their effects and to the emergence of the body's "resistance." After a few months, some patients complain of no longer having as great an appetite or of losing weight, and any weight loss is seen as a threat of the illness's return. Patients derive these notions from antimalarial treatment resistance. The example of chloroquine, broadly used during prevention campaigns, is cited: authorities progressively increased the dosages recommended for preventing malaria because of the plasmodia's growing resistance. Patients say that chloroquine "doesn't treat anything" and that HAART could also, eventually, become ineffective. The reasons for this supposed diminution of HAART effectiveness are, however, distinct: patients thought that it would be due not to a resistance of the pathogenic agent, which they did not mention, but to the saturation of medication in the body, as Awa, for example, described.

Awa complained of losing weight, two years after having gained 20 kilos at the start of treatment: "I don't know, I figured that always drinking the medications that accumulate in my stomach could cause my loss of appetite. I figured that the fact that each day, each month, I drink at least 300 pills, and all that stagnates here, plus all the water that I drink, I figured that it stagnates in my stomach. I figured that that could create other illnesses, you never know…. I wonder if there isn't a definite period of time to live when we take these medicines. […] I think of that sometimes. How long does it last, the time when the medications work, 20 years of 30 years or 10 years. I wonder if for this period the medications always work, or if, when the organism is really 'drunk, saturated [with medicines],'[10] they don't work anymore."

The idea of a time limit on life for PLWA profoundly affects people taking treatment. The fear that HAART's effectiveness will wear out does not seem to be

[9] Such perceptions were not reported by patients over the following years.

[10] "mandi" in Wolof.

inferred from information given by doctors. It stems rather from a reinterpretation of the drugs' mechanisms according to local perceptions of physiology, and reveals the perpetual fear patients have of a resurgence of AIDS, which is perceived, after all, as a terminal illness.

Side Effects

Patients' definitions of "side effects" may not match biomedicine's. For doctors, "side effects" are essentially undesirable effects that occur simultaneously with — and secondarily to — the desired therapeutic effect. For patients, however, the order of importance may be reversed. Depending on the meaning given to treatment in the local socio-cultural context, a "side" effect, in the biomedical sense, could be the principal effect sought by the patient.[11] HAART's clinical effects can be perceived by patients as normal or pathological, principal or secondary, depending on their logic.

Most patients had limited knowledge of the possible side effects described by biomedicine, and nausea, vomiting, and tingling feet were interpreted negatively, positively, or with ambivalence. These interpretations do not always depend on the seriousness of symptoms, though their repetitiveness, visibility, and resulting physical and social incapacity are negative factors. Patients tend not to see diarrhoea or hepatitis as possible side effects of HAART but rather as signs of treatment failure and AIDS resurgence. Women were particularly disturbed by nausea and vomiting, as the family naturally associates them with early pregnancy.

While for some, side effects are signs of the treatment's toxicity, for others, their intensity attests to the "strength" of HAART, which, in accordance with the locally popular etiological model, "takes out" the illness. After having been seriously ill, one young patient had a strong allergic reaction at the onset of her treatment. She saw it as a manifestation of the power and effectiveness of her medication: "As soon as you take it, you realize that it's powerful. Because of its effects on your body, how it jolts you, the way it twists up the insides of your stomach, your dizziness, that's how you know the medicine is strong. I never drank medicines that gave me so many side effects. In the beginning, I swelled up and my skin looked like a snake's — if the medicine weren't strong, it wouldn't have caused all that. The medicine is very strong but the virus is even more so, because what it does to a human being is terrible, it's too much." The perception of physical symptoms from taking HAART paradoxically reinforced this patient's confidence in the treatment's efficacy. However, some patients interpreted disabling symptoms differently; they declared having been "surprised to discover the emergence of other illnesses while they were under treatment." Following the advice given by their family, they suspended or reduced the prescribed dosage. For some people we met, "side effects" were reminders of the reality of AIDS. They saw these symptoms as revealing the virus's presence in the body and reviving the illness despite the presence of other physical improvements.

[11] For example, weight gain induced by corticoids is sought after by users in Southern countries.

Improvements as Symptoms

From a medical point of view, weight gain is due essentially to increased appetite, noticed by most patients. Some confess to taking five to six meals a day and attribute this to HAART, particularly those who felt their stomachs "hollowed out" when they took medication on an empty stomach. All those questioned appreciated this recovered appetite, which to them showed the efficacy of their therapy. They were, however, forced to eat more and according to regular hours, which created additional financial expenses and required rearranging living habits. PLWA who were in precarious situations, lacked personal resources, or depended on family group meals were annoyed by this increased appetite. Some said that they occasionally skipped their HAART when they did not have enough to eat well. But the majority of patients set up strategies to adapt: meals taken alternatively at homes of different family members, buying food for in between meals, etc.

For some patients, improved health was also accompanied by revived sexual desire, which actualised questions tied to sexuality. Perceived as a beneficial effect of treatment, this renewed desire went along with, for some men, erections and nocturnal emissions, which were seen as signs of toxicity. The women we spoke to feared transmitting the virus and having to confront questions or criticism if they used condoms with unaware partners.

These two aspects — appetite and sexuality — show patients' ambivalence towards treatment effects. Treatments and their effects can be perceived positively and can create new limitations, as well, which, irrespective of patient confidence, lead some patients to adjust their medicine intake.

Conclusion

In addition to perceptions of HAART's efficacy, patients' ideas about its toxicity, exhausted potency, benefits experienced as annoying symptoms, and side effects reveal their interpretations of the effects of HAART. Patients are a priori confident in ISAARV objectives, treatment regimens, and treatment restrictions. But representations of the body, physiology, and bodily fluids are marked by individual perceptions and cultural models that influence confidence. Although the information delivered by doctors and the media are not based on the same concepts, these examples, which relate to fundamental notions of "strength," "saturation," "compatibility," and "toxicity," structure long-term confidence. This construction of confidence in treatment becomes particularly important when patients stop considering treatment a privilege, when they have noticed its first beneficial effects, and, in some cases, when the treatment's bio-clinical efficacy fades from the patient's view.

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Part III
Treatment Efficacy and Impact

Chapter III.1
Clinical and Biological Assessment of HAART in the ISAARV Programme

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The use of antiretroviral (ARV) combination therapy has markedly decreased morbidity and improved the survival and quality of life of people living with HIV (PLWA) in the North [3, 6, 15]. In the South, and especially in Africa, the use of these drugs has been hindered by the high costs of drugs and reagents [17], inadequate infrastructure and a lack of trained medical staff [16], unreliable drug and reagent supply, and limited access to screening. These obstacles are compounded by problems inherent to this type of treatment, such as its complexity, drug interactions [22], adverse effects [4], the frequency of viral hepatitis potentiating ARV hepatic toxicity [1, 26], problems with adherence [7, 10], the emergence of resistant viral strains [2, 32], the poorly documented clinical and biological efficacy of highly active ARV therapy (HAART) in patients infected by non subtype B strains of HIV-1, and the reduced efficacy and increased risk of toxicity and severe immune reconstitution syndromes in patients treated at an advanced stage of HIV disease [12, 27]. Launched in August 1998, ISAARV was one of the first African antiretroviral access programmes. An interim assessment at 18 months [20] gave encouraging results in terms of feasibility; virological, immunological, and clinical efficacy; adherence; clinical and biological tolerability, and the emergence of viral resistance in the first 60 treatment-naive patients to receive three-drug regimens. Clinical and biological results were similar to those seen in industrialised countries, despite the very different distribution of HIV-1 subtypes (predominance of recombinant strain CRF02_AG) and participants' poor clinical status at enrolment. Contrary to studies in other African countries, viral resistance rarely emerged during follow-up (only two cases). The objective of this analysis was to obtain an updated and more detailed assessment, with longer follow-up (30 months) and a larger number of patients, some of whom had received HAART before their enrolment in the ISAARV programme.

Methods

Study Design

A prospective observational multi-centre cohort study was conducted in Dakar among ISAARV participants enrolled in the program between August 1998 and February 2001, with approval from the Senegalese National Ethics Committee on HIV/AIDS. After giving their written informed consent, HIV-1-infected patients were eligible if they met certain social (cf. Chapter II.1) and medical criteria. ARV-naive patients were eligible if they were asymptomatic and had a CD4+ T lymphocyte count below 350/mm^3 and plasma viral load above 100,000 copies/ml; or if they were paucisymptomatic and had a CD4+ cell count below 350/mm^3; or if they had AIDS and a Karnofsky score of at least 70% but no major opportunistic infections (such infections had to be treated before beginning HAART). Patients who had received ARV before enrolment in the programme did not have to meet these criteria. At the outset of the programme, first-line treatment consisted of three-drug regimens combining two nucleoside reverse transcriptase inhibitors (NRTI) and one protease inhibitor (PI). However, paucisymptomatic patients with plasma viral load below 10,000 copies/ml, and patients whose viral load and CD4 cell count were already controlled by a two-drug regimen received only two NRTI. After new guidelines were issued in October 2000 [31], all treatment-naive patients received a three-drug regimen combining two NRTI and one PI or one non-nucleoside reverse transcriptase inhibitor (NNRTI). Four NRTI (stavudine [d4T]; didanosine [ddI]; zidovudine [ZDV]; lamivudine [3TC]) and one PI (indinavir [IDV]) were available at the outset of the ISAARV programme; another PI (nelfinavir [NFV]) and an NNRTI (nevirapine [NVP]) became available in late 2000. Patients had monthly clinical examinations throughout follow-up.

Laboratory Methods

Plasma HIV viral load was initially determined using the Bayer bDNA HIV-1 Quantiplex assay (Bayer Diagnostics, Emeryville, California, USA) version 2.0 (cutoffs 500 to 800,000 copies/ml), and subsequently with the ultrasensitive version 3.0 (cutoffs 50 to 500,000 copies/ml) on plasma samples stored at -80°C. T lymphocytes were counted in fresh blood with a Facs-Count device (Becton Dickinson, Mountain View, California, USA). Viral load and CD4 cell count values obtained less than three months prior were required at enrolment. Viral load was measured after one month of treatment, then, together with CD4 cells, after six months of treatment, and subsequently every six months.

HIV-1 isolates were characterised genetically by sequencing analysis of the *env* and *gag* genes [30]. Part of the *pol* gene coding for the viral protease and reverse transcriptase (RT) was also sequenced to detect mutations associated with resistance [33]. In brief, RNA was extracted from plasma (QIAAMP Viral RNA Mini Kit, QIAGEN, France) and reverse-transcribed into complementary DNA (Expand RT, Boehringer Mannheim, Germany). The gene encoding the viral protease and RT was then amplified from this cDNA by means of nested PCR, and directly sequenced (ABIPRISM Big Dye Terminator Cycle Sequencing Ready Reaction Kit, Applied Biosystems, France). The sequence thus obtained

(1800 bp) was analysed phylogenically (CLUSTAL W programme) to determine the genetic subtype of the isolate [29, 33]. The deduced protein sequence was then compared with a reference sequence to detect resistance mutations.

Medical Evaluation and Adherence Monitoring

The clinical stage of HIV disease at enrolment (including AIDS) was determined according to 1993 CDC classifications [5]. Adverse effects of HAART were assessed according to the World Health Organization toxicity scale. If mild (grade 1) or moderate (grade 2) adverse events occurred, HAART was continued under close medical monitoring. If severe (grade 3) adverse effects occurred, the culprit drug was discontinued until the event subsided to grade 1 or 2. The culprit drug was permanently withdrawn if life-threatening adverse events (grade 4) or recurrent severe adverse effects occurred. The adherence data reported here were collected by the clinicians during oral interviews with the patients at each monthly visit. Adherence was calculated as the ratio of the number of effective intakes to the number of prescribed intakes.

Statistical Analysis

The main endpoint for efficacy was the proportion of patients with plasma viral load below 500 copies/ml in an intention-to-treat analysis. Missing data were equated to failure. We also conducted an as-treated analysis, which excluded patients who discontinued their treatment, partially or totally, in the month preceding the measurement.

Regarding plasma viral load, the relevant test cutoff values were attributed to samples with values below the detection limit or above the upper limit of quantification. The reduction in viral load was analysed on a decimal logarithmic scale ($\log_{10}$). Wilcoxon's rank test for paired data was used to analyse changes in adherence, viral load, the CD4 cell count, and the body mass index relative to baseline. Survival probabilities were estimated with the Kaplan-Meier method. Risk factors for death were then sought using a Cox proportional hazards model. For this purpose, the hypothesis of risk proportionality over time was verified using the Schoenfeld residuals. If this hypothesis was rejected, a stratified Cox model was used. Independent variables associated with mortality ($P < 0.25$) in univariate analysis were included in the multivariate analysis. A descending stepwise selection procedure was used to obtain the final model containing only significant variables and confounding variables [18].

The analysis of drug-resistant strains was restricted to patients who had a minimum virological follow-up of six months. The test was done at enrolment in a random sample of naive patients and in all previously treated patients, then at each viral load rebound during follow-up. Viral rebounds were defined by viral load values above 1000 copies/ml, i.e. the detection limit of the genotyping test.

Patients accrued gradually in this cohort study between August 1998 and February 2001. Thus, at the time of this analysis, the length of follow-up varied from one patient to another, and was sometimes less than 30 months. This meant that a diminishing number of patients were analysed as follow-up increased.

All tests were interpreted at the 5% level of significance, and 95% confidence intervals were calculated. The computer programmes Epi Info version 6.04 (Centers for Disease Control and Prevention, Atlanta, U.S.A) and Stata 7.0 (Stata Corporation, College Station, Texas, U.S.A.) were used for statistical analyses.

Results

Patients' Baseline Characteristics

Ninety-six patients over 15 years of age were enrolled in the study, of whom 81 (84.4%) had never received antiretroviral drugs. Median age was 39 years, and the two genders were equally represented (cf. Table 14). Most patients were at an advanced disease stage, with severe immunodeficiency and high plasma viral load; 84.4% of patients already had AIDS.

Only four patients had dual HIV-1/HIV-2 infection (cf. Table 14). Broad genetic diversity was observed in both the *env* gene (n = 80) and the *gag* gene (n = 74). Two patients were infected by group O strains, while all the other patients were infected by group M strains. The recombinant strain CRF02_AG was found in about half of patients.

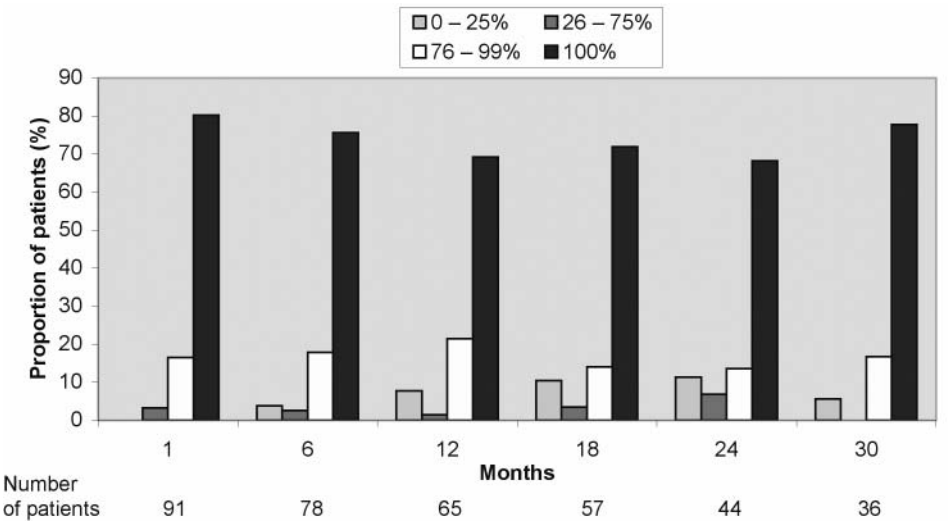

Figure 23
Patient distribution according to adherence category

After enrolment, most patients (89.6%) received a three-drug regimen combining two NRTI and one PI. Together with IDV, 60 patients (62.5%) received d4T and ddI, 17 patients (17.7%) received ZDV and 3TC, three patients (3.1%) received ZDV and ddI, three patients (3.1%) received d4T and 3TC, and one patient (1.0%) received ddI and 3TC. Two other patients received NFV, combined with d4T and ddI in one case, and with ZDV and 3TC in the other case. Only two patients received a three-drug regimen combining two NRTI (d4T and ddI or ZDV and 3TC) with one NNRTI (NVP), and eight patients received only two

NRTI (d4T and ddI). However, 10 patients (10.4%) started treatment without the prescribed PI, owing to concurrent antitubercular therapy; the PI was only added at the end of rifampicin therapy. Cotrimoxazole prophylaxis for opportunistic infections was prescribed to three-quarters of patients (70/96).

Table 14
Characteristics of patients at enrolment

Characteristics	Value	
Sex – n (%)		
Male	47 (49.0)	
Female	49 (51.0)	
Age in years		
Median	39	
IQR*	32–46	
HIV type – n (%)		
HIV-1	92 (95.8)	
HIV-1+2	4 (4.2)	
Subtype – n (%)	*env*	*gag*
Group O	2 (2.5)	2 (2.7)
Group M subtype A	18 (22.5)	17 (23.0)
" " " B	5 (6.3)	4 (5.4)
" " " C	6 (7.5)	6 (8.1)
" " " D	3 (3.8)	1 (1.4)
" " " G	4 (5.0)	5 (6.8)
" " " J	1 (1.3)	-
CRF02_AG†	40 (50.0)	39 (52.7)
CRF06_AGJK†	1 (1.3)	-
Clinical stage – n (%)‡		
A	5 (5.2)	
B	29 (30.2)	
C	62 (64.6)	
CD4 cells/mm^3		
Median	124	
IQR*	38–236	
Plasma HIV-1 viral load – copies/ml		
Median	95,740	
IQR*	17,970–225,200	
Hemoglobin – g/d		
Median	10.6	
IQR*	9.2–12.1	
Body mass index		
Median	20.1	
IQR*	18.5–22.6	
Karnofsky score – n (%)		
70	3 (3.1)	
80	10 (10.4)	
90	51 (53.1)	
100	32 (33.3)	

* Interquartile range; † "Circulating Recombinant Form"; ‡ Centers for Disease Control and Prevention classification.

Follow-up and Adherence

Twenty-eight patients (29.2%) were recruited and monitored at the military hospital and 68 patients at Fann Teaching Hospital — 38 (39.6%) in the Ambulatory Treatment Centre and 30 (31.3%) in the Infectious Diseases Unit. During the

study period, patients were followed for a total of 164 person-years and for a median of 23 months (interquartile range [IQR]: 11–30 months). Two patients withdrew from follow-up, one patient in the first month and one in the second.

On average, monthly adherence was 100% in 72% of patients, between 76% and 99% in 17.7% of patients, between 26% and 75% in 3.4% of patients, and between 0% and 25% in 6.9% of patients. Adherence tended to diminish during follow-up (cf. Figure 23): it was significantly lower at 12 months ($P = 0.04$), 24 months ($P = 0.01$), and 30 months ($P = 0.02$) than during the first month of follow-up. Indinavir was the drug most often responsible for problems in adherence (82.5%), followed by ddI (44.8%), d4T (43.2%), ZDV (16.8%), 3TC (14.3%), NFV (0.9%) and NVP (0.5%); the frequency of prescription at enrolment was as follows: IDV 87.5%, ddI 77.1%, d4T 76.0%, ZDV 22.9%, 3TC 24.0%, NFV 2.1% and NVP 0.5%.

Virological and Immunological Responses

After one month of treatment, plasma viral load was below 500 copies/ml in two-thirds of patients (cf. Figure 24). This proportion fell during the first year before stabilising at approximately 50%. It was markedly higher (by up to 25%) in the subgroup of patients receiving whole treatment (as-treated analysis).

Plasma viral load was significantly lower during follow-up than at enrolment ($P < 0.001$). After the first month of treatment, the median reduction was about 2.3 $\log_{10}$ copies/ml (cf. Figure 25). However, virological efficacy appeared to diminish in more and more patients. CD4 cell counts became significantly higher than at baseline from the sixth month of treatment ($P < 0.001$) and increased gradually (cf. Figure 26).

Clinical Responses

The body mass index only increased significantly during the first year of treatment (median, 21.7 [IQR, 19.7–24.3; $P < 0.001$] and 21.2 [IQR, 19.3–24.2; $P = 0.01$] at 6 and 12 months, respectively), tending to fall thereafter (median, 20.7 [IQR, 19.4–23.6; $P = 0.3$], 20.8 [IQR, 18.8–22.9; $P = 0.5$], and 20.9 [IQR, 19.2–23.2; $P = 0.5$] at 18, 24, and 30 months, respectively).

Nineteen deaths occurred (19.8%; CI, 12.4–29.2%), mainly during the first year (median, 6 months; IQR, 4–11 months). The incident mortality rate was 11.6 per 100 person-years and the survival probability was 89.4% (CI, 81.1–94.1%), 82.3% (CI, 72.8–88.8%), 81.1% (CI, 71.3–87.8%), 79.7% (CI, 69.6–86.7%), and 78.0% (CI, 67.5–85.5%) after 6, 12, 18, 24, and 30 months of treatment, respectively. All the patients who died had AIDS at enrolment, and treatment was interrupted in 12 cases several weeks or months before death (median, 2 months; IQR, 0.9–3.5 months), for either medical reasons (n = 8) or non-adherence (n = 4).

After adjustment for the other factors, mortality was significantly associated with a low Karnofsky score at enrolment and with mediocre or poor adherence to HAART (cf. Table 15). The causes of death were infections in nine cases (septicemia, gastroenteritis, pneumonia, malaria, tubercular meningitis, *Mycobacterium avium* infection, acute hepatitis), altered general status in three

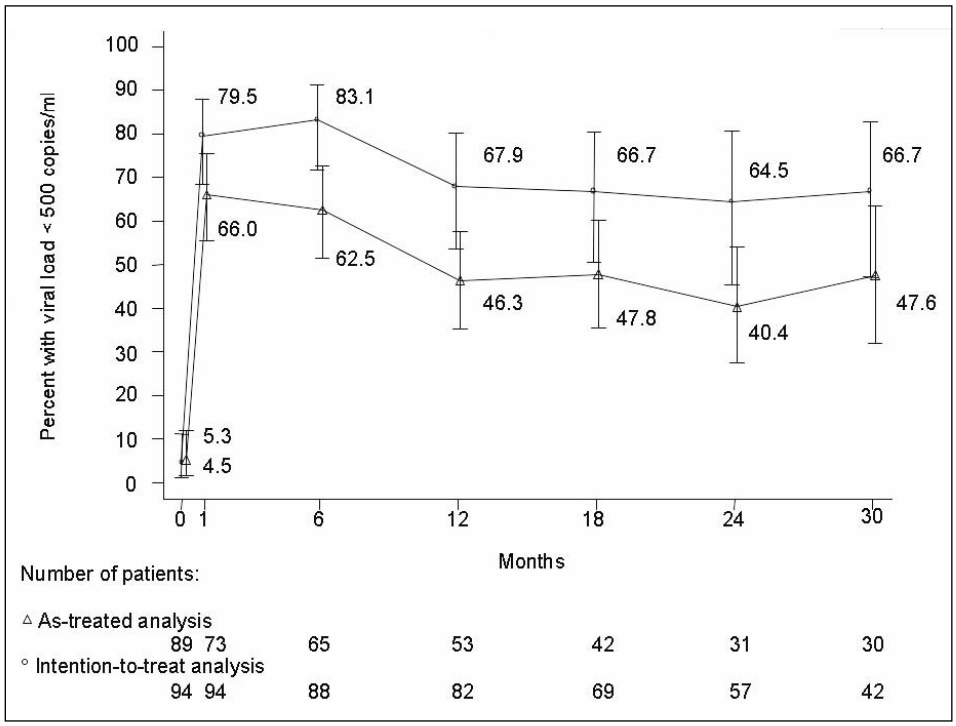

Figure 24

Percentage of patients with plasma viral load < 500 copies/ml in the intention-to-treat and as-treated analyses (confidence interval)

cases, pancytopenia in one case (this patient had stopped taking ARVs six months previously) and unknown in four cases. A link between death and HAART could not be ruled out in two cases: one patient, treated with d4T, ddI, and IDV, died of severe metabolic acidosis with coma, but a bacterial infection was also diagnosed; the second patient, treated with d4T and ddI, died at four months with fulminant hepatitis after using traditional remedies, but liver dysfunction was present from enrolment (ALT 167 IU/l). Laboratory tests showed virological and immunological efficacy in four patients, paradoxical results in two patients, and virological and immunological failure in three patients. Changes in the CD4 cell count could not be assessed in six patients, but virological efficacy was noted in four cases and virological failure in two cases.

Adverse Events

A total of 79 adverse events occurred in 47 patients (49.0%). Three-quarters of these events were gastrointestinal disorders (nausea, vomiting, diarrhoea), but there were also eight cases of lipodystrophy, four cases of hepatitis, two cases of anaemia, and two episodes of urinary lithiasis in the same patient. Most adverse events were mild (41/75, 54.7%) or moderate (23/75, 30.7%), but six severe adverse events occurred (8.0%) (hepatitis [n = 4], jaundice with gastroin-

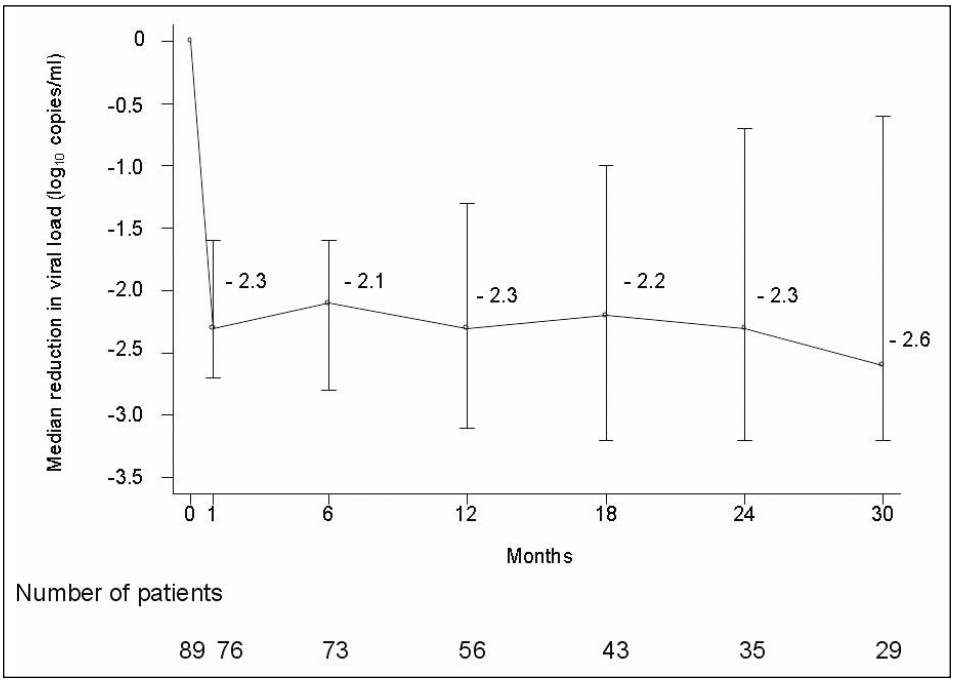

Figure 25

Median reduction in plasma viral load (interquartile range)

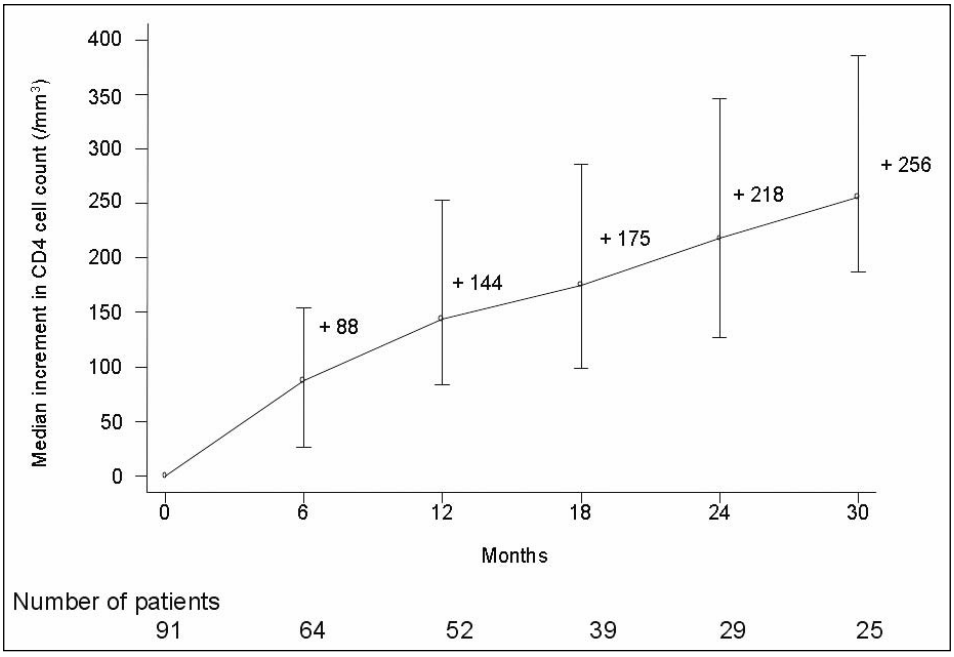

Figure 26

Median increment in the CD4 cell count (interquartile range)

testinal disorders, and abdominal pain) and five events (6.7%) were life-threatening (anaemia [n = 2], pancytopenia, jaundice with gastrointestinal disorders, and isolated gastrointestinal disorders).

Adverse events led to partial or total treatment interruption in 26 cases, followed by a treatment switch in 10 cases. In about half these cases (14/26), the treatment interruptions were due to IDV-related gastrointestinal intolerance.

Table 15
Factors associated with mortality

Variables	Univariate analysis			Multivariate analysis		
	HR	95% CI	*P*	HR	95% CI	*P*
Follow-up centre						
Centre 1	1.00					
Centre 2	1.03	0.36–2.98	0.95			
Centre 3	0.79	0.24–2.59	0.70			
Gender						
Male	1.00					
Female	1.87	0.74–4.76	0.19			
Age						
≤ 45 years	1.00					
> 45 years	1.70	0.67–4.34	0.26			
Genotype						
Pure subtypes	1.00					
CRF recombinants	0.95	0.32–2.84	0.93			
Other recombinants	1.66	0.32–8.56	0.55			
Baseline CD4 cell count						
≥ 500/mm^3	1.00					
200–499/mm^3	0.87	0.20–3.86	0.85			
< 200/mm^3	0.51	0.09–2.79	0.44			
Baseline plasma viral load						
≤100 000 copies/ml	1.00					
> 100 000 copies/ml	2.30	0.87–6.07	0.091			
Baseline hemoglobin level						
≥10 g/dl	1.00					
<10 g/dl	2.36	0.95–5.87	0.065			
Baseline body mass index						
(per 1-unit increment)	0.87	0.75–1.02	0.097			
Baseline Karnofsky score						
90–100%	1.00			1.00		
70–80%	2.54	0.91–7.05	0.075	3.35	1.17–9.60	0.025
HBs antigenemia						
Negative	1.00					
Positive	0.70	0.09–5.66	0.73			
Previous ARV treatment						
No	1.00					
Yes	1.44	0.48–4.34	0.52			
Dual-agent therapy during follow-up						
Never	1.00					
Sometimes or always	0.93	0.35–2.46	0.89			
Number of adverse effects during follow-up						
0	1.00					
1	0.65	0.20–2.07	0.47			
≥2	0.92	0.31–2.70	0.88			
Mean monthly adherence						
≥ 95%	1.00			1.00		
< 95%	2.51	1.01–6.24	0.048	3.03	1.18–7.74	0.021

Drug Resistance

Of the 80 patients who had a minimum virological follow-up of six months, 68 had never previously received HAART. At enrolment, isolates from 41 treatment-naive patients (60.3%) and six of the eight previously treated patients with detectable viral load were screened for resistance mutations; the other two previously treated patients could not be analysed because their viral load was below the detection limit of the resistance genotyping method (<1000 copies/ml). Only one isolate showed resistance to an ARV (ZDV) and possible resistance to d4T and abacavir, due to a combination of mutations M41L, D67N, L210W and T215Y; this patient had previously received ZDV and ddI.

During follow-up, resistant strains emerged in eight ARV-naive patients (11.8%; CI, 5.2-21.9%) and in five previously treated patients (41.7%; CI, 15.2–72.3%) after a median of 18.3 months (IQR, 16.4–23.1 months) and 17.8 months (IQR, 12.4–19.7 months), respectively. Observed genotypic mutations conferred resistance to 3TC (n = 5), ZDV (n = 4), nelfinavir (n = 1), d4T (n = 1), ZDV/3TC/PI (n = 1), and indinavir/ritonavir/nelfinavir (n = 1). Surprisingly, three patients developed mutations associated with resistance to compounds they had never received (ZDV, n = 2; nelfinavir, n = 1) and two patients to ARVs they had received 18 or 36 months ago.

Discussion

This study, involving longer follow-up and a larger number of patients, including antiretroviral-experienced patients, confirms and extends the results of the previous interim analysis [20]. Well-conducted antiretroviral treatment is thus feasible and as effective in the African context as in the North, despite the advanced clinical stage at treatment initiation among patients infected by non subtype B strains of HIV-1.

Virological and immunological results were also similar to those obtained in Northern countries [3, 11, 14, 15, 28]. The proportion of patients with undetectable viral load in the as-treated analysis remained stable and satisfactory beyond the first year, and the immunological status improved gradually throughout the 30 months of follow-up. The relatively small proportion of patients with undetectable viral load in the intention-to-treat analysis would mainly be due to the large number of patients who died or dropped out of follow-up, in whom treatment was considered to have failed.

Mortality was particularly high (11.6 deaths per 100 person-years). However, all the patients who died already had AIDS at enrolment, and antiretroviral treatment is known to be less effective in the later disease stages [6, 13]. In our study, this was confirmed by the observed link between mortality and altered general health status at enrolment. Furthermore, most deaths occurred during the first months of treatment, before immune defences had time to recover [8, 19, 21, 23] and infections were the main cause of death in these profoundly immuno-depressed patients. This calls for greater efforts to diagnose and treat intercurrent infections. Moreover, HAART had been interrupted for at least several weeks before most deaths, because of medical reasons or non-adherence.

The good overall adherence based on patient-physician interviews was probably overestimated [9], but was nonetheless corroborated by data collected by

participating pharmacists (cf. Chapter II.1). It was also supported by the good virological and immunological responses to treatment and the low incidence of viral resistance during follow-up. Nevertheless, it must be noted that adherence was poor in several cases, generally for financial reasons (most data used in this study were obtained before ARV price reductions, and some patients were unable to pay for their treatment despite governmental subsidies). During certain months, more than 10% of patients had very poor adherence (<75% of prescribed intakes). The minimal level of adherence required for good treatment efficacy is not precisely known, but the analysis of factors associated with mortality showed that an adherence level of at least 95% was crucial in our study, confirming results reported by other authors [24, 25]. An analysis based on an adherence cutoff of 90% showed no significant difference in mortality (data not shown). Further studies are needed to determine the adherence threshold below which patient support must be reinforced.

Overall, antiretroviral treatment was well tolerated, and most adverse effects were mild or moderate. Nevertheless, gastrointestinal disorders, often linked to indinavir, caused major problems of adherence and patient management, sometimes leading to partial or total treatment interruption. This problem was amplified by the fact that indinavir was initially the only compound available for combination with two NRTI as part of three-drug regimens. Another PI and an NNRTI became available in late 2000, and this should strengthen the global efficacy of the programme.

While this study shows that antiretroviral treatment is feasible and effective in the African context, it also reveals certain limitations of the ISAARV programme, especially regarding the diagnosis and treatment of intercurrent infections. This information is particularly welcome at a time when the programme is gradually being expanded to cover the entire country, following the recent ARV price reductions. Management of intercurrent infections should now be a top priority in health-care structures already distributing ARVs, and should be made an integral part of new structures. High-quality patient management must continue to be the guiding principle of the ISAARV programme.

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Chapter III.2
Living with HAART in Senegal

K. Sow, A. Desclaux

Highly Active Antiretroviral Treatment (HAART) inevitably has a major impact on patients' daily lives. In addition to being financially restrictive, as was discussed in previous chapters, the bio-clinical effects are manifold. The treatments are so effective that the resulting improved health triggers what is described in Northern countries as a "biographical change" in what patients had theretofore perceived as their fatal course [3]. The treatments' somatic side effects and concomitant medical follow-up leads patients to view their condition instead as a chronic illness. Socially, ARVs are loaded with implications: they are considered "markers" of HIV infection, exposing PLWA to stigmatisation and fears of contagion, and giving them a "sick" role and status.

The patient must simultaneously manage these restrictions, somatic effects, and social implications, which are in constant interaction and which assume relative importance depending on the individual and her or his living conditions and social engagement, according to terms that can evolve over the course of treatment.

Thus, ARV treatment has multiple repercussions on how patients live with their illness and on their perceived quality of life. These repercussions do not affect only patients — who attach varying significance to each — but also everyone in their lives. Patients' close relationships can instil varying meanings in the medications; and the relationships can in turn be changed by these meanings.

More and more, international organisations and PLWA associations are calling for the establishment of family-based HIV treatment, in which PLWA are not considered or treated in isolation: his or her "family" (mainly his or her partner — or *partners* in polygamous homes — and children) is also tested and receives treatment. Within ISAARV, the family element of treatment is based on social worker interventions with patients and on setting up therapeutic regimens for children. Although this system has only been progressively and partially operational, the experience of ISAARV patients has shed light on how partners and families cope with treatment, dynamics that must be considered when designing a real family treatment programme.

Our objective in this chapter is to understand the experience and effects of treatment in Senegalese patients' relationships with their family circle, by way of comments gathered from 26 patients over a two-year period.[1]

[1] The study population and methodology were presented in Chapter I.5.

Living with Treatment in Couples and Families

The patient comments cited in Chapter II.4 attest to the importance of their primary symptoms disappearing. In addition to restoring well-being, this clinical recovery removes the AIDS stigma and reinstates patients' "social normality," allowing them to recover their former social status. Most patients express their "gratitude" to the ISAARV team for their renewed health.

One of the main determinants of quality of life under HAART is whether or not the patient has kept a secret of her or his HIV status and the medical treatment that it entails. In the ISAARV programme, the medical and social team does not directly suggest HIV testing to partners, but recommends that patients disclose their serological status and mention testing with their partners; the doctor offers to help patients with this announcement if they wish. Many of the deciding factors in disclosing HIV status to partners or to family members were mentioned in preceding chapters, such as the confidants' presumed attitude towards PLWA, their knowledge about the illness, and their resources and abilities to support the patient. Other aspects are presented below.

Treatment within the Couple

One partner's taking ARVs will certainly trigger questions from the other about HIV status and treatment access.

Among the 26 patients we questioned, 12 had partners. Two couples had different serological statuses; eight were jointly HIV-positive; and two patients did not know the status of their partner, one of whom, in a polygamous marriage, did not disclose his HIV infection to his wives. With no income, he is supported by his brothers. He is scared that his family would reject him if they discovered his status, but more than that, he fears not being able to pay for the treatment of his wives if it turns out that they are HIV-positive.

All patients mentioned difficulties in sharing their HIV information with their partners. Some admitted having deliberately concealed their status before being compelled to break the news, usually under the influence of health professionals. For the majority, access to HAART facilitated this revelation. But at the beginning of ISAARV, the onus of a double financial commitment was a major limitation in treatment access, causing patients to question the benefit of disclosure.

In some couples, the financial contribution created conflicts or rekindled old points of contention, as in Astou's case. Astou's husband, an immigrant from Central Africa, was assumed by her family to be responsible for transmitting the HIV virus to his wife. A labourer in the informal sector with precarious resources, he was enrolled in the ISAARV programme and had declared himself incapable of paying the contribution for his wife's ARV treatment. His in-laws ordered the young woman to divorce him. Humiliated, her husband ended up accepting the responsibility for treatment costs upon the mediation of an ISAARV social worker. Astou felt that her husband's responsibility in transmitting the virus justified his paying for her treatment, and inversely, that his acceptance to pay proved his culpability: "If it hadn't been him, he wouldn't have agreed to pay." In the end, Astou was granted fully subsidised ARV treatment due to her husband's inability to maintain his financial commitment.

The difficulties that couples face are closely linked to the culpability and censure of the partner suspected of introducing the virus. Partners who see themselves as “victims” consider themselves entitled to wield power over their partner. A power dynamic founded on each partner's levels of financial resources and guilt is thus established, which determines their future conjugal relations. The capacity of the partner presumed “guilty” to cover treatment costs is a key issue. The case of a businesswoman who paid the treatment costs for herself and her partner illustrates these loaded interactions. Suspected by her husband of bringing on their infection, she threatened him in every argument with the ultimate retort: “If that's the way it is, you can say good-bye to treatment.”

The ability of two partners to have simultaneous treatment access can also be a stabilising force for the relationship. In the early months of ISAARV, the practice of sharing ARVs was observed in cases where one partner lacked the means to participate in the programme. In other couples whose relations were already confrontational, the financial restrictions to ARV access could destabilise the relationship. The programme's price reductions thus facilitated access for partners, encouraged patients to share information, and allowed for greater couple solidarity. Most couples we met felt that their HIV status precluded the possibility of separation, condemning them to stay with their partners “forever.” On the other hand, some felt that being a couple was an asset to managing the illness and its treatment.

All the couples we questioned feared the repercussions of disclosure to family members and wished to handle their daily lives on their own. They try not to seek family mediation in marital conflicts for fear that this involvement would destabilise the relationship. If the couple has sufficient resources, the management of HIV and HAART remains strictly between themselves. But in the reverse scenario, each member turns to his or her own family for financial support, which tends to result in other people interfering in the couple's private life. Because of this, Ndeye said that despite her and her partner's financial struggles to pay for treatment, she “keep[s] up appearances. When I have a problem, even if it's very hard, I prefer to keep[s] it to myself.” Divorce is no longer considered by partners, despite the conflicts which, under other circumstances, might have initiated a separation. Coupledom becomes a space for confidentiality in which priorities are redefined to make them more conducive to treatment access.

Effects on Sexuality

Patients' sexuality was discussed at the start of the ISAARV programme, particularly with married couples. Others refused to talk about it, asserting that they have maintained abstinence since their HIV diagnosis. This attitude is often indicative of shame and guilt that single, divorced, or widowed patients feel about their sexuality. Moreover, contrary to popular beliefs that PLWA who are aware of their status have unprotected sex because “they have nothing to lose,” interviews conducted with patients at the start of their treatment indicated that the majority no longer had sex for fear of contaminating others and due to feelings of depression. After a year of ARV treatment, more married patients and some who were single or widowed agreed to talk about their sexuality.

Improved health tends to reawaken sexual desire. Resuming sexual relations

becomes a sort of resocialisation indicator for patients on HAART. Divorced, single, and widowed patients talk about the difficulty of going back to their partners and having sex after long periods of abstinence. Some get back together with former lovers, but most seek new HIV-positive partners in PLWA associations or discussion groups. The issue of protected sex inevitably comes up in contexts similar to those in the general population, which was also described in Abidjan [1]. Condom use may be difficult to enforce, especially for those who have not disclosed their HIV status, and above all for women, whose partners do not take kindly to a woman taking this initiative. Despite the fact that protected sex is medically recommended, all those we spoke to felt that condom use was incongruous with an "established" relationship, especially when both partners are infected. The attitudes of seropositive couples were varied; some incorporated condoms into their sex lives, while others refused. Bachir, for example, withdraws before ejaculation, and his wife washes the vaginal area with antiseptic. Patients whose partners were seronegative said that they used condoms, though a learning and adjustment period was necessary. However, they reported constantly fearing sexual contamination of their partners, which disturbed their sexuality to the point where one of them ceased sexual relations with his wife.

Thus, patients' comments do not indicate a "slackening of prevention." Patients consider condom use necessary, but its incompatibility with relationships limits its use, as is the case in the Senegalese population as a whole. Only seropositive couples are justified, according to patients, in having unprotected sex, because of their "common fate"; the risk of superinfection with another HIV strain, rarely mentioned by patients, thus appears secondary. This maintaining of prevention under HAART could be explained by the fact that 1) prevention advice was reiterated by doctors and in discussion groups and 2) ISAARV doctors did not mention "undetectable viral load," which in Northern countries led some patients to consider themselves non-transmitters.

Renewed Desire for Children

Patients' desire to have children is renewed with improved health. Early in treatment, patients were cautious in mentioning it, but as their physical capacities improved and as pressure from the family, unaware of their HIV status, grew, so did the desire for children. In addition to the "usual" motivations, having a healthy, HIV-negative child could prove the absence of toxicity in HAART, as well as its effectiveness.

Some women under treatment make plans to become mothers. When Astou recovered her health after a few months on HAART, she began to seriously consider the possibility of pregnancy. This prospect depended on a number of conditions: she could not jeopardise her own health, she could not transmit the virus to the baby, and she had to ensure proper living conditions for the child. She sought out information from ISAARV doctors to no avail. She contacted a foreign doctor involved in the research programme who explained to her that if her viral load was low, she could consider pregnancy. The possibility of participating in a prevention of mother-to-child transmission (PMCT) programme set up by ISAARV was encouraging. She made sure that the biological test results were adequate and decided to stop using condoms. She got pregnant. Despite

fears of HAART's toxic effects on her child, she pursued treatment in accordance with the previous medical recommendations. Astou was an active member of a PLWA association, and her pregnancy reinforced other association members' confidence in treatment. They began to raise the issue of pregnancy more openly.

Keeping Suffering to Oneself

All patients who were asked said that they would like to share their HIV status with those close to them; some, though, feared the suffering that such a disclosure would cause them. Salif, for example, said, “I know them, I'm afraid to tell them. If I say something it will be difficult to handle — they won't be able to handle it, and I risk hurting them more than myself.” So, most patients chose to selectively share information with family members, in order to avoid not only stigmatisation and fear of contagion but also the multiplication of suffering that would be experienced by a greater number of people.

Despite the medical facts on modes of HIV transmission, some patients and their families still fear contamination by direct contact. Patients thus take numerous precautions: avoiding eating with the same utensils as family members, refusing direct contact such as kisses, not sharing clothes, etc. Concern for protecting the family from HIV is continuous. Some of these patients know that HIV is not transmitted by ordinary gestures, but their attitude could be understood according to an interactionist analysis: Not knowing exactly what their family fears in terms of HIV transmission, they prefer to avoid creating any discussion. Patients' feelings of guilt furthermore encourage the “assimilation” of restrictive rules that distance them from those who are uninfected. Finally, the information on modes of transmission and prevention delivered in discussion groups focus more on proscriptions than on safe behaviours, thus contributing to the adoption of multiple restrictions that are not reduced by taking HAART.

HAART As a Force of Individual and Social Change

That drug treatments effect a change in individuals is clear from bio-clinical results and patients' own testimonies. For families, HAART's effects on patients' relationships are not limited to just a few adjustments. Some indirect effects of treatment are obvious for many patients, and they combine to create collective tendencies. We will examine the changes in individuals' chosen priorities, the impact on their familial integration, and the trend towards “individualisation.”

Prioritising Health

AIDS and access to HAART changed the priorities of those we spoke to. When patients were enrolled in ISAARV, they prioritised expenses related to their health: fees for HAART, nutritional supplements, etc. Maintaining or improving health took precedence over other social obligations, above all when patients' health had seriously deteriorated. But in a socially precarious environment, these measures were costly and compromised patients' socioeconomic obligations vis-à-vis their families. The patients we met questioned the customary practice of systematically turning to familial solidarity for various needs. In sep-

arating their individual priorities from those of their families, most patients had to create strategies to adapt to and bypass the normal expectations: refusing to grant family members' requests for financial support, taking meals outside the home, etc. These attitudes could provoke criticism, ostracism, or questions about their motivations.

Distance from the Family

Most patients we spoke to created strategies to individually manage HAART and to exercise caution with regard to family requests. Taking some distance from the family allowed patients to safeguard appearances of their social status. Keeping their HIV status a secret and continuing to live without any apparent change allows them to maintain an image of good health. Efforts to maintain social status in spite of difficulties is not specific to AIDS; the practice is commonly observed in Senegalese society, which places importance on modesty, dignity, and appearances. But PLWA are particularly vigilant in keeping their HIV status a secret and to that end tend to distance themselves from the family. The need for a private, personal space to keep and take ARVs also leads many patients to live on their own, which frees them from the daily fear of being “found out” by their family and from having to make excuses for their behaviour. Patients on HAART still, however, adhere to community principles of solidarity even at a distance from the family. Some continue to accept occasional or regular support from family or friends for food, clothing, or in some cases, lodging. But issues surrounding illness and treatment remain private. Patients create new spaces of freedom for themselves, out of family view, and acquire a degree of autonomy within their extended family.

Patients must have sufficient economic resources to fund this distance. Once patients recover their health with HAART, they must tackle the problem of social and professional reintegration. Patients who don't have paid work expressed an intense desire to find or go back to work that would allow them to meet their needs and to save up for their children. Despite regained physical capabilities, the potential threat of an AIDS resurgence still looms. Most patients seek lucrative work that would substantially improve their income and thus allow them to deal with such a relapse. Financial autonomy and distance from the family are two major advantages in coping with seropositivity and treatment adherence.

For women, seropositivity and then HAART access was the trigger — and the opportunity — for numerous conflicts that allowed some young married or widowed women to demand greater autonomy from their spouses and families. Being “victims” of what they claimed to be their spouses' sexual misconduct prompted some women to become influential members of the National Network of PLWA (Réseau national de personnes vivant avec le VIH; RNP), against the advice or their partners or families. They progressively liberated themselves from social norms of submission for married women. Through their involvement with RNP, they sought to obtain financial autonomy. Fifi, for example, counter to her husband's advice, felt that earning revenue was a priority: “I told him he could continue like that, but that I was prepared to do anything. I'd even become a maid for 15,000 CFAF a month to get treatment for myself and my daughter. I would prefer that to wasting my time hearing him say 'I don't have this, I don't have that' while not backing my treatment. I'm not going to sit here

waiting to die while he doesn't take care of me, while he takes another wife. Every day he gets up to go work, and I take my bag and go. He asks me where I'm going and I tell him that I'll walk up and down the streets looking for money." Her husband felt that she took advantage of her illness "to be free," with her family's complicity. Thus, the limitations and meanings connected to treatment led patients to seek escape from the social order, and sometimes gave them the opportunity or the psychological strength to break out of social roles and power relationships in Senegalese society.

Individualisation and Its Limits

Establishing independence and keeping secrets from the family are not easy tasks. Most patients confided to us the suffering of not being able to talk about their illness with their family: "What is so terrible in this disease is that you live with so much pain but you can't talk to anyone." Freeing oneself from the communal values of Wolof society is difficult. Here, as Sylla [4] describes, "a person would feel even mutilated to be isolated from his environment, which nourishes his body and spirit, because … everything is planned and organised for each person to open up to the other in a web of relationships and solidarities that become integral parts of the personality of each member of that society." According to Marie, individual autonomy also cannot be compared to that in Western countries, because "the communal ethos, internalised in the individual, just tolerates individuation — affirmations of individual differences and uniqueness or even the emergence of exceptional individuality. These must not lead to individualisation, i.e., independence from the group, whereby the individual feels no indebtedness or conditional obligation to the community" ([2], p. 414–34). The autonomous individual, solely responsible for and sole judge of his or her actions, is not accepted by the community and could invite criticism, a "quarantine," or even rejection.

Strictly individual management of HIV infection and treatment is practically impossible. When patients withdraw from their families, the first place they look for financial or psychological support is with health personnel. Whatever their reasons for not disclosing their infection, individualisation and the burden of keeping secrets are difficult to bear over the long term. Individualisation in managing seropositivity may protect patients from rejection or stigmatisation, but it isolates them. Djeïnaba said that she "only felt good at the hospital" because at home she constantly feared giving herself away, and at the same time was ashamed of lying to her family. This fear comes under what is described among the Wolof as the hold of the collective moral conscience on the conscience of individuals [4].

Acts of autonomy and strategies for withdrawing from the family in opposition to "traditional" social values are not particular to AIDS; they have been described in various contexts of social life in Africa [2]. According to Vuarin, individualisation among Africans cannot be complete: they can only attain "truncated individualism" [5]. Individuals thus tend to opt for a strategy combining solidarity and individualism, negotiating an optimal distance from community relationships — not too close, not too far; neither dependent submission nor autocratic independence, but community membership that is reflective and critical of the independent self, responsible for him- or herself and his or her loved ones.

The suffering of PLWA's who try to keep a distance from their families testifies to the fact that individual emancipation is limited. They adopt individualistic behaviour, which guarantees their privacy but stigmatises them and could ostracise them from their society when they most need the support of their community.

Following their retreat from the family, the majority of patients turn to others in the same situation, which allows them to break their isolation and rebuild a network of solidarity, mutual aid, rivalries, and conflicts, following the example of the society. Within this network, members are free of societal pressures to dissimulate and can behave in accordance with community values. In a context where AIDS is still perceived negatively, PLWA resocialise through peer support. But social perceptions of those affected, considered guilty of their illness, do not allow these networks to publicly display an identity founded on HIV status.

Conclusion: HAART As Catalyst for Social Change

Access to HAART in Senegal contributes to a “rupture” in the biographical course of those enrolled in the ISAARV programme. Beyond reversing patients' prognoses, ARVs must be socialised, which necessitates innovations for patients: distancing from the family, overinvestment in the pursuit of financial or residential autonomy, etc. Thus, HIV treatment is an area apparently affected by the forces of individualisation already identified in other areas, such as business. These “arbitrations between individualism and community” [2] are one of the social characteristics of modernity in contemporary Africa.

ISAARV established a coherent system of overall treatment that facilitates the integration of ARVs into patients' social lives. Our study shows that the clinical and biological effectiveness of treatments, detailed in the preceding chapters, does not require a significant drop in patients' quality of life. Although they live with myriad difficulties, some of which were discussed in this chapter, patients are for the most part satisfied with the impact of treatment on their health and on their daily lives. Patients' comments indicated, however, that obstacles to a real family-based treatment remain. For patients to be able to discuss their seropositivity with their partners, the latter must also have access to good information on the risks of transmission and to quality medical care. It is also indispensable that perceptions of the illness do not engender blame of those affected. This is not sufficient, obviously, to eliminate the inherent suffering that goes with having a fatal illness. But the identification of these obstacles should enable targeting of priority areas of intervention. One of patients' requests not yet covered involves tending to the desire for children, which will be a new challenge for ISAARV.

Living with HAART in Senegal still comes with discrimination due to social perceptions of AIDS, still popularly associated with morally dubious behaviour. If people under treatment, who are liberated from their fatal prognosis for at least the short term, appeared publicly en masse and challenged, by their very presence, the prejudices and stereotypes, we could hope for an evolution in this area; but the evolution has not yet taken place. The national and international media play a central role in the diffusion of information on AIDS and ARVs. Patients see the media as giving mixed messages — redeeming as well as pejo-

rative information about the disease, those affected, and ARV treatments. Senegalese stations followed their presentations of ISAARV with images of people who were dying, emaciated or skeletal patients, and commentaries on the likely death of people infected with HIV. These negative messages discouraged some patients, who feel that the press overemphasises the negative aspects of the illness which do not conform to their new reality of visible good health. Patients see the media as inciting and perpetuating fear of the effects of AIDS among the population with a view to prevention. This hinders acceptance of PLWA by their families, tending instead to create distance between them.

The medical progress attained with ISAARV has not yet given rise to any obvious evolution in perceptions of PLWA. The challenge for health authorities of improving social perceptions of AIDS remains topical; whereas patients adapt to the constraints of treatment, the experience of living with HIV remains laden with fear — fears of being discovered, fears of stigmatisation and rejection, and fears of contaminating others — well after the clinical signs have disappeared and physical capacities have been restored.

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Chapter III.3
Psychological Care and Support for Patients on HAART in Senegal

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“It's often difficult, they're anxious, sometimes aggressive... of course, they'll need to see a 'shrink,' but if this continues, we're the ones who'll need one!” This is how ISAARV prescribers, health workers, and social workers responded to our question about the psychological needs of the people under their care.

It goes without saying that having HIV in Senegal, as in other places, can bring about anxiety and unhappiness, which in turn complicates medical and social treatment. ARV access alone does not eliminate the reasons for this malaise. Patients would benefit from the services of a “shrink” to discuss and sort out these issues; but this simple notion carries with it several theoretical and practical difficulties.

The non-somatic disorders of people living with HIV/AIDS (PLWA) under HAART and patients' obvious needs for therapy consist of many components, pathological and otherwise. Depending on the patient, these may include despair, shame and guilt, social fear or isolation or even banishment, loneliness or a life of unhappiness and misfortune. Some will experience depressive or anxious disorders, others still will dwell on relational problems, particularly difficulties in the doctor-patient relationship, which are sometimes attributed to institutional strictness towards patients, sometimes to the irritability of patients who are suffering.

Psychological care within an innovative health-care programme such as ISAARV is important, but the psychological problems to be tackled are vague and diverse. Although the need is obvious, the means to offer it are less so: should it minister to problems related more or less to HIV infection? Improve patients' comfort or that of caregivers? Monitor the caregiver-patient relationship? Strengthen patients' confidence in and adherence to HAART?

After reviewing the issue's main theoretical aspects and the nature of the experience acquired in ISAARV, we will describe the psychological care and support system that appears necessary in a national ARV access programme.

Psychological Treatment of PLWA on HAART in Africa: The Current Conventional Wisdom

Psychological Impact of HIV Infection

The few psychological studies conducted with PLWA in medical follow-up found high levels of anxiety and depression, with more than a third of patients depressed [12, 14].

In the last few years, a psychopathological approach has been established to better understand the experience and psychological issues of PLWA. Although psychologists and psychiatrists have since the disease's onset offered their services and have sometimes been actively involved,[1] specific psychological care systems, and research projects on the psychological aspects of HIV/AIDS, remain few and far between.[2]

Psychopathological analysis allows the therapist to describe patients' psychological states, both those that are not acute or critical as well as conditions that may be serious, such as medically diagnosed anxious or depressive syndromes. It identifies patients' recurrent issues: the idea of her or his own death, shame and low self-esteem, guilt [15, 17], the desire for children and fertility [9], etc. In Northern countries, patients consistently mention the lack of and need for a place to talk [5, 20], which is confirmed by researchers [8], and the benefit of psychological intervention to resolve these conflicts is well argued [6].

These symptoms and complexes were long considered to be a logical and inevitable consequence of infection, not warranting much medical, and particularly therapeutic, consideration [19]. And yet the connection between depression and aggravation of the illness [11], and more generally the influence of psychological difficulties on the patient's general health [17] is clearly established. Confidence in treatment and in the value of adherence are solidly linked to, among other things, the patient's psychological state and to the quality of the doctor-patient relationship [4]. Psychological treatment is moreover an axis for numerous adherence-support programmes.

Psychological Impact of HAART Access

Access to ARV treatments changed PLWA's perceptions of the future. Some authors argue that it is the source of a subtle — but notable — decrease in depressive disorders [13]. Nevertheless, ARVs will not entirely resolve psychopathological conflicts, and they will raise some new ones.

With treatment, patients experience a new psychological crisis tied to the idea of an indeterminate respite from illness, and this situation requires some mental

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[1] For example, the Association Didier Seux, Santé mentale et sida, created in 1987.

[2] The Canadian project PHASE (Programme in HIV/AIDS Education), appears to be the pioneer. PHASE is organised by the Canadian Psychological Association (CPA) and focuses specifically on the psychological aspects of HIV/AIDS. Research is carried out on anxiety and depression; counselling; psychotherapy; loss and mourning; the impact on caregivers; the psychological impact on families, friends, and partners; psychological aspects of the illness and recovery; drug use; mental illness; and HIV's neuropsychological consequences. B. Coleman, L. J. Phillips, P. C. Veilleux, J. Hendrick, and S. B. Rourke are the authors, and the texts are available on CPA's website: www.cpa.ca.

efforts towards recovery [1], of “deuil du deuil” — of “mourning mourning” [22]. ARVs also changed patients' relationships with their families. The general tone of hopefulness in society surrounding the new treatments effectively leads to a reduction in family support and compassion, since some no longer recognise the patient's struggle [16]: she or he is less entitled to complain. The patient and her or his family [16] must negotiate a mental reorganisation that will also change their relationships.

Doctors, who prior to HAART access had been in patient relationships marked by powerlessness, were now able to prescribe accessible and reportedly effective medication, granting them a new power and thus radically transforming doctor-patient relationships. Patient dependency (and sometimes imagined submission) begins to appear, influencing the way patients express their complaints.

The African Context

Relationships to illness and to death — and consequently to health care and caregivers — are profoundly linked to patients' cultural perceptions. Studies introducing cultural data into psychopathological analysis of patients have been carried out for decades in the Fann psychiatric department and have been published, notably in the journal *Psychopathologie africaine*.

Anxious and depressive syndromes among PLWA have not yet been studied in the African cultural context; simple screening tools adapted to this context are practically nonexistent [3]. A clinical study in Abidjan did, however, show that two-thirds of patients suffered from moderate or severe depression, suggesting that the prevalence of depression could also be high in Senegal [3]. Some studies on the desire for children [2], the effects of announcing HIV infection [21], and feelings of betrayal among patients under treatment towards their friends and family not receiving treatment [7] show that the African context can engender these conflicts.

Study on the Psychological States of ISAARV Patients

A psychiatrist heads ISAARV's Welfare Committee (CTAS; see “ISAARV: An Introduction” for its composition). The results of social pre-enrolment surveys, describing the social, economic, and family profile of each new patient, are presented at each committee meeting; cases of patients struggling with adherence for various reasons (economic, socio-familial, etc.) are also reviewed. At this time, the need for psychological or psychiatric treatment is sometimes indicated. The committee can then propose a psychiatrist consultation, which is communicated to the patient via a social worker.

In practice, only three people requested psychological support (one couple and one individual patient). Requests from social workers or clinicians were also few (five people at the most); and none of these patients showed up at their scheduled appointments.

This resistance to accepting psychological support was often mentioned in CTAS meetings: With the psychiatrists' offices located in the psychiatry unit, it is possible that this department's pejorative connotations — the department for

"crazy people" — deterred some patients. Secondly, the increase in the number of treatment levels (doctor, social worker, pharmacist, psychiatrist) led to increased hospital visits that some patients may have wanted to minimise. And finally, the doctors were not always able to initiate a bond of trust between patients and psychiatrists.

At the same time, psychiatric sessions were available every week on request at the Ambulatory Treatment Centre (Centre de traitement ambulatoire; CTA) for all PLWA, whether or not they were on HAART. Thirty people took advantage of this service on a temporary or long-term basis.

In order to move beyond the practice of dealing with situations on an "emergency" basis or as they arise and to expand responses to pre- or non-critical situations, we sought to identify patients' psychological difficulties and the possible needs they entail via an approach combining a quantitative questionnaire survey and a qualitative study.

Quantitative Survey

A questionnaire survey was conducted, between February and April 2001, among 50 ISAARV patients selected from the three treatment sites who had been receiving HAART for at least two months. The GHQ28 questionnaire, translated into Wolof when necessary, was chosen. The questionnaire is designed to evaluate general mental health and is most often used in health-care structures that are not specialised in psychiatry and are not seeking to make specific diagnoses. Four categories (somatisation, anxiety and insomnia, social dysfunction, severe depression) were divided into seven items corresponding to various levels of poor mental health. The results, based on patient responses, were expressed as tallies. A second part of the evaluation comprised open questions.

Although almost all patients reported having at least one of the itemised psychological problems, the questionnaire was on the whole of limited interest. We encountered a significant discrepancy between the tallies, which were low on the scales that were used, and the psychological issues clinically observed by the psychiatrist-interviewer: more than 80% of patients had a tally below the detection line for psychological disorders, but nearly all of them affirmed their good mental health in a defensive manner that was accentuated by an obviously anxious clinical state.

Very low tallies for psychological problems were similarly found in social worker screenings: in more than 90% of cases, patients could be placed in the "good" or "very good" psychological health categories, a result which also runs counter to health workers' general impressions.

Qualitative Survey

To better understand these discrepancies and to go beyond the limitations of this questionnaire, we conducted a qualitative survey with three volunteers, selected by caregivers as patients presenting no serious psychological or relational problems. The absence of any critical or acute psychological disorder (agitation, withdrawal, acute anxiety, etc.) facilitated a more in-depth psycho-

logical examination.[3]

We saw these patients for ten hours each. At the same time, we frequently met with the prescribers and social workers, alone or in groups. Many interesting points emerged, which we present here, distinguishing between that which concerns patients, health professionals, and patient-professional relationships.

Patients

• Illness and treatment perceived within a merit system

Using a merit system, patients tend to place themselves in a human chain of contamination composed of victims and culprits. Contamination is a fair or unfair sanction depending on whether or not the alleged fault or "sin" was committed. The positions (victim/culprit) are not stable; the patient moves fluidly from one to the other, without much comfort on either end: "It's my fault.... I sinned, it's true, but I don't deserve that.... But she should have told me that she had the disease — I wouldn't have done it."

This mental conflict emerges above all in the period following the discovery of HIV status, and it fades slowly over the years. The patient does not necessarily find a satisfying answer, but s/he loses interest in the question: "I spent three years questioning who was at fault, who I wanted to hold responsible — me or the person who gave it to me.... Now I realize that it's not important and I feel better." In the merit system, treatment and HAART, in particular, follow from the illness: "With these treatments, God maybe gave me a chance to redeem myself." Upon enrolment in the treatment regimen, complaint is self-censored: "They tell me that I had enormous luck to get these medications.... It's like a miracle.... Few people have this opportunity, and I'm not going to complain!"

In extending the merit system to treatment, patients forbid themselves from complaining. This aspect was a near-constant element in initial interviews. The inhibition is rationalised by the patients themselves with the rarity of free HAART access. Those "included" in the regimen become its "representatives," and once included, expressing anxieties and malaise could seem impertinent or inappropriate, particularly if s/he is speaking to the person prescribing the medication. Even side effects can be consciously minimised: "It's a gift from God.... Don't disappoint him... you have to tolerate the side effects..."

• ARVs as bad "anxiolytics"....

"In the beginning, it made me happy... to know that I had these medicines... but even if they cure me, the suffering I went through won't go away.... Besides, these medicines may be good, but what will happen when they stop giving them to us?" Clearly, patients find hope in these drugs, but they don't resolve past trauma. What's more, this "opportunity" of ARV access in a programme very quickly becomes a new source of anxiety — the fear of loss. Patients have not

[3] A qualitative psychopathological approach seeks to isolate the principles of mental function or dysfunction in a given topic or situation. These models are more easily derived from in-depth analysis (i.e., from many hours of discussion) of the psychopathological dynamic of a few patients (or even one), rather than from superficial analyses of a large number of patients. The isolated psychopathological elements become the assumed models, which are presumptively applicable to anyone, and the effect they produce determines their pertinence, or lack thereof (i.e., they have no absolute value). The approach employs ideas (which are not obvious a priori) to facilitate the understanding of the patient experience.

reconciled the prospect of this programme closing: how will everyone find a "lifetime supply" of ARV? (Many consider the possibility of living in Europe, for example.)

Finally, as the literature indicates, HAART access reorganises patients' life prospects, raising new lines of questioning that have no clear answers: the possibility of having children, conjugal and sexual life, professional investment, etc.

• Solitude and requests for psychological help

Sharing information with either family or friends is uncommon. "They tell me that I have to talk to my family to feel better.... I can't.... They'll know that it was my fault... and even if I tell them I have medicine, they'll think I'm ruined.... I can only talk about it when I come to the hospital." Patients note the lack of places and times for talking both within and outside of the treatment system, and psychotherapeutic interviews were well appreciated. Regular attendance was high (more than 90% of appointments kept), and the psychological issues that came out sparked serious interest. For example, many patients tackled and then resolved, over the course of many interviews, the topic of fault in HIV contamination.

Health Professionals

The uneasiness some health professionals feel facing some patients and situations is not rare. Prescribers and social workers are well disposed toward discussions on the psychopathological topics mentioned above. These discussions can bring about changes in their perceptions of patients and their difficulties, and can thus help them view difficult situations more objectively. Indeed, they seem to look forward to an opportunity to "vent" about psychological and relational conflicts that they experience more or less implicitly.

The Patient-Professional Relationship

• Belated effects of patients' diagnoses

"I hold such a grudge against the doctors who told me that I had AIDS that I don't trust them anymore...." For each of the three patients, it took nearly two complete interviews to recount the notification of their diagnosis. What interests us here are the consequences of this notification, perceptible many years later, on the doctor-patient relationship. The announcement is often one of the first intimate encounters patients have with the medical system, and deep-rooted prejudices of the medical class can easily crystallise. Trust in the doctor can be weak and can remain so up to the point of programme enrolment: "They told me it was important to take the medications in the protocol, that I can't pass up an opportunity like this... but I didn't believe that they worked, so I didn't want them.... They called me at my house, often, so I would take them. I thought that these medicines must be important for *them!*"

• Fear of medical power

In the interviews it became apparent that patients had problems confiding their psychological issues to caregivers. It seems that patients' fears of imagined exclusion from the programme for "bad conduct" (complaining, needy, dissatisfied, etc. behaviour) was one of the causes for this restraint. The "luck" that

patients feel in having been included in the programme heightens their fears of being excluded. Not all caregivers are aware of these positions and thus cannot adapt their responses appropriately.

Our surveys highlighted the presence of major psychological conflicts among patients, as well as a strong need to talk to someone and sort out these conflicts (for example in psychotherapy); their psychological bearings within their illness history and their treatment are very poor and tend to produce anxiety. They are not easily able to extricate their history and treatment from a merit system. Questions about the long-term reliability and accessibility of medicines, the possibilities for having children, and the reconstruction of social and familial roles are common.

Most patients only complain when they are put in a situation for that purpose; this is often difficult in somatic consultations, not to mention questionnaire surveys. Other problems only appear in psychopathological analyses of dialogue. It thus seems necessary to develop a specific space for PLWA to be listened to and cared for, whether or not they are in a crisis situation.

Psychological issues are expressed with intensity in the patient-caregiver relationship. Health professionals, who perceive the difficulties that they are exposed to, seem to be in favour of psychological effort to resolve them.

Towards an Adapted Psychological Care and Support System

Psychological needs are substantial and varied; they concern patients, of course, but also all the actors involved in medical treatment. An adapted system would take into account the needs of both, and respond in an organised, coordinated, and continuous way. But, will the human and material investment necessary — particularly in a country where resources are limited — be seen as a priority? We cannot assume so; such experiments have not yet been conclusive.

The system must accompany and support patients in their treatment route and facilitate the integration of the illness and treatments into their personal lives. It should also offer real mental-health care when psychological conflicts or problems inhibit adequate everyday development, and especially when they prevent quality biomedical follow-up. Finally, they should facilitate the resolution of relational difficulties or conflicts that health professionals may face that can greatly damage overall treatment and adherence.

Position Within the Treatment Programme

The support system should not exist beside that of somatic treatment; on the contrary, it should be fully integrated within it. The creation of an isolated "psych" sector within an overall treatment system such as the ISAARV programme is not an adequate solution. There would be a significant risk of stigmatisation (as the sector for the "mentally ill"), first of all. Secondly, if it deals with, among other things, the patient–health professional relationship, it would be more constructive operating from within — for a better understanding of the issues, and so the work it produces could be easily and directly usable by all.

Collaboration with other actors in the system must be direct and continuous. It should, however, remain secondary to medico-social treatment, simply facilitat-

ing it. In other words, the system should be present at all levels, but in small doses.

System Functioning

The armature: regular meetings

The system takes form in continuous and organised collaboration with caregivers. This facilitates the establishment and coordination of responses to patients' needs, including those involving teams of actors. Coordination and collaboration of psychological actions will have two distinct axes.

• Work with caregivers and other actors

Regular meetings with different groups of participants (prescribers, social workers, association members) are designed to:

– develop case-by-case follow-up instructions

– report on changes (while respecting the rules of professional confidentiality, which are particularly important here)

– establish psychological equilibrium with health workers. This generally applies to situations in which a health worker might be uncomfortable with a patient, whether or not it is apparent.

• Work with the “psych” team

System regulators must devote time to overall system analysis. They must meet to centralise information, which enables adjusting or even redirecting practices. This is the last level of coordination in the system.

Psychological actions to propose to patients

The psychological help that patients might need assumes very diverse forms:

• Accompaniment and support

These actions could be led by non-professionals in mental health and are presumed necessary for almost all patients; they will sometimes be all that is required. Dialogue would serve as an outlet and a positive, even empathetic, connection to combat feelings of isolation and confusion. The framework for dialogue is not strict, but it should be thorough. Support groups are part of this domain, in which associations and social workers have the largest field of action.

This level of intervention has the advantage of being rather easy to set up and to access. It must not, however, exist without a *minimum* of psychological regulation, as we will see below.

• Psychotherapies

Psychotherapies, aimed at changing the patient's mental state in a controlled and precise way, should be conducted by trained personnel. Depending on the techniques used, it may directly modify a pathological attitude or behaviour (behaviourism, cognitivism), profound psychopathological conflicts (psychoanalysis), or a familial dynamic (systemic therapy).[4] Therapy would only be carried out in a strict framework established beforehand with the patient

(psychotherapeutic contract). Particular attention should be paid here to the cultural aspects of the treatment approach (transcultural psychotherapy).

Group therapies (psychotherapy groups) are the psychotherapeutic corollary to support groups. They require patient preparation and the establishment of a strict organisational framework.[5]

Psychotherapies have an important medium- to long-term value, but they are not sufficient in emergencies or critical phases.

• Chemotherapies

The use of psychotropic drugs, in accordance with the prescription regulations and generally accepted follow-up, is a possible recourse. Possible drug interactions and biological side effects must be discussed with the somatic medical team.

The system's secondary functions and benefits

• Specific and practical continuous training of all contributors

Regular meetings between caregiver personnel and the "psych" teams allow for progressive follow-up of cases. The meetings deal with difficulties arising in the course of interviews with patients and should allow for better future practice.

• Constant and extended source of psychological data

This organisation creates a sort of dynamic and permanent observation of the psychopathology of PLWA on HAART, and of the health professional-patient relationship. Follow-up forms could be made rather easily.

Requisite Material and Human Resources

The structure we propose could follow the example of the Itinerant System for Mental Patient Care (Dispositif itinérant d'assistance aux malades mentaux; DIAMM), in the psychiatry unit of Dakar's Fann Hospital. The objectives of this programme are to 1) develop the capacities of local health workers (nurses and doctors) in the regions beyond Dakar so that they can provide partial psychiatric treatment under the regular supervision of the team, and 2) provide decentralised psychiatric treatment if this is not offered by the local medical team.

One DIAMM team consists of a psychiatrist, a nurse or social worker, and a driver. Each team is responsible for one region and a given number of health-care structures (known as district health centres).

The system was set up in April 1977, on the initiative of Prof. A. Collomb, to compensate for the country's shortage of psychiatrists [18]. Inoperative for many years, the programme was revived in 1990; four teams currently cover five health-care structures spread over two regions (Thiès and Diourbel); the teams make one visit per month.

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[4] Currently there are more than ten recognised techniques.

[5] The group could consist of a small number of patients (two to six) and should be regulated by a psychotherapist. The prospective participants should be seen individually by the group organiser. After an initial introduction session for future participants, a contract is proposed which sets out the number of sessions that should be attended and the organisational rules that should be respected to guarantee the security and sustainability of the group.

1. Central unit (Dakar)

A team of psychiatrists and psychologists must be coordinated by a psychiatrist whose medical status facilitates interventions in the health-care system. The participants should be trained in psychotherapy, chemotherapy (for the psychiatrists), and institutional management, and have the ability to organise and supervise a hospitalisation in a psychiatric setting. Finally, at least one of the actors must be available and reachable each day.

Consultations should be carried out in an office within somatic health services, but also outside the hospital depending on patients' needs and/or their reluctance to visit the health facility.

Team members must be able to provide daily (for short periods) to monthly appointments (follow-up is generally weekly), as well as organise monthly meetings with the various teams of collaborators (prescribers, social workers, association members, etc.). Finally, the “psych” team should meet monthly amongst themselves.

To establish the system within ISAARV in Dakar, we assessed the volume of work for full- and part-time staff.

2. Services in the outlying regions of Senegal

There are few, if any, psychiatrists or psychologists in the countryside, but the system's services must be regular and continuous. Support and accompaniment work could be provided by local caregivers, social workers, or association members, preferably trained by the system's “psych” participants. The latter should thus be able to regularly travel to the regions to conduct therapy for patients as well as medical or social staff or to hold meetings with association members. The frequency of these trips could vary according to the distance involved, but they must be at least monthly. Continuing practical and theoretical training of local professionals must be a priority during these visits.

After a period of interaction between the “psych” worker and his or her local collaborators, communication by telephone or other means could occasionally back up direct efforts. Coordination with a central unit in Dakar would facilitate work in the regions.

Conclusion

The need for collaboration and coordination of various actors is even greater in the support of infected children. More than adults, children need guidance in understanding their situation, and the (re)constitution of psychological bearings is even more crucial. Therapy with children is only possible via intimate contact with the family. This then becomes a new actor in the system, increasing the need for regulation and coordination of all those involved.

A system of psychological care and support should identify, and then control, the most diverse psychological and affective problems. Within ISAARV, it focuses on the PLWA's experience of their illness, their care, and their caregivers. The approach to and regulation of related psychopathological conflicts must effectively facilitate the overall treatment. Psychological care and support interventions with patients could vary, and the system must coordinate these responses. Direct, regular, and formalised collaboration with the various actors

is the second crucial aspect of such a system. Its chief aim is to regulate psychological conflicts or difficulties that arise in the course of medical or social care. The function of the system is to develop patients' psychological tools and connections to facilitate — or even simply enable — treatment in their daily lives.

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Part IV
The Programme's Impact on the Health-Care System

Chapter IV.1
HAART's Impact on the Senegalese AIDS-Association Movement

F. Mbodj, B. Taverne

In countries of the South, as in the North, concern over AIDS has extended beyond the medical community to become the focus of social campaigns. The roles of associations in the North and the South, however, differ almost by definition.

In Northern countries, the movements have themselves prompted activity by governments. With their complete independence, these movements have played the part of an alternative power centre in public-health decisions. For example, they called for highly active antiretroviral treatment (HAART) to be made available as soon as it was discovered [2, 5].

In Southern countries, civil society and non-governmental organisations have played a very different role. In Africa, governments long ignored the scale of the epidemic [4, 6]. Society responded only very slowly, and with a few exceptions, associations only became involved at the request of and with the help of national AIDS programmes or public-health organisations.

Senegal has seen a rapid growth of non-governmental organisations, movements, and community-based organisations (CBOs) involved in the fight against AIDS, even though the level of HIV infection has been relatively low compared with that of other African countries. With the support of the National AIDS Control Programme (Programme national de lutte contre le sida; PNLS) and other organisations, their activities were, from the outset, concentrated on prevention. Associations were used to communicate prevention messages, and their authority depended on how close they could get to the target populations. Access to antiretroviral (ARV) drugs was not demanded, and associations only played a small role in setting up the Senegalese Antiretroviral Drug Access Initiative (ISAARV), even while the PNLS expressed the wish to be associated with this very early on. Only recently have associations become involved with HAART, at the instigation of health workers.

A description of the main associations and of their political history will shed light on their present place and role in HAART and in ISAARV, and suggest responses to the following questions: why was their initial involvement so meagre? What impact did ISAARV have on the association movement? What role do the associations now play in ISAARV?

A History of NGOs and Major Associations: 1986 to 2002

Many associations and NGOs in Senegal are currently involved in AIDS. Some of these organisations devote only part of their efforts to AIDS, while others are involved with nothing else. We are only concerned here with organisations focused on support, care, and advocacy for PLWA, which are very few.

The data for this survey has been obtained from detailed conversations with members of all associations identified as working with PLWA, NGO officers, and health workers involved in medical care of PLWA. We met with regional organisations outside Dakar and analysed each organisation's available reports and minutes of meetings and training sessions. This information provides a survey of the association movement over two years (2000 to 2002).

The historical dynamic of the association movement in Senegal must be analysed in order to understand the political commitment of these associations and the links between them.

The history of the association movement in the fight against AIDS in Senegal began in 1986 with the NGO Environment and Development Action (ENDA). Active in Senegal since 1972, it proclaimed itself an international organisation and nonprofit association in 1978. Based in Dakar, it comprised some twenty teams, each with its own focus, who all worked in areas concerned with the environment and development. Twenty-one decentralised branches were gradually set up around the world. ENDA's reputation was thus established well before it got involved in the fight against AIDS. ENDA set up a health team, wholly devoted to AIDS, in 1986, the year when the first case of AIDS was detected in Senegal. In 1991, it launched a training and capacity-building programme for communities to respond locally to the problem of AIDS. Its social legitimacy, its previous donor relations, and its established role in development all contributed to make it the leader among associations in the fight against AIDS. The highly professional profile of its staff ensured its legitimacy and its recognition both nationally and internationally.

The Society for Women and Aids in Africa (SWAA), set up in Harare in 1988 and in Senegal in 1989, was the other major pioneer in the fight against AIDS. It soon became the mouthpiece for a population noted for its vulnerability and its silence in the face of AIDS. It received a great deal of publicity and attracted "notable" women to its cause, in particular the wife of the head of state, who officially supported its activities and its views, conferring credibility and legitimacy on the organisation. The professional nature of its participants (doctors, teachers, etc.), together with its experience in prevention and in training women (in the work environment, for example) and women's associations, added to its legitimacy on the national and the international scene. One of its activities concerned treatment for women and children infected or affected by HIV, which included sponsoring HAART for some children while also helping their families.

In 1990, ENDA begot the National Alliance Against AIDS (Alliance nationale de lutte contre le sida; ANCS). This NGO sought to "encourage and support NGO and CBO participation in the fight against AIDS in Senegal," by promoting "associations' HIV prevention programmes and PLWA support programmes," as well as "initiatives and mechanisms for cooperation among actors involved in the fight against AIDS." In 2002 the NGO had more than 100 association mem-

bers. ANCS joined the ranks of fund managers, thus allowing associations to bypass the PNLS in accessing funds and establishing itself as a full partner of the PNLS. Primarily funded by the International Alliance,[1] ANCS devoted nearly a third of its budget to patient care, with the rest going to prevention and sensitisation activities. ANCS was involved in setting up regional support centres and associations (Louga, Saint Louis, Tambacounda).

In 1991, five years after the first cases of AIDS were detected, the first association of people infected and affected by AIDS was set up at the Infectious Diseases Unit of Fann Teaching Hospital: the Senegalese Association for Support and Aid to PLWA and Their Families (Association sénégalaise d'aide et de soutien aux séropositifs et à leurs familles; ASASSFA). It had neither its own premises nor financial autonomy. Most of its members said they did not know each other and had not participated in any association meeting or activity, which earned it the reputation of a sort of phantom organisation. It had 25 members, though some board members were unsure, and the assistant social worker at Fann, a member of the board [1], generally controlled association enrolment. As the organisation did not meet the needs of its members, some patients left to join Oasis Solidarity (Oasis Solidarité), the second PLWA association, set up in 1994.

ENDA was behind the 1992 opening of ICASO/Senegal, the Council of Senegalese AIDS Service Organisations (Conseil des ONG sénégalaises de lutte contre le sida). This network was affiliated with the International Council of AIDS Service Organisations (ICASO), created in 1990 and based in Toronto. Its aim was to "co-ordinate the activities of NGOs and member organisations, to promote the circulation and exchange of information and experience among them, and to promote cooperation between all participants, in order to enhance the effectiveness of their work." ICASO/Senegal dealt with some 200 Senegalese NGOs and associations, but has struggled since its creation to attain its coordination objectives. ICASO is now based in the PNLS, which raises questions about its independence from the health authorities. At the request of the PNLS, ICASO was granted the role of intermediary between the National Network of PLWA (Réseau national des PvVIH; RNP) and the PNLS in 2000. This role was disputed by the RNP, whose members claimed to be "sufficiently adult to speak directly [to the PNLS]."

The association AIDS Service (Sida Service) was set up in 1992 and subsequently renamed the Centre to Promote Health (Centre de promotion de la santé; CPS), to remove any reference to AIDS. The CPS originated in a Catholic health centre, and initially had no ties to other AIDS associations. Prevention activities, targeting young people in particular, were its first efforts, carried out informally by volunteers, mostly from Catholic health centres. Some permanent staff were taken on with funding from the Catholic religious network. The CPS is the only AIDS association with a medical laboratory and a centre for free and anonymous testing, opened in 2000. This made it well-known, and it was made a full partner of the PNLS.

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[1] NGO set up by the Rockefeller Foundation and based in Britain. The International Alliance works in countries of the South severely affected by AIDS. Its primary aim is to mobilise and collaborate with communities to develop an overall response to AIDS, through the establishment of liaison organisations in designated countries to coordinate the work of local NGOs. It has provided training and technical assistance to many NGOs and CBOs in 40 countries in Africa, Asia, and Latin America.

In 1994, ENDA supported the creation of Oasis Solidarity, a PLWA association, some of whose members had come from ASASSFA. From its beginnings, it received technical, material, and financial supervision from the ENDA Health team and medical treatment for its members. Because of this provision and training, this association was more successful than ASASSFA. The Care, Advice, Support, and Training Unit (Unité d'accompagnement, de conseil et d'appui et de formation; UACAF) was launched at the ENDA Health headquarters to respond to its HIV-positive members' needs for medication and training. This centre was one of the pioneers in PLWA treatment outside the medical structure. HIV-positive association members here found easy access to doctor-prescribed drugs (cotrimoxazole, etc.), as well as assistance in medical assessments. Two social workers and a nurse were in charge of follow-up. From 1994 to 1997, Oasis Solidarity and UACAF were supported by ENDA.

The same year (1994) saw the emergence — with the support of UNDP and the bacteriology laboratory of Le Dantec Hospital — of a third PLWA association, the Senegalese Network of Development Actors (Réseau sénégalais des acteurs du développement; RESAD). RESAD was created by an ASASSFA board member who had left that organisation after an internal conflict. This new association, after leading prevention and sensitisation activities, merged into the National Network of PLWA upon the latter's founding in 1997 (see below).

Two years later, in 1996, the association Synergy for Children (Synergie pour l'Enfance) was formed. It was chaired by a paediatrician (who now prescribes ARVs in ISAARV) and developed its reputation by concentrating on specifically medical matters. Synergy worked discreetly, but it became known by word of mouth as a model facility for HIV-positive women and children. It consisted of 20 people, all volunteers, from different socio-professional categories (doctors, nurses, midwives, etc.). It extended its field of activity with the arrival of ARVs. Synergy was able to build good relations with PLWA associations and thus became a reference for follow-up for most women and their children in associations. In 2002, some 200 children were being cared for, including 80 who were HIV-positive.

In the same year (1996), Djiguisembé, the first regional PLWA association, was established. It was supported by the Tambacounda Hospital's counselling committee and was intended to be "a framework of mutual support, solidarity, and counselling." Its activities and its visibility have so far remained very limited. AIDS Survival (Survie sida), which provides care and support to PLWA, was the second regional association, instituted in 1997 in Saint Louis.

In 1997, the National Association for PLWA (Association nationale des personnes séropositives; ANP) was established in the offices of the PNLS by a group of people who had been excluded from Oasis Solidarity after an internal dispute. It should be noted that these conflicts were not due to differing opinions on policies, but usually to disputes in which personal interests overshadowed those of the group.

Beginning in 1997, ENDA withdrew its support from Oasis Solidarity and UACAF because of lack of funds. After a few months of disarray, these organisations were taken over financially (rent and office expenses) by the PNLS.

In view of ever-increasing requests from these various associations, the PNLS proposed that a national network of PLWA be formed, grouping all the associa-

tions to become a single representative for the PNLS and likely donors. In October 1997, under the direction of the president of the Ethical Committee, a general assembly created the National Network of PLWA (RNP), in the presence of six representatives from each association (ASASSFA, Oasis Solidarity, RESAD, Djiguisembé, ANP). With the encouragement of NGOs and the PNLS, RNP focused mainly on prevention.

Two other PLWA associations emerged in Dakar after the initiation of ISAARV: "Working Together" (Bok Jëf), came out of the Ambulatory Treatment Centre (Centre de traitement ambulatoire) of Fann Hospital. After a training period financed by Family Health International (FHI), Working Together members got involved in follow-up and support for those infected, supporting the medical team. The second association was called "All together with one hope" ("And Bok yakkar"; ABOYA), an association for infected and affected women. Its creation was motivated by the wish to distinguish themselves from RNP and associations "directed by men." It aroused great interest among health professionals (half its board members were clinical staff) and NGOs that targeted women in their activities. This association does not yet have any activity to its credit.

This historical summary has shown that the associational landscape is perpetually under construction. Although SWAA, CPS, and ANCS appear stable, the PLWA associations have undergone several reshuffles. Over a period of ten years, eight PLWA associations have been created, most often at the instigation of health structures, NGOs (ENDA, in particular), or health personnel. However, questions related to biomedical aspects, and particularly treatment access, are still given little attention by the associations.

Senegalese PLWA Associations: Prisoners of Their Own History?

In an area of many political vested interests, the world of AIDS associations has experienced serious tensions. In 1992, the theme of World AIDS Day, "AIDS: A Community Commitment,"[2] translated into a certain willingness from public-health decision-makers to seek representatives in civil society. International organisations and donors pressured African national AIDS programmes to nurture the emergence of this "essential" community. Pressure also came from Northern associations: when the emergence of this community seemed feeble, they accused the national programmes of suppressing the opinions of the association movement. It followed, then, that for national programmes to have an acceptable international image, massive community mobilisation and a strong voice of the PLWA associations must exist — proof of sound democratic health.

In Senegal, for instance, the involvement of PLWA associations is encouraged by the PNLS and by the medical organisations. Some PLWA associations "play along" at major events or at official ceremonies, and in return, expect the PNLS to assume the role of social worker and disburse the funds obtained thanks to their good performance. The PNLS does not always fulfil this expectation, however, which can create conflict between the two, even if they are essentially

[2] This theme was again adopted for the XII International Conference on AIDS and STDs in Africa in Ouagadougou in 2001.

linked in a state of interdependence. Tension also exists between the PNLS and some NGOs that see this governmental structure as leading a kind of dance, drawing them in and pushing them out as the occasion demands.

Even if the associations gain increasing independence from government bodies, they still do not have sufficient autonomy to criticise public-health decisions concerning AIDS. Their leeway, however, varies according to their history, reputation, and technical and/or financial autonomy. ENDA, for example, Senegal's pioneer NGO for development, has assumed a position that is more or less independent of the health bodies. Most associations and NGOs also suffer from "brain drain," with their most dynamic members leaving to work in the international sphere.

Among the NGOs themselves, partnerships often turn into competitive relationships. To preserve or increase the organisation's legitimacy is a matter of survival in the AIDS "market," which "is like a conflict zone for actors, where the PNLS is the cornerstone" [3]. In several situations, PLWA associations have served to strengthen the legitimacy of the PNLS and of other NGOs, already nationally and internationally well-known, to the detriment of an effective partnership. They are quoted in prevention or sensitisation campaigns to lend the message more credibility. Inexperienced and with meagre skills compared to many NGOs, which enjoy reputations and know-how that may date from before the onset of AIDS, associations struggle to carry any political weight. Often created as a result of outside pressure, lacking financial autonomy and skills, they are rarely involved in public-health decisions. The policy of providing them with financial aid, followed from the start by NGOs, does not grant them legitimacy or autonomy. Their history and the context in which they were founded challenges their independence and their ability to be a real political force.

The fear of being seen is another obstacle to PLWA associations members publicly taking firm political stances. Concerns about rejection by society moves most association members to keep their illness — as well as their association membership — a secret. In addition, Senegal's reputation as a political success story in the fight against AIDS, with its low prevalence compared with the rest of Africa, does not encourage PLWA to come forward. On the contrary, it can even contribute to their stigmatisation; those afflicted are regarded as a minority, the exceptions, and are held responsible for their illness.

Some association members, particularly those of RNP, lead a very marginalized life. The association provides its members with a new therapeutic meeting ground, where they can socialise and create bonds of moral and material support and solidarity. Most members are unemployed. Various individual strategies to "get out" are worked out in these associations. The opportunity for some members to make money from participating in seminars and the endless disputes over managing funds show how these organisations can fall prey to a sort of parasitism, where individual and collective interests become muddled or opposed. Even when the willingness to form a pressure group exists, daily survival may take precedence over political activity.

Some associations in the North have sought to defend the interests of Senegalese PLWA associations. They accept, however, the difficulty of establishing any real communication and reaching any common ground. To the extent that the nature of Senegalese associations, in terms of their histories and back-

grounds, escapes these Northern associations, the latter run the risk of committing a “transfer of activism” (a transfer of ideology or techniques for political activism) [3]. This approach reduces the chances of their interventions being successful.

The Role and Influence of Associations and NGOs in HAART Access

Statements About and Attitudes Towards HAART

We analyse below the statements and attitudes of NGO and PLWA association members regarding the introduction of HAART.

NGO and association statements about HAART

When ARVs first appeared, their reputed expense and inaccessibility seemed to suppress any possible demands for access to this treatment. NGOs and associations continued with their work in prevention and information, which seemed more accessible and better adapted to the economic conditions of Southern countries.

It was in 1998 that the PNLS first launched HAART in Senegal, without any demand from associations or NGOs. The planning and negotiations for access to this treatment took place between government authorities and pharmaceutical companies. Association representatives were invited to participate in the process, but they did not seize the opportunity to take part in decisions. Nor did the associations consider or organise any campaign to demand treatment access. None of the associations or NGOs we met had advocacy for HAART access among their objectives.

Thus, the PNLS set the levels for patient treatment contributions. Even though the minimum contribution for HAART (20,000 CFAF a month initially) was too high for the majority of patients, it did not provoke any protest from association activists, who proposed 100% treatment subsidies.

HAART strengthened the PNLS's legitimacy. Arrangements for the arrival and the distribution of ARVs were kept under strict control, as were the conditions for medical prescriptions. Those few associations who had access to the medicines through gifts from Northern associations affirmed having transferred them to officially designated prescription sites. The recognized difficulty of accessing and using these medicines and their known toxicity and side effects kept their use limited to the health facilities. NGOs and associations only heard far-off echoes about this treatment and its results, usually from comments made by a few patients.

Caught off-guard, most NGOs and associations were reluctant to take up the question of HAART. Their statements about the treatment were vague, and they were ignorant about the criteria for enrolling in the treatment programme and the procedures for determining how much patients would contribute to their treatment. Many associations admitted having problems over how to respond to questions put by patients and the general population. Because of the treatment's delicate and technical nature, and also because of the rapid progress of scientific discovery and statements made about it, the debate seemed most of

the time over their heads. Some of them felt it was more than plausible that health-care authorities wished to keep them out of this “ARV business.”

HAART was also regarded by NGOs as a threat to the results gained from prevention, which was their main claim to legitimacy. It was feared that the introduction of this treatment might lead to a revival of high-risk sexual behaviour. This explains why the content of prevention messages has hardly changed since HAART's introduction: most of them do not refer to HAART, even to encourage testing, instead still dwelling on the disease's fatal nature. The few references to ARVs are timid, and focus on how expensive and inaccessible they are. All the NGOs we met emphasised HAART's eclipsing of other equally important questions facing patients: problems of diet, transport, medical tests, etc.

Some NGOs justified their caution towards HAART by the impossibility of giving up the treatment once started, but also by the difficulty they had in following all the arguments in the scientific world about HAART. This caution could also be justified by the fact that very few patients are actually undergoing ARV treatment, and furthermore, that the political views of donors who finance the NGOs do not always favour HAART access, or at least do not prioritise it.

HAART still has a highly medical nature about it, which conceals its possible social impact. ARVs are seen by NGOs as coming exclusively under the technical domain, and thus concerning medical authorities alone. NGOs thus struggle to find a place in any discussion about HAART.

PLWA association statements about HAART

Three phases can be distinguished in associations' statements and attitudes towards HAART. Its arrival in 1998, far from evoking loud demands for its accessibility, aroused both fear and suspicion. There were various reasons for this scepticism: treatment access was presented by doctors as a privilege for patients; the medicines had not been requested by PLWA but rather proposed by the health system; disputes between the PNLS and the RNP hindered acceptance of the new treatment in the association sector; and the doctors’ insistence on how costly the treatment was did not encourage their acceptance in a world of poverty, where the priority was to meet essential needs, particularly for food.

In a second period, associations' refusal of this treatment was justified by the trend of opposition to these drugs. Because those people who attended seminars and colloquia in Europe or in Africa heard objections to HAART's effectiveness,[3] a core of activists, association members since the 1990s, went around sowing doubts about HAART. Finally, the side effects, which some patients complained about, fuelled speeches about the treatments' toxicity and dangerous nature.

In the face of all this, association members adopted differing positions. Some of them opted not to take HAART. Others, already following the treatment and condemned for doing so by their comrades, decided to reduce the number of pills they were taking, in order to “reduce the level of toxicity in their blood” and thus reduce their risks. One association member under treatment decided to stop altogether, claiming that the medical personnel lacked proper judgment. Some

[3] Association members have followed the debates and controversies in South Africa that are perpetuated by “revisionists” expressing views close to those put forth, for example, at: www.virusmyth.net/aids/.

patients who had once criticised HAART struggled to reconcile their change of heart. Treatment initiation was delayed, or kept secret for several months, or put off altogether, often to the detriment of their health.

Following the PNLS's decision to provide free treatment to association members and health professionals, one might have expected a rush to join the associations to obtain free treatment access. The news was not, however, widely broadcast, no doubt in order to avoid a possible increase in demand. Association membership, thus, did not significantly increase when free treatment access was granted, and most patients, apart from some association members, were unaware of this advantage.

In the third phase, improvements in the health of those undergoing HAART, including association members, and particularly their rediscovered ability to plan for the future (have children, get married, etc.) effected a clear change in what was being said about the treatment. This change has also been encouraged by Northern-based associations, which have been able to "validate" the therapy regimens proposed in Senegal. The closer an association or its members are to the medical system and the better its relations are with it, the more likely their ideas on HAART are in synch, that is to say, positive. This is what happened with the association Working Together.

Even if HAART is increasingly accepted, and even if a few timid demands for free treatment access followed, associations still do not make strong demands for generalised HAART access.

Association Involvement in ISAARV

In the Eligibility Committee

The PLWA associations are represented in the Eligibility Committee (Comité d'éligibilité; CE) by two members of RNP. No other association or NGO was invited. This participation follows a PNLS decision and not a demand made by the associations. Their official reason for participating is "to defend patients' interests."

Interventions by association representatives at these meetings remain very timid. They explain this by their difficulty in understanding doctors' comments. One association representative also referred to his struggle to contradict some doctors, who are regarded as being in a dominant position. Clearly the respect for the social hierarchy, well established outside the field of AIDS, plays its part in this area, too.

For fear of disclosing information, these association representatives, obliged to uphold confidentiality, keep what has been said at these committee meetings to themselves. This has sometimes led to tension with other association members, who complain that they cannot understand the nature of the exchanges and of CE decisions, and who reproach their two representatives for not carrying out their duty to inform.

In the prevention of mother-to-child transmission programme

In the prevention of mother-to-child transmission (PMCT) programme, initiated by the International Therapeutic Solidarity Fund (Fonds de solidarité thérapeu-

tique international; FSTI), the involvement of Act Up France has encouraged the associations' participation in the programme. Synergy, SWAA, and RNP were chosen to act as mediators with pregnant women in prenatal consultation centres, in order to encourage them to take an HIV test. This community intervention begged the question of who should carry it out. The choice of Synergy and SWAA was justified by their expertise with women and children who had been infected. RNP seems to have been included as a representative of PLWA.

The medical world was not ready to accept this invasion of its domain by association members. Their arrival provoked conflicts of status with the medical personnel. The association members who claimed experience of having lived with the disease, rather than any specific skills, also struggled to accept — and be accepted in — the role of mediator.

Thus, for RNP members who had to "prove themselves," intervention in hospitals was more difficult than for mediators in other structures. The choice of who should take part was another test for the association. The allocation of these positions, which are paid, engendered numerous tensions. Education, a discriminatory criterion put forward by men, excluded women from these posts.

Working Together, following training received at the Ambulatory Treatment Centre, led activities in caring for PLWA. They organised support groups, home visits, and hospital visits with the help of medical staff. But several areas related to the introduction of HAART, such as adherence support, follow-up for non-enrolled patients, and advocacy for access to care are still not pursued by the association and NGO domain.

Conclusion

In the field of ARV treatment access, Senegal is in the relatively unusual situation wherein government bodies were able to propose and implement strategies well ahead of those hoped for by associations. The potential beneficiaries living with HIV are represented by activists from the associations who often remain silent during the course of discussions, are prey to contradictory opinions and attitudes concerning ARV treatment, and feel that they are being used as pledges by the medical and health authorities. This situation is very different from that in other West African countries: in Mali, the PLWA Centre for Support, Activities, Discussion and Counselling (Centre d'ecoute, de soutien, d'animation et de conseil pour PvVIH; CESAC) has consistently argued in favour of the Malian Initiative to Introduce ARVs; associations in Burkina Faso actively participate in establishing HAART access channels; and association activism in Côte d'Ivoire has been used to open up access to ARV treatment, which is perceived very positively.

Several aspects of the origin of PLWA associations explain the absence of aggressive claims for ARV treatment access in Senegal. These associations were formed as a result of initiatives taken by other organisations and have never secured any genuine financial independence from their sponsoring organisations or their associated financial partners. Incapacity to raise funds, weak enrolment, fear of visibility or requests of anonymity, the dearth of charismatic activists, and the endless reshuffling of these organisations after internal disputes, have all combined to reduce their effectiveness in prevention, treatment,

and advocacy interventions. These PLWA associations have not been able to structure themselves with the help of Northern-based associations (Aides, Act Up) to create a real force of opposition to the health authorities. In the three years since ARVs became available, most association activists have remained ignorant or doubtful about the opportunity for free HAART proposed by ISAARV. This therapeutic "object," which was "captured and offered" by health authorities, was met with reserve and caution. The acquisition and mastery of biomedical knowledge related to HIV infection and its treatment have also caused divisions between associations and even between the members within associations.

The ISAARV health professionals, now engaged in spreading and decentralising the HAART access programme, say that they would like active cooperation with PLWA associations, that this is essential to the success of programme expansion. On the other side, members of several new associations assert their willingness to get involved. A quality partnership will depend on the clear definition of activities, recognition of areas of competence, and the establishment of a statute empowering these key collaborators in the health-care system.

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Chapter IV.2
Social Security and Covering the Costs of AIDS

G. Laborde-Balen, B. Taverne

In most African countries, various centralised systems for social security exist, "generally set up by the former colonial powers, and maintained and developed since by the newly independent states" [12]. Although these systems have features similar to their European counterparts, one can hardly carry the comparison any further, since they usually cover only a small proportion of the total population — less than 5% — and the coverage they provide is very limited [12]. The expansion of arrangements for social security is one of the strategies being discussed nowadays to provide widespread and equitable access to high-quality health care in countries of the South [10].

In looking for ways to provide sustainable funding for highly active antiretroviral treatment (HAART) access programmes in Africa, it is often suggested that, along with international and national financing, social security systems, such as mutual health insurance societies and commercial health insurance, should be used to cover these expenses, either completely or partially.

A recent survey in Senegal showed that 17% of the population in the Dakar region had at least some partial coverage for health expenses [6], through one or another of the various social security organisations that provide arrangements for health insurance. We have tried to estimate how far these organisations could cover the health expenses of PLWA, particularly those receiving HAART through ISAARV. In the current context of payments for medical consultations and medicines by the users, would the present arrangements help PLWA to access health care, and provide them with medical attention appropriate to their condition? The underlying objective was to evaluate what could be expected from such systems of African social security for quick and widespread access to HAART.

After presenting the different organisations that provide arrangements for social security in Senegal, we describe how people join these organisations and the conditions and the nature of the coverage provided. We then examine the strategies of these various organisations in the face of the HIV epidemic. Finally, accounts by the users enable us to describe and analyse what use has been made of these organisations by ISAARV patients.

Method

We interviewed managers and promoters of mutual health insurance societies, human resources directors and health professionals (nurses and doctors), as well as staff from insurance companies, in both Dakar and Thiès. This survey covered five mutual health insurance societies, five health insurance schemes from large companies, and two private insurance companies. We met most of the people interviewed on two occasions, with a year's interval between the interviews (August 2000 and then August 2001). In 2001, we also spoke to 21 PLWA to evaluate the use they made of the social security apparatus.

The Social Security System in Senegal and Its Benefits

There are six institutions involved in these arrangements: the system covering civil servants, Social Security, institutes for health-care provision, institutes for retirement provision, mutual health insurance societies, and private insurance companies. Social Security and the institutes for retirement provision play no direct role in health care; the first provides for maternity, family allowances, and accidents at work; the second concern themselves solely with retirement. Four institutions, therefore, are concerned with reimbursing health costs. They are briefly described below.

The Scheme for Civil Servants

The scheme for civil servants concerns government employees (and staff from other organisations who enjoy similar conditions of employment). There are about 66,000 such people in Senegal, and this scheme covers around 300,000 beneficiaries (salaried employees and those family members who are covered). Their scheme provides employees the right — without any contributions or salary deductions — to "budgetary imputation," i.e., 80% coverage by the government of the costs of hospitalisation, related medical tests, and medicines provided while in hospital. The remaining 20% of costs must be met by the users. The cost of medicines received when not in hospital is not reimbursed. Health care is arranged by means of agreements with various providers of health-care services, in particular the Principal Hospital of Dakar and the Institut Pasteur clinic.

In theory, the system is straightforward: a letter guaranteeing payment, approved by the Finance Ministry (which pays the bill directly), allows the employee to enter hospital or to have an external examination. The employee's 20% contribution is deducted from his or her salary. In practice, however, fewer and fewer health-care providers are willing to follow this procedure, which is time-consuming. They prefer to ask the employee for immediate payment, whether complete or partial. To compensate for not having the costs of medicines reimbursed, some employees have joined mutual health insurance societies that cover this.

There is no national strategy nor any national directive for the care of government employees who are infected with HIV. By a Ministry of Health decision, health professionals receive totally subsidised HAART. There is no special

administrative procedure for this that must be followed, and the decision is made by the ISAARV Eligibility Committee (Comité d'éligibilité; CE) This provision comes under the policy of free health care, from public-sector health-care providers, granted to civil servants by the Ministry of Health

Health Care Provision Schemes (IPMs)

Health Care Provision Schemes (Instituts de Prévoyance Maladie; IPMs), established by decree in 1975, concern employees of the formal private sector. Every company employing more than 100 people must have such a scheme, join a scheme that covers several firms, or organise a system that is equivalent or more favourable to its employees. The organisation of these IPMs is decentralised, and each scheme operates as an autonomous organisation. Its board of management, made up of employees, elects a manager. Two employer's representatives sit on the committee.

Many of these schemes are saddled with serious problems. According to a doctor working in a support unit, "25% of IPMs work well, 50% not too badly, and the remainder have gone bust. There are endless problems: poor training for managers, falsification of bills, unauthorised items of care, extravagance and indebtedness of employees to the system." A reorganisation is in progress, with the support of NGOs and the Ministry of Health's Agency for Assistance to Mutuals, IPMs, and Health Committees (Cellule d'appui aux mutuelles, IPM et comités de santé; CAMICS). A lack of resources holds up the reforms that have been announced: the creation of a federation and of a control agency, a revision of contribution levels, the setting up of an institutional framework, training for the managers, and the creation of a guarantee fund.

In spite of all these problems, the Ministry of Employment's Coordinator of IPMs believes that the IPMs handle 8 milliard CFAF each year. The Ministry estimates that in 1996, the IPMs contributed 60% of the cash flow of doctors and pharmacists in Dakar, and covered nearly 10% of the Senegalese population, with 120,000 members and 720,000 people who had rights.

The employees' contributions are at least equal to those made by the employers. A scale dating from 1975 fixed the contributions at three percent of monthly salary, up to a ceiling of 60,000 CFAF (or 1800 CFAF a month). In practice, this scale of contributions is no longer adequate for the fees charged by health-care providers, and is due to be revised soon. Depending on salaries, employees' contributions vary from 3000 to 9000 CFAF a month. The services provided by inter-company IPMs and by "in-house" IPMs (set up by the company) do not greatly differ: 50% to 60% of health costs (medical consultations, medicines, hospitalisations, and biological tests) are reimbursed. The senior staff, who often also take out complementary insurance, contribute more (10,000 CFAF a month) to get a higher level of services, generally with 100% reimbursement.

The employee contribution (40% to 50% of the costs) is deducted from her or his salary, with no requirement of advance payment. This system, called "third-party payment," often involves their running considerably into debt. Companies are thus directing their social policies towards a resolution to this debt problem:

– repayment is generally made in instalments, and the monthly deduction is limited (for example, to 25,000 CFAF a month);

– some IPMs fix a limit to the amount of debt that can be incurred (for example, 100,000 CFAF) and suspend the provision of services once this limit is reached. In exceptional cases, however, medical services can call for vital treatment to be reimbursed, even over this limit;

– in order to reduce the employee's debt, the company advances to its staff — but not to their families — an additional reimbursement of 80% of the patient's contribution, which reduces the employee's contribution still further to 8% of the cost;

– some companies are willing, as an exceptional measure, to accept an annulment of the debt, following an agreement between the medical services (which have to justify the need for the treatment), the company's director of human resources, and the IPM's board of management;

– companies provide other forms of assistance (foodstuffs, financial help), on the basis of a financial survey.

These measures are left to the initiative of company managers. Requests from the employee are examined in committee by those running the company's medical services, by the IPM, and by the directing staff. Implementing this procedure implies that the beneficiary is willing to disclose the reasons for his request to this committee.

Complicated procedures are set up to prevent any abuse of this system. The IPM creates a file for each employee with his or her contract of employment, marriage certificate(s), and birth certificates. The employee has a health register which records for every member of his family the date of any medical consultation; the name of the doctor, confirmed by his stamp; and a summary diagnosis. S/he must show this to the IPM with any request for health care. Depending on what s/he needs, the patient is given a specific document — a letter of guarantee or an illness record with several sheets — copies of which are sent back to the IPM with the bill.

The deficits incurred by IPMs are often ascribed to poor management or to fraudulent reimbursements (collusion between the IPM and certain laboratories; fraudulent agreements between a pharmacy and an employee, who pockets part of the cost of the prescription rather than taking the drugs prescribed; payment for a member of the family who is not entitled to it, with the complicity of the prescriber; etc.). Companies closely follow their employees' medical expenses. They oblige their IPMs to provide a monthly list of names of all beneficiaries.

Taken altogether, these complicated procedures are hardly compatible with maintaining medical confidentiality. When there is so much fear of fraud, confidentiality is not a priority; the tendency is rather usually towards strengthening controls. The manager of an IPM explained that when his attention is struck by an unduly costly medical prescription, he telephones the doctor who has prescribed it or else the pharmacy to request an explanation of the cost. A company doctor confirmed "that it is not possible to keep a diagnosis secret from the management, at least if they are to be persuaded to pay all of a patient's bill or to reduce his or her debts. They call for explanations. That's normal, and you have to tell them."

Mutual Health Insurance Societies

The first mutual health insurance society in Senegal — Fandène — was set up in 1989 at the initiative of the Saint Jean de Dieu Hospital in Thiès. It remains a model for the others set up later in the region. The mutual movement has gained momentum in the last three years, thanks to the Ministry of Health's CAMICS, which was created in 1997, and to several other organisations[1] that provide technical and logistical support. The mutual health insurance societies are firmly supervised, and promoting them has become "fashionable" among "development partners" [1, 9]. The two main types of mutual organisations are popular ones (mutual societies in particular neighbourhoods, for women, for religious groups, etc.), which generally reimburse the first part of any expense incurred, and professional mutual societies (connected with an occupational group: customs officers, teachers, etc.), which are often organised to supplement contributions made out of the government budget.

The popular mutual societies are designed to meet the needs of people with low or irregular income, particularly workers in the informal sector. The entry fees and the contributions are fixed according to people's capacity to pay. It costs 1200 CFAF to join one of them, for example, and each beneficiary has to subscribe 200 CFAF a month. Their ability to make reimbursements is thus often very limited. Their ceiling is ten days in hospital a year and 50,000 CFAF of medical expenses per person a year. Illnesses that are chronic (arterial hypertension, diabetes, heart problems, asthma) or serious (cancer) are automatically excluded from reimbursement. This restriction is considered absolutely necessary for the financial survival of these societies.

The professional mutual societies cover groups of senior staff, and often supplement what individuals receive directly from official funds. The Customs Officers Mutual Society (1400 members with 12,000 beneficiaries) is one of the more organised and most well-off societies. Contribution levels depend on the grade of the officer and therefore on her or his salary scale, and run from 1500 CFAF to 5000 CFAF a month, to which is added a contribution every three months towards a capital sum on retirement. The same benefits are made available to all members: the 20% of costs not covered by the government (see above) and 40% of the costs of medicines received outside hospital; 50% of the cost of spectacle lenses (up to 50,000 CFAF); a death benefit; a supplementary retirement benefit; and disability insurance. The chronically ill are not excluded from benefits. Procedures are cumbersome: the patient has to have her or his prescription confirmed by a doctor from the Customs Medical Centre before presenting it to the mutual society's office. S/he is then given a voucher, which allows her or him to buy the medicines at a particular pharmacy, paying only 60% of the cost. At the end of each month, the pharmacist sends the bill to the mutual society, together with copies of the prescription and the vouchers. This procedure prevents any confidentiality about the nature of the illness.

We estimate that there are 35 mutual health insurance societies in full operation in Senegal in 2001. More than half of them are in the Thiès region; they cover some 100,000 people. The International Labour Organisation in Dakar gives

[1] The ILO (International Labour Organisation), USAID (United States Agency for International Development), ANMC (Alliance nationale des mutualités chrétiennes – Belgium), WSM (World Solidarity Movement), and GRAIM (Groupe de recherche et d'appui aux initiatives mutualistes-ENDA-GRAF).

much higher figures (95 popular mutual societies, and a total of 450,000 beneficiaries for all types of mutual societies over the country as a whole). These figures seem to us to be too high, since they include organisations that are no longer functioning.

Private Insurance

There are seven major insurance companies in Senegal. Their activities are governed by the Interafrican Confederation of Insurance Markets (Confédération interafricaine des marchés d'assurances; CIMA). They offer health insurance coverage in a more or less developed way. Their main clients are companies, which insure all or part of their staff, and a few schools and private institutes that insure their teaching staff. Some international companies run an internal insurance scheme, usually for their senior managers. It is less usual for individuals to take out health insurance, which is extremely expensive. The insurance companies say they provide health insurance coverage for around 100,000 people.

For individual insurance, the premiums depend on the amount of coverage required. In one of these companies in 2001, the premium for a family of five (two adults and three children) was around 85,000 CFAF a month, for 80% coverage of costs, and 110,000 CFAF a month for 100% coverage. To get coverage agreement, a rigorous medical questionnaire has to be submitted, in which any serious illnesses (including HIV/AIDS) must be declared. The qualifying period can be as high as nine months for pregnancy, and two years for some chronic illnesses. These conditions and their premiums put these policies out of reach of most of the population.

Employment in Senegal

The majority of the labour force in Senegal works in agriculture. The agricultural labour force was estimated to be 2,220,000 at the end of 1989, out of a total rural population of 3,960,000 and a total population of 7,600,000. The agricultural sector consists mostly of small peasant holdings and is dominated by groundnuts. As in many African countries, the modern sector is only found in a few towns. The comfortable classes, who are the main consumers of most services, are not very numerous and are only in a few urban neighbourhoods, very often only in the capital. The working population numbered about 3 million in 1991. Urban areas contained 40% of the active workforce in 2000. The working population in the towns was estimated to be 635,000 in 1979–80. Some 152,500 of these were working in the formal sector, and 482,500 (or 76%) in the informal sector.

The number of people working in Dakar's informal sector was estimated at 665,000 by the Survey of Production and Consumption of Informal Sector Businesses in the Urban Region of Dakar in 1996. The number of employees declared in the private sector could be estimated at 135,000; government employees numbered 66,500 in 1996. The number of jobs in the recorded sector was nearly 200,000.

Source: [3, 4]

In fact, this kind of insurance is usually confined to the senior staff of large companies, which cover them completely or as a supplement to IPM coverage. The amount of premiums to be paid is negotiated company by company, and

depends on the number of people to be covered. The more people insured, the lower the premiums. The annual premiums at present range from 100,000 CFAF to 150,000 CFAF for an adult, and 100,000 CFAF for a child. The benefits are limited to between three and ten million CFAF a year. The senior staff of a large Dakar company, who contribute two percent of their salary — the company pays seven percent — receive complete coverage for hospitalisation costs and a reimbursement of 80% of the cost of biological tests, medical consultations, and medicines.

The medical advisers of the insurance companies keep a close watch over clients' files to see that no undeclared illness is made the subject of a claim, and if necessary, they make contact with the health facility treating the patient.

Paternalistic Care Provided by Employers

It is worth mentioning one other form of health coverage: the informal payment for health care by employers. This does not form part of the formal arrangements for social security, but it is too widespread to be ignored. In many businesses, the employees are not declared and they have no social security. Some employers, however, personally contribute to the cost of their employees' health care. Obviously there are no rules about what costs can be covered. Everything depends on the employers' generosity and on their relationships with employees.

The kind of help provided is at the discretion of the employer, and means that his or her employee almost has to beg for help. As everything depends on the employer's goodwill, this form of help is precarious. If relations between the boss and his or her employees worsen, or if the profits of the business go down, the employer can always renege on any verbal promise.

This way of providing for health care is based on particular relations with the employer. In light of the Labour Code, and the legal obligation to declare any employee, any paternalist protection of this kind, where the employer appears to be providing charity, could be regarded as completely unlawful. But in a country where 83% of the population has no access to any formal social security, help of this kind forms part of the customary relations of protection and of the complex forms of sharing related to the social fabric and to a social activity quite outside the formal social security system.

The Lack of a Social Security System Strategy for HIV Infection

The social security system in Senegal provides no clear or specific response to the problem of HIV infection. With very few exceptions, the institutions concerned have no experience dealing with this illness and no strategy to confront it.

The managers of mutual health insurance societies, whom we met in 2000 and 2001, did not express any concern about HIV, except that it was a very costly illness. Coverage for it would upset the financial soundness of these organisations, with their low income. To meet the expenses connected with HIV seemed quite impossible. This lack of awareness also meant that there was no plan to inform their members about prevention or to offer them testing or counselling.

In addition, some of the managers still made stigmatising comments about PLWA.

Much the same situation applied to the professional mutual health insurance societies, even those dealing with well-off people. Some of the managers justified this lack of any plan by the fact that none of their members had ever asked for help in this field.

The same lack of any plan to deal with HIV was found among the inter-company IPMs and the medical services of big companies that we interviewed — little or no information given to the staff, no move to provide testing or counselling, and no treatment policy. This was in spite of the fact that all the services we spoke to had had to deal with cases of employees who were infected, and despite the existence of training courses given by health professionals in 2000 on the subject "AIDS and Business." Managers of IPMs and company doctors and nurses thought it was their duty to tell the management about any HIV-positive person in the company. One doctor said that "it was part of his responsibility to the company, because it was necessary to arrange for the employee to be replaced." The problems that disclosing his or her illness would impose on the employee were never referred to as factors that might discourage him or her from asking for health care.[2]

Only two of the five companies we approached had set up any policy for treating PLWA. The initiative for this came from two company doctors, who had been involved for several years in the fight against AIDS. It is worth describing the arrangements set up by one of these doctors, in cooperation with the insurance company who provided coverage:

– X company, an international company based in Dakar, has around 7000 employees working in 16 African countries. All employees are covered by private medical insurance. The first case of AIDS in the company was identified in 1996. Three or four employees have died of AIDS since then. The company decided to pay for HAART for one of its managers in 1997. Afterwards, it negotiated a contract with a local insurance company to cover this cost. The cost of the premiums took into account that a dozen patients might need such treatment. The level of contributions paid by the employees was similar to those paid to an IPM. At present, three employees in Dakar are receiving HAART. The company doctor himself arranges to provide them with their drugs. A simplified procedure for reimbursement has been set up by the company doctor and the doctor of the insurance company, to ensure that the patients' identities remain unknown. The company doctor himself looks after the files of these patients and undertakes to keep them secret, so that neither the pharmacist nor the company management know who they are.

The procedures for reimbursement were specially adapted in this company, in order to meet the specific needs of PLWA, and this was arranged at the behest of the company doctor, with the agreement of his management and the insurance company's doctor. This suggests a possible alternative approach to that of public financing along the lines of ISAARV. Some studies have indicated the socioeconomic benefits to African companies that might follow from employers paying for HAART [8], and experiments are under way in large companies in

[2] For more on the ambiguous role of company doctors in employees' medical secrets, see [2].

Côte d'Ivoire [5] and in Cameroon [7]. In Dakar, the arrangements made after the first conclusive experiences may encourage other companies in the formal private sector to consider following the same route.

Self-Exclusion of ISAARV Patients from Social Security Benefits

In order to judge the effectiveness of the approaches made by PLWA to the social security system, we had discussions with 21 of them, 20 of whom were receiving HAART in the ISAARV programme. Out of these 20 people, seven were obtaining free treatment through one of ANRS/IMEA's clinical trials, and three others received free treatment as a result of an Eligibility Committee decision. The ten others were paying from 5000 to 10,000 CFAF a month at the time of our conversations with them. Six of them had joined ISAARV before its prices were reduced in November 2000 and had been paying between 20,000 CFAF and 25,000 CFAF a month for several months. One of them had been paying 75,000 CFAF a month.

Of the 21, 18 were members of a social security organisation that covered medical expenses: eight belonged to the civil servants' scheme, of whom three had supplementary coverage through a mutual society (Customs and Armed Forces); three were covered through their company IPMs; three by private insurance; one by his country's embassy; and three were receiving informal payments from their employers, one of whom was benefiting from social security. Three of them had no social security coverage. These people had been chosen because they had been identified by ISAARV health professionals as benefiting from social coverage.[3]

Whatever institution they belonged to (IPM, mutual society, or insurance company), all the people we interviewed revealed that they were not benefiting as much as they should from the provisions available to them. They had partial coverage from the organisation that reimbursed them. One of them had even decided to claim no reimbursement at all. Some extracts from his account show us the main problems that AIDS patients face in dealing with social security:

– B.L.[4] is a 35-year-old labourer. He earns 55,000 CFAF a month, and pays 5000 CFAF a month for his HAART. He took sick leave three times in 2001. He decided not to ask for any reimbursement from his company's IPM for the following reasons: 1) after being hospitalised for six days in 1998, he became heavily indebted to the IPM, which arranged to deduct 21,500 CFAF a month from his pay — nearly half his salary — for four months; 2) to claim reimbursement for a prescription, it had to be issued by a doctor appointed by the IPM, who charged 15,000 CFAF for a consultation, whereas a doctor at the Principal Hospital gave free consultations and the patient had to pay only the cost of the prescription; 3) the reimbursement by the IPM for the cost of medicines had to follow a predetermined procedure — you had to present the prescription to the manager, who gave you a voucher for the approved pharmacy — and he thought he could not

[3] It should be noted that 19% of the ISAARV programme's first 160 patients benefited from a more or less significant payment of their medical expenses through a social security system; see Chapter I.1.

[4] All initials have been changed.

otherwise get a reimbursement afterwards; and 4) he was frightened that he would be asked to explain the cause of his illness.

The four reasons why this man on a low income decided not to apply for the reimbursement of his medical expenses were: the low rate of reimbursement, the costs involved in the procedure, the way the procedure worked, and his fear of a lack of confidentiality. These various factors, which applied differently to different people, led them to limit their claims for reimbursement.

Low Levels of Reimbursement

Partial reimbursement, which was what the majority of social security customers were entitled to, acted as an obstacle to their making claims. It is clear that social security institutions follow this policy, in order to limit the amount of medicines used and therefore the costs of health care, by making the users bear part of the cost themselves. A fear of over-prescription or even of fraud is a constant theme of all those concerned with the running of schemes for reimbursing health-care costs.

Partial reimbursement of expenses soon leads to the most-ill patients incurring debt. Deducting the cost of the patient's contribution from his or her salary leads to a reduction in pay, which creates hardship for people and rebounds on their families.

Terms for Claiming Reimbursement

Each institution lays down its own procedures for reimbursement. Their main concern is to prevent fraud. The instructions are very strict, and any request for treatment must follow a rigidly defined course and often very complicated administrative procedures. If the place of medical consultation is not designated, the prescription must be confirmed by a doctor or administrative officer of the agency that is to provide reimbursement before the medicines can be obtained. The medicines can usually only be obtained at one of a short list of authorised pharmacies. The patients are often widely scattered geographically, and the delays caused by waiting at every step in the procedures are very discouraging. The two accounts given below illustrate this.

– T.D., a 40-year-old woman, is a mother of three children, one of whom is HIV-positive. She does not request reimbursement of her medical expenses because she finds the procedure lengthy, complicated, and costly in itself. She would have to go to the office of the mutual society to get a coupon upon showing them the prescription, and then she would have to go to the designated medical centre, where she would wait a long time to see the doctor who would confirm the coupon. She would then go to the secretariat, back to the office of the mutual society, and finally to the authorised pharmacy.

– B.E., a 35-year-old man, is a civil servant posted to a frontier region of Senegal. On sick leave for several months, he is seriously ill from the aftereffects of a cerebral toxoplasmosis. He lives with his family 200 kilometres from Dakar. To obtain reimbursement, he would have to take his prescriptions to be authorised in the town where he used to be posted, although he has not been there since the beginning of his illness.

Delays in Reimbursement Procedures

In addition to the procedures being complex, they are also slow. The complicated itineraries require several journeys, since not everything can be completed in a single day. It can be impossible for a person who has to work to lose so much time doing all this.

Administrative delays can sometimes result in a salary deduction that represents several months of medical expenses, which means a massive reduction in net pay.

The reimbursement for ARVs gives rise to a special problem, because they are supplied only at two places connected with public organisations, and therefore outside the usual arrangements with social security institutions. Several patients have told us that reimbursement for these drugs can only be made through special procedures, which inevitably means a loss of confidentiality.

The Cost of Procedures for Patients

The duration and complexity of the procedures carry a cost in themselves for those who use them. There are transport costs and the costs of lost time when all the organisations that have to be visited are widely dispersed. These costs are sometimes thought to be higher than the amount of reimbursement expected.

The Lack of Confidentiality

The lack of confidentiality in the various steps in the procedures for reimbursement is the main argument for explaining why reimbursement claims are not made. All those we spoke to raised this point, whatever social security organisation they belonged to (IPM, mutual society, or insurance company). This fear was based on objective facts (for example, procedures that required confidentiality to be broken) and subjective considerations (situations that people thought might lead to a loss of confidentiality).

Requests for exceptional payments from an IPM or a company always had to go through the stage of justifying the reasons for the request in front of a special committee and of revealing the identity of the applicant. Neither the employees nor the company doctors had much confidence that these committees were any good at observing medical confidentiality.

– B.C. is a 46-year-old woman who is a manager in an international company. She joined the ISAARV programme, making a monthly contribution of 75,000 CFAF a month. She tried to get her company to pay for the cost of the treatment, but the insurance company's doctor advised against this. AIDS was not covered by insurance. She would have to submit an application to him that would have to pass through the company's headquarters. The fact that she was HIV-positive could be leaked. Fearing that her condition might become known to her company, she did not seek reimbursement for this amount, nor for the cost of medicines that would allow people to guess what her illness was.

– A company doctor said that he had obtained agreement in principle from the company to pay for the cost of HAART, but he faced a problem which he thought he could not overcome. If the bill passed through the usual channels, it would have to bear the person's name, so that a deduction could be made from that

person's salary. If he tried to obtain 100% of the costs, the request would have to be specially justified and the contents of the file might enable people to guess the patient's identity. He feared that in either case, the person's confidentiality would not be preserved. The patient was thus not reimbursed the 10,000 CFAF monthly contribution to his ARV treatment.

Ordinary reimbursements also raised fears about a breach of confidentiality. Most of the people insured feared that those responsible would be sufficiently interested by the repeated requests for reimbursement to pursue their own enquiries. To remove suspicion, the ploy most often used was to limit the number of prescriptions for which reimbursement was sought, so as not to appear a "big consumer," and to make a choice among the prescriptions, to remove those that might give away the nature of the diagnosis. Obviously, prescriptions for ARVs were the first to be removed, but the motives for choosing what to leave out could be more subtle, with people taking out any prescription which they thought might "look too much like something connected with AIDS," such as prescriptions for cotrimoxazole or for twice-yearly blood tests. These ploys could be taken even further, as the following account shows:

– K.N., a 46-year-old man, had his prescriptions directly reimbursed by his employer, but he sorted out his prescriptions, according to the drugs they referred to and the illnesses they were meant to treat, and also according to where the prescription came from. He thus felt that diarrhoea, skin problems, and allergies would "make people think of AIDS" and did not submit prescriptions for treating these illnesses. He also withheld those with the "Fann Hospital" heading. When he had an intercurrent illness, he preferred to go for a consultation at Principal or Le Dantec Hospital.

In addition to the drugs or the illnesses, the patients thought that the identity of the medical service where the prescription was issued might risk stigmatising them. This fear, linked to the heading printed on the prescription form, also appeared in other situations, where patients thought their confidentiality might be compromised. Some people said they tried to avoid going to their mutual health insurance society, so as not to risk meeting people there whom they knew and who might ask them questions about what they were doing there. This fear was linked to the complaints about the complexity and the slowness of procedures, which added to the risks of meeting people who might ask questions.

Most of the people we met had excluded themselves from social security. When their expenses were connected with HIV/AIDS, they deliberately did not use all the possibilities for reimbursement that their health coverage might provide. The costs of the system, the cumbersome nature of the procedures, and the lack of confidentiality all represented insurmountable obstacles for these patients. Without simplified procedures where anonymity can be guaranteed, provision for covering the health costs of HIV-positive patients appears to be far from satisfactory.

Conclusion

The reimbursement of health expenses through the social security system in Senegal currently concerns only a small part of the population (17% in Dakar). The present arrangements for social security have no redistributive role. The people with the best coverage are those from better-off socioeconomic classes, precisely those who have less need than the rest of the population.

The level of reimbursement, particularly for the cost of medicines, is very limited. Patients have to meet a large part of the cost, which can lead to their falling heavily into debt. More often than not, the current procedures for reimbursement do not guarantee respect for medical confidentiality. People living with HIV prefer to forego the reimbursements rather than reveal the nature of their illness.

When this survey was carried out in 2000 and 2001, it was clear that in most social security institutions, no concerted and specifically defined strategy had been established to provide coverage for the treatment of HIV infection. With a few exceptions, the cost limits imposed on patients did not permit reimbursement for HAART, unless patients were subsidised by the government.

From every point of view — the level of subsidy, the simple nature and low cost of the procedure, and the maintenance of medical confidentiality — the subsidy given by ISAARV allowed for a better quality of service than that provided by any of the systems of reimbursement available to PLWA who had social security protection with health cover. Very few social security organisations had the capacity to provide the financial resources needed to treat HIV correctly (average monthly cost of ARVs of around 60,000 CFAF, plus a cost of 10,000 CFAF for complementary treatments for the first year of treatment [see Chapters I.2 and I.3]).

In most African countries, the current arrangements for social security are embryonic, and in some countries, consideration of strategies for universal access to health coverage excludes illnesses such as cancer and AIDS, which are thought to be too costly [11]. In the short term, it is therefore unlikely that existing arrangements for social security could play an important role in covering universal access to HAART. The only way to guarantee immediate access to this treatment that is more widespread and equitable is through subsidies — national and international — which could cover more than 90% of the actual current costs of these medicines in Africa.

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Chapter IV.3
The Circulation of Antiretrovirals in Senegal

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When the effectiveness of antiretroviral (ARV) multi-drug therapy was announced in 1996, those infected with HIV in most African countries tried to obtain these medicines for themselves, before the public-health system had made any decisions or launched any programmes to this end. Various personal strategies were devised to overcome their very high cost and their lack of availability: buying them abroad (in Europe or North America), buying them through private pharmacies or from drug importers, visiting or even migrating to Northern countries, or arranging networks of donations (within families, or through personal networks or association connections). Some of these networks now feed the informal drug market, but they all sprang up before, and quite independently of, public-health directives — indeed, at a time when AIDS health policies specifically excluded the use of such medications in Africa. During this same period, a large number of "traditional" or "neo-traditional" medicinal remedies emerged. They filled the market for anti-AIDS therapies, so much so that in some countries they ended up competing with highly active antiretroviral therapy (HAART).

The national HAART access programmes, such as ISAARV, have now become the main channel for obtaining these drugs, but they have still not eliminated other distribution networks. The distribution of ARVs is therefore far from a linear path from the drug manufacturers, through the prescribers, to the users, which is why "circulation" is a particularly appropriate term to describe the complicated routes sometimes followed by these medicines.

This chapter will explore the circulation of ARVs outside the ISAARV programme.[1] How were the different ARV supply routes in Senegal affected by the establishment of the ISAARV programme? How did ISAARV influence the development of these distribution channels? Were they fuelled or slowed down? How and why do some means of circulation seem to avoid any system of control? These questions are considered in the context of the three main operators in the field of distribution: the drug wholesalers and private pharmacies; drug donations; and the informal drug market. Although for the sake of clarity, a distinction is drawn between these different channels, they are often closely interlinked, as we shall see.

[1] The results presented in this chapter have been obtained by qualitative methods. Between 2000 and 2002, surveys were carried out via conversations with PLWA, association members, health professionals, pharmacists, market traders, and professional drug distributors. In many cases, direct observation was conducted by anthropologists from the programme (private pharmacies, Fann pharmacy, or in associations) or by surveyors (markets).

Wholesalers and Private Pharmacies

The role of wholesalers and private pharmacies is closely linked to the history of the arrival of ARVs in the country.

The Wholesalers

From 1996, several doctors and pharmacists in hospitals felt the need to have a stock of the principal ARVs in use in Northern countries. They were used mainly to avoid any interruption in the treatment of people passing through Senegal who prolonged their stay in the country, either because they were hospitalised or, less commonly, because they were living in Senegal and ran out of their medication. Stocks of small quantities of the medicines were established from gifts made by doctors or associations in the North (see below).

In 1997, following an agreement with the National AIDS Control Programme (PNLS) — and with the approval of the National Pharmacy Agency (Direction Nationale de la Pharmacie; DNP) to import ARVs, which were not at that time authorised for public sale — three wholesalers (Cophase, Laborex, and Sodipharm)[2] agreed to carry stocks of some of these patent medecine. Clinical practitioners could then send patients who had the resources to pay for these drugs, in particular those with medical insurance. The wholesalers issued the medicines directly to patients, which was outside their normal field of activity, and agreed to take no profits from the medicines, which were then still extremely expensive, in order to keep costs down for patients. From 1997 onwards, the wholesalers assured regular provision for patients, and ARV distribution went from an occasional relief measure to one of regular supply. There was no other supply source in the health-care system at that time.

The launch of the ISAARV programme in August 1998 did not fundamentally change this situation. Those few people who bought their drugs from the wholesalers on a regular basis could not be — or less often, did not want to be — enrolled. In order to control ARV distribution, ISAARV programme managers and wholesalers agreed that the latter would only issue ARVs per the prescription of a doctor whom the PNLS had deemed competent in AIDS treatment. It was further agreed that the medications would be issued directly to the patient, and that their supply to private pharmacies would be banned. This was an oral, not written, agreement.

At first, the Fann Hospital pharmacy did not issue ARVs to people not enrolled in the ISAARV programme, but this restriction was lifted in March 1999. The drugs were thenceforth sold at the same price at all outlets. This opening up to "off-programme" patients followed an agreement whose main purpose was to prevent the medicines from expiring and the outlets from running out of stock. This agreement shows how close cooperation was between the wholesalers and ISAARV programme managers. Thus, up until the end of 2000, wholesalers sometimes loaned boxes of ARVs to Fann pharmacy in case of delayed shipments.

[2] The firms are referred to in alphabetical order.

This system carried on until the October 2000 reduction of ARV prices. This reduction applied only to the public sector, however; wholesalers maintained the old prices,[3] which on average were four times as high as the new ones. The PNLS, concerned that "all Senegalese people" benefit from the reduced prices and aware that the ISAARV programme could not be the country's sole source of ARVs, proposed that wholesalers obtain their stocks from Fann pharmacy. It then undertook to compensate them for the difference in price of their existing stocks by giving them a quantity of drugs valued at the amount of the difference.

In March 2000, a first estimate of wholesaler-dispensed ARVs showed that between 20 and 30 people were supplied. By April 2002, only one wholesaler still had a patient who came each month to buy his drugs, the second wholesaler only made occasional deliveries, and the third had made none at all for several months.

At Fann pharmacy, a survey of prescriptions issued to "off-programme" patients over a period of three years from April 1999 to March 2002 shows a total of 225 issues. Only 38 of them were made during the first two years, an average of between one and two a month. Fifty were issued in the following six months (April to September 2001), an average of eight patients a month (minimum two; maximum 19). In the final six months (October 2001 to March 2002), 134 issues were made — an average of 22 patients a month (15–28). The opening of Fann pharmacy to "off-programme" patients resulted in a progressive and almost complete shift in ARV supply from the wholesalers to the hospital sector. The possibility of a rush of patients from neighbouring countries, which was raised when the ARV price reduction was announced, seems so far not to have been realised. During recent months, the number of new patients being treated "off programme" has been offset by the number in the ISAARV programme. In addition, the fact that the ISAARV programme is able to treat an increasing number of people (up from 80 in April 2000 to 450 in April 2002) has rendered marginal the number of patients treated "off programme" in the biomedical sector (from 35 to less than 7%).

ARV access for "off-programme" patients responds to several different demands. Some people come from neighbouring countries (Guinea, Mauritania, Mali, etc.)[4] and have sufficient financial resources to pay for their journey and to buy their drugs every month. Among people living in Senegal are some who refuse to join the ISAARV programme because of the risk of exposure that accompanies so well-known a programme. For the same reason, some others continue to obtain their drugs abroad. Finally, a high proportion of "off-programme" patients (between four and ten people in the past two years) are salaried employees of Dakar-based firms. Some of them actually live in Dakar, others in neighbouring countries, and three come from more distant countries (Chad, Central African Republic). They have medical insurance, which covers between 80% and 100% of the cost of treatment. A few patients are not enrolled in ISAARV because of wrong ideas about it or from a lack of information. In addition, a considerable number of provisions to "off-programme" patients are made irregularly. They are made to people travelling or to those who

[3] The Accelerating Access Initiative contract, signed by pharmaceutical companies and the government, stipulated that the undersigned drug manufacturers would no longer fill orders from private wholesalers in Senegal.

[4] Not being a resident in Senegal is one of the exclusion criteria for ISAARV.

receive only intermittent treatment. They are sometimes made on a preventive basis, in the case of accidental exposure from sexual relations, and are paid for by certain Dakar-based organisations (in particular the health services of the Senegalese and French armed forces), or if there is a risk of mother-to-child transmission.

Most of these "off-programme" patients are treated by ISAARV doctors, sometimes in association with another doctor, particularly a company doctor. Some doctors from outside the programme, who work in hospitals or in private practice, provide repeat prescriptions for visiting patients or to prevent transmission. Only three doctors issued regular prescriptions for ARV triple therapy after having initiated treatment for the patient.

Private Pharmacies

People wanting to obtain ARVs soon turned to private pharmacies. The district of Dakar has more than 200 such pharmacies.[5] Three surveys have been carried out in the past two years: the first by telephone, covering about 40 pharmacies (October 2001), a second by partly structured conversations with six pharmacists (2000–2001), and finally, a third survey of the ethnography of one pharmacy (August 2001).

Of the 44 pharmacies surveyed, ten had stocked ARVs in recent years; three have had them in stock but have never sold any (one of them through a donation from France, two others by orders placed with a wholesaler); seven others have supplied ARVs, sometimes several times to a patient. One of them had supplied ARVs for three years to two patients from The Gambia, the last provision being made in January 2002. In another one, more than ten prescriptions had been issued in two years, mainly to prevent transmission during sexual relations.

One pharmacy had obtained ARVs by express courier from a supplier in France for an occasional delivery of a first prescription for HAART, presented by a foreign resident who was about to leave Senegal. All the other pharmacists said they had ordered them directly from wholesalers in Dakar. The way the medicines were supplied was always the same: the wholesalers, who had been approached by telephone, asked the pharmacist to ensure that the patient was present, or failing that, to keep the prescription, and the drugs were delivered within hours of the order being placed by telephone.

Even if they do not receive many clients, the fact that ARVs have been supplied through pharmacies shows that patients in search of treatment do look to the private pharmaceutical sector. Some pharmacists, who have not supplied ARVs, say that prescriptions for these medicines are sometimes presented to them. Various sources say that these enquiries mainly come from people from other countries or from visitors who are not fully aware or informed of the situation. The survey also showed that the level of knowledge among pharmacists about the ISAARV programme and about ARVs was very mixed. This lack of knowledge often gave rise to unsuitable practices or advice (HIV testing without patient knowledge), lack of respect for confidentiality, bad advice to patients about the health-care system, sporadic provision of ARVs).

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[5] 173 pharmacists in the Health Professionals Guide, provided by the National Council of Doctors; 233 in the list of pharmacists registered by the DNP in 2000.

Up to now, the circulation of ARVs in the biomedical arena, outside the ISAARV programme, is mainly carried out by wholesalers and Fann pharmacy. The PNLS controls this circulation. In 2002, about 20 patients were concerned (nearly five percent of the total number under HAART in Senegal). This treatment is almost always prescribed within the health-care system by doctors experienced in the use of the drugs in conformity with prescription recommendations. The circulation of ARVs from private pharmacies still seems very limited. It concerns only a small number of people, usually for the occasional supply of visitors or foreign residents.

Donations

Medicine donations from Northern countries to those of the South is an old tradition, one of the principal expressions of contemporary medical humanitarianism towards "poor countries." A great many social activists are involved in collecting and sending medicines — individuals acting of their own accord, charitable and professional organisations, health organisations, governments, international organisations, manufacturers, etc. Donations can equally be made by people in the South and can be made between PLWA, sometimes as a way of sharing treatment. A very wide range of different situations of donations and donors has been identified in Senegal.

The sharing of treatment between spouses, family members, or friends can be regarded as the first kind of donation. Donations between individuals made on their own account can be hard to identify, but several health professionals and patients have cited examples. These gifts are often made among members of the same family, as shown in the following account:

In May 2000, a woman came for a consultation with the nurse at the medical centre in the town of Kidira, a small town near the borders of Mali and Mauritania, some 400 kilometres from Dakar. She brought with her two boxes of Retrovir® 250,[6] saying that they had been sent to her by her husband living in France, with a message that she should go to the nurse to have an explanation of how the medicine should be taken, but without any word about the illness it was supposed to cure. The nurse then heard that the man had been "very ill for two years, and had gone to France for treatment."

The extension of the number of intermediaries involved in sending personal donations sometimes leads to unfortunate results over where the drugs end up. In April 2000, a French hospital doctor asked one of his colleagues coming on a mission to Senegal to take with him a one-month ARV treatment. It was intended for a young woman living in Senegal, whom the doctor had been treating for a long time in France. Passed on to a third doctor working in Dakar, these drugs never reached the person they were intended for, because of a mistake in the woman's address. Several months later, they were handed in to the Fann pharmacy before they reached their expiry date. The same thing happened with two packets of Videx®, sent from a hospital in France to a doctor working with ISAARV, after having followed a complicated trail — through a woman working

[6] The two packets were unopened, but there was no label. Both packets had the same batch number and the addressee of this batch from the pharmaceutical firm that had produced them, which assured that this batch of medicine had been distributed only in France.

in France, her mother living in Dakar, the owner of a pharmacy who kept them for several months, one of his employees, and then a social worker. Donations are not necessarily sent to someone in need of them. They are often given to health professionals, but can sometimes also help to stock the informal drug market (see below).

A large number of charitable organisations in the North collect and send medicines to health centres or associations in the South. Two associations have been identified as having received ARV medications. One has received Retrovir® from time to time; the other has received ARVs regularly, at least up to the beginning of 2000. After that date, no further entry of ARVs are recorded in the association's medication log, although some doctors reported that this place was an occasional supply source and that a portion of their ARV stocks came from here.

In 2002, most of the doctors involved in treating PLWA had set up small stocks of ARVs — usually not more than four or five packets of the drugs most commonly used — from donations sent by their colleagues in the North or from donations found with local associations. These medicines are used in emergencies, most often to prevent any interruption in treating patients who are "off programme." These doctors manage these stocks themselves, along with all the other small lots they come by, notably those they receive as samples from laboratories.

Through the relationships that they have established in countries of the North, ISAARV doctors have been able to obtain more substantial donations from institutions. Thus in 2002, a lot of 50 packets containing eight different molecules was provided by the Bordeaux Town-Hospital Network (Réseau Ville-Hôpital de Bordeaux). This gift followed contacts set up during a professional meeting between doctors from ISAARV and those from this network. This lot of medicines was incorporated into the Fann pharmacy stock.

ARV donations are very seldom made directly to the Health Ministry or to the PNLS. Contributions to the development of ISAARV through bilateral cooperation almost always come in the form of money.[7] Some drug manufacturers, who refuse to reduce the price of their products, make an "offer" of one or two packets for each packet that is bought. This kind of donation is really a form of commercial negotiation. In April 2002, for the first time, a substantial in-kind donation was made to the Health Ministry by a Senegalese association Africa Helps Africa (Afrique Aide l'Afrique), which offered 1424 packets of ARVs.[8] Donations to the Ministry of Health or to the PNLS are put into the usual distribution circuit for ARVs (Fann pharmacy).

In order to reduce improper use of these drugs, the PNLS soon recommended that all donations pass through Fann pharmacy. This was aimed at preventing these drugs from circulating without any control and to make the best use of them through ISAARV. This policy of centralisation allows for use of the largest donations, in particular the donations from institutions, which have sometimes been encouraged by ISAARV professionals. This centralisation only works in

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[7] This is the case with the most recent French initiative: the ESTHER programme provides for a fund of 600,000 euros, to be managed by the PNLS, to provide for the treatment of 450 patients over three years. The ARV medicines are provided from the usual ISAARV circuit.

[8] This donation was made up of three molecules in the form of four patented medicines (Retrovir® 100 mg; Epivir® 150 mg; Trizivir®; and of Combivir®), for a value of 70,868,000 CFAF.

part. It is clear that most individuals in the country are unaware of this provision. Nevertheless, some associations supporting PLWA have submitted the few packets that they may have been able to obtain. On the other hand, some doctors who prescribe ARVs keep for their own patients the small number of packets of these drugs they receive.

The value of some donations is limited by the variety of molecules that are sent in small quantities and cannot be used, because they do not fit into the antiretroviral regimens used in Senegal. Between August 1999 and July 2000, 100 packets of ARVs from various donations were registered at Fann pharmacy. The sample comprised seven molecules (3TC, AZT, d4T, ddI, ddC, nelfinavir, saquinavir) in the form of eight patent medecines (Combivir®, Epivir®, Hivid®, Retrovir®, Videx®, Viracept®, Zerit®, Fortovase®). One was in two forms and the other in five (thus in 13 different forms). Among these patented medicines, three have not yet been used by ISAARV (Hivid®, Fortovase®, Viracept®).

In addition, some of the drugs are at, if not beyond, their expiry date. They therefore need to be destroyed, which means extra work and extra expense. Forty-seven of the 81 packets in stock in July 2000 were already expired. At the beginning of 2000, two cartons of ARV medications, sent by an association in France, had to be burnt, since they reached Dakar after their expiry date. This lack of care is not peculiar to associations alone. At the end of July 2000, the local representative of the firm Bristol-Myers Squibb donated 30 packets of Videx® 100 mg, due to expire at the end of the following month.

When medicines are received by the Fann pharmacy, their future use is straightforward and guaranteed to conform to the recommendations, as they are simply added to the existing stocks. They are given to ISAARV patients or to "off-programme" patients, or else they are destroyed if expired. The use of drugs controlled by ISAARV doctors creates no special problems.

Some donations, for various reasons, fall outside the centralised system of the Fann pharmacy and circulate within the care system, with the PNLS unable to control their distribution. Some of these donations can be recovered by ISAARV doctors, which means that their proper use can then be assured, usually for "off-programme" patients. These are usually donations inside families or between persons, made on compassionate or humanitarian grounds, and are connected with the non-availability of treatment, either genuine or supposed through lack of information. These donations are not made very often, are small in quantity, and can easily be reduced, as more and more patients are included within the ISAARV programme and as better information is spread about treatment availability and accessibility in Senegal. Some of these donations end up with people or associations uninvolved in the fight against AIDS, untrained professionals, or health services that have little to do with AIDS. In all these situations in which the donations are badly targeted, the risk of loss and of drugs being sold off is particularly high, with some of them reaching the informal drug market.

The Informal Drug Market

The sale of medicines in markets or on the streets is a well-developed commercial activity in Senegal, as it is in the rest of Africa [3, 6, 7]. The low prices usually charged, the chance to buy individual tablets, the less restrictive nature of exchanges about the illness and the medicine [5], are all factors that contribute to its flourishing. The most recent molecules are sold there very quickly, and one would expect to find ARVs there as well.

The sale of these drugs in African markets has been observed in Cameroon and in Togo since 1998.[9] The hypothesis that ARVs would be circulating in the markets in Dakar was thus made at the start of the programme. In Senegal, medicines are on sale in practically every market and everywhere that people go (crossroads, bus stations, ports, etc.). In February–March 2001, a preliminary survey conducted in Dakar covered 29 such places, where 135 sellers were identified. Each seller dealt in 20 to 60 different patented medicines, depending on the extent of his activities. None of these sellers we met during this initial survey had any ARVs, and none of those who agreed to speak to us knew about these medicines.

But the informal trafficking of medicines in Senegal is not confined to these widely dispersed locations, which form only the base of a highly organised and structured commercial edifice, largely controlled by members of the Muslim Mouride Brotherhood. Two places are particularly known for their sale of pharmaceutical products: Touba, the holy city of Mouridism, some 190 km east of Dakar (founded by Cheikh Amadou Bamba, the Brotherhood's founder [2]), and the Keur Serigne Bi Market in Dakar, which, as its name suggests, is the "House of the Marabout" of Touba. The scale of commercial activity in these medicines in these two places is quite high because the wholesalers that supply all the country's vendors are based there, and the volume of products sold is substantial. A wide range of pharmaceutical products is available, and one can even find the most recent medicinal products there, sometimes before their arrival on the official distribution circuit.[10] The ARVs identified on the informal drug market have all been found in these two places. Injectable Retrovir® was the first product identified at the beginning of 2000. Later the same year, Retrovir® in capsules was also seen, as were Videx® and Zerit® 40. Altogether at the beginning of 2002, eight molecules were identified in the form of ten patent medicines, three of them in different dosages: Epivir® 50, Combivir®, Crixivan® 400, Efavirenz, Retrovir® 100 and 250, Trizivir®, Videx® 100 and 200, Viracept®, Zerit® 30 and 40, and most recently, Avocomb®.

The prices of these medicines followed the reduction of prices agreed to by the pharmaceutical industry: injectable Retrovir® was being sold at Touba at the beginning of 2000 for 125,000 CFAF per packet; in June 2001, three packets of Crixivan® 400, Retrovir® 100, and Videx® 200 were being sold at 40,000 CFAF. In the same way, Zerit® 40 was sold for 120,000 CFAF per packet in July 2000, and at 12,000 CFAF the packet in January 2002. In September 2001, two boxes of Epivir® 150 and of Videx® 200 were on sale for 30,000 CFAF for the two boxes.

[9] They had not appeared in Burkina Faso at the time of the first survey on this topic in 1998 (cf. [1]).

[10] This was particularly the case with Viagra®, which appeared almost immediately after it was put on the market in the United States.

The batch numbers showed that most of these products came from countries in the North. No counterfeit products have yet been identified. What is happening is the resale of donations, or of products that have leaked from the health facilities, or through more elaborate plans of collecting medicines in the North for sale in Senegal. Only 13 packets had batch numbers identical to those in the official distribution system (ISAARV and wholesalers), which suggests a very marginal outflow from one of the official centres of distribution, or the return of medicines after a change in therapeutic regimen, or alternatively, which is more likely, the resale of drugs by a small number of patients.

Various indicators suggest the emergence since the end of 2001 of strategies to expand this commercial activity: several sellers are aware of different ARV medications, and can clearly identify them as "AIDS medicines." Some others test the possibility for sale by offering "samples," which they do not want to sell immediately, reserving the possibility of a supply adjusted to demand. One of them in January 2002 held a lot of 20 packets of Zerit® 40,[11] which implied a considerable investment and suggested that he already had a guaranteed sale. And some sellers put ARVs on the market and themselves proposed inadequate prescriptions: Weekly or monthly injections of Retrovir® cited in 2000 seem to have been given up. Instead, the sellers advise, dual therapies (AZT + ddI), or a mono-therapy with Zerit® 40, would be more effective than a triple therapy.

These surveys confirmed the presence of ARVs on the market, but showed the limited nature of their presence. The rigorous control of distribution within ISAARV makes it very difficult to attempt any diversion of drugs. The attention and the follow-up given to patients also restricts the possibility of medicine resale.

Conclusion

We have deliberately excluded from this chapter the vast subject of "traditional" or "neo-traditional" medicines, although a great number of healers propose such remedies for AIDS and some even propose "new treatments derived from ancestral wisdom and confirmed by experiment."

The results of our research show that very few patients receive HAART prescribed by doctors outside the ISAARV programme (about 20 people in 2002). A third of these people have medical insurance from their employers based in Dakar. Most of these patients are not enrolled in ISAARV because they work or live outside Senegal. The rest are well-off people who live in neighbouring countries or who prefer to be treated in the private medical sector or abroad, or those treated by doctors in the margins of ISAARV, who sometimes prescribe non-conventional HAART. At the end of the first half of 2002, almost all these patients obtained their ARVs from Fann pharmacy; one obtained them from a wholesaler.

[11] The batch numbers of all the ARVs found in these markets were noted. The pharmaceutical firms producing these patented medicines were asked at the end of 2001 and the beginning of 2002 to identify the institutions to which these different batches had been sold (depending on the medicine, a batch contains between 1500 and 9000 boxes). Two firms, which had agreed to provide this information, had not responded by the time this article went to press, which is why we cannot state for certain the origin of this lot of 20 packets.

Aside from those places officially authorised to distribute ARVs to people not enrolled in the ISAARV programme, the other medicines that circulate in Senegal outside the programme mainly come from donations from Northern countries and, very infrequently, from sales by private pharmacies. Some ARVs that have been sent as donations have been found on the informal market or, in small quantities, in private pharmacies, with doctors, or in associations.

Some writers have expressed fears that the creation of HAART access programmes in Africa would lead to the uncontrolled trafficking of these drugs [4], particularly through indirect supply to the informal market. The situation in Senegal shows that most of the channels of circulation had been set up before ISAARV was launched, by a group of operators who sought to improve accessibility to these drugs and sometimes to profit in so doing, and that most of the drugs in circulation, apart from those controlled by the PNLS, did not come from the programme itself.

Senegal combines a low rate of HIV prevalence, a government initiative for treatment access, and strict control of ARV distribution. From the agreements made with wholesalers, the opening of the Fann pharmacy to "off-programme" patients, and the centralisation of donations, the PNLS has succeeded in restricting a significant portion of the circulation network that existed prior to ISAARV.

Despite this very favourable situation, there is some circulation of ARVs outside the distribution networks officially authorised by the PNLS (ISAARV and wholesalers), though it is at a very low level. This will probably persist for some time, largely for reasons outside the control of ISAARV. Most public-health programmes (the fight against tuberculosis and leprosy, the promotion of contraception, etc.) — including but not limited to those that provide free treatment access — do not bring an end to the informal-sector circulation of the drugs they distribute. The issue is understanding this circulation: to control it and to keep it at as low a level as possible calls for an analysis of the networks and of the reasons for the circulation, as well as a system of surveillance that is capable of quickly detecting any possible expansion. It also means facilitating access to high-quality biomedical treatment in the health-care system. The expansion of the programme, its decentralisation, access to ARVs at a reduced price — or free—and good information for the population and health professionals (doctors, pharmacists, associations, etc.) about the programme and how to access it will probably eliminate many channels of circulation, particularly interpersonal donations and some donations from associations in the North.

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Conclusion

ISAARV: An Assessment (1998–2001)

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This assessment describes and analyses the impact of the ISAARV programme from the point of view of its beneficiaries (i.e., its results in the medical, social, and psychological fields) and from a public-health perspective (i.e., its scope, organisation, consequences for the association movement, and impact on the circulation of medicines). It also reviews the principal lessons learnt from ISAARV's pilot phase.

The Success of the ISAARV Programme

The ISAARV programme has demonstrated that the introduction of antiretroviral (ARV) medicines to treat HIV/AIDS is feasible in an African capital city. In the first place, the treatment initiated in Senegal was a success, from a biological and a clinical point of view, comparable to that observed in developed countries. Nearly two-thirds of the patients monitored over a period of 30 months receiving an available treatment had undetectable viral loads (below 500 copies/ml) after the first year (see Chapter III.1). The ARV multi-drug therapies have been, on the whole, well tolerated. This good virological response was accompanied by a low occurrence of ARV-resistant HIV-1 strains: 13 patients among 80 (16.3%) had resistant viruses after a median follow-up period of 24 months, the selection of resistant viruses being more frequent among patients who had taken highly active antiretroviral therapy (HAART) before their admission to the ISAARV programme than with treatment-naive patients (41.7% compared to 11.8%; see Chapter III.1). These good clinical, immunological, and virological results must be seen in direct relation to:

– the type of treatment regimen: apart from of a few dual therapies prescribed at the start of the programme, all the combinations prescribed were triple therapies that included a PI or an NNRTI. These first-line regimens with high potential efficacy were a guarantee of success among patients who were mostly treatment-naive;

– the high degree of adherence reported by patients to prescribing doctors or to the dispensing pharmacists (see Chapters II.1 and III.1). This adherence to treatment was supported by several of patients' own attitudes: most of the patients being symptomatic, they were highly motivated, and many felt privileged in a context of scarce treatment (see Chapter II.2). Other contributing factors were related to the health-care system (i.e., adherence counselling provided at the pharmacy, the absence of any shortages in stock at the pharmacy, and the reduction of treatment cost for patients who had economic difficulties; see Chapter II.3) and to the therapeutic regimes (i.e., the use of simplified regimens, in particular of triple therapy in a single daily dose); and

– the skill of the medical team in organising regular patient follow-up and the rational use of HAART.

The level of efficacy obtained, achieved nowhere else in Africa in a follow-up cohort study, can be further explained by other factors.

Government commitment was significant and sustained. The Senegalese programme for access to HAART was a government initiative whose project manager is the National AIDS Control Programme (PNLS). The subsidies provided in its first year of operation enabled some 50 courses of treatment, and the necessary immunological and virological tests, to be carried out each year. When a change in the political majority at the highest levels of the government occurred in 2000, the same attention was given to treating PLWA with HAART. Government funding for this practically tripled over three years.

ISAARV developed its activities at the institutional level, by bringing onto its steering committee the people most closely involved with medical care for PLWA, counselling, and biological follow-up of HIV infection. These links brought together principally health authorities, the university medical sphere, and health-care system professionals. These actors were already involved in the fight against AIDS before HAART was introduced, and they brought their scientific knowledge and experience of HIV management in the Senegalese context, as well as their leadership abilities, to the health-care teams. This dynamic group organised preliminary training before HAART was introduced and developed the necessary level of technical expertise. Existing partnerships in the research field helped to attract support from Northern-based teams to create proper follow-up conditions. The fact that this group remained intact throughout the programme's first three years helped provide a close and interactive collaboration among the different groups of people involved in patient care (for biological follow-up, clinical and psychosocial care, and the provision and delivering of reagents and drugs). The ability of the ISAARV managers to mobilise drug firms (Glaxo-Wellcome, Merck Sharp & Dohme, Bristol-Myers Squibb, Boehringer), research partners (ANRS, IRD, IMEA), and in due course, funding organisations (the EU, IDA, and the Global Fund to Fight AIDS, Tuberculosis and Malaria) strengthened national commitments. In addition to their current and future support for activities, these scientific and financial partnerships have already helped to support and structure the planning and scheduling of ISAARV's activities and setting deadlines for results[1,2].

In addition to the dynamism of this founding group, the prudence of the chosen strategy should be emphasised: the scope was to show that providing high-quality treatment in the African health context was feasible, for a benefit similar to that achieved in developed countries, at the lowest possible risk regarding selection of drug-resistant viruses. This implied geographical and financial accessibility of drugs, adequate clinical and biological follow-up, and a high degree of adherence. During this experimental phase, quality of treatment was prioritised over its wide distribution, with the size of the programme being equally constrained by the limited resources available.

One of ISAARV's major strategic choices was to make HAART available to everyone whose condition medically justified it. The principles of equity and

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[1] Initiative sénégalaise d'accès aux antirétroviraux "ISAARV." Plan d'action 2000–2003. République du Sénégal, ministère de la Santé, Programme national de lutte contre le sida, octobre 2000.

[2] Plan stratégique 2002–2006 de lutte contre le sida. République du Sénégal, Conseil national de lutte contre le sida, décembre 2001.

social justice led to treatment subsidies according to the patient's resources. ARVs were therefore made available at the lowest prices set by the first African initiatives for HAART access (Uganda, Côte d'Ivoire).

Regarding organisation, conditions for access to treatment were strictly laid down during the pilot phase: the prescribing doctors had to be authorised by ISAARV; there was a single dispensation site; procedures for accepting patients were uniform; and a standardised system for clinical and biological follow-up was established, as well as a tightly controlled network for ARV distribution. The continuity in ARV supply was maintained, even when the molecules were diversified and the number of patients increased.

The experimental aspect of the project created special conditions for confidence in the treatment and the programme among patients and health professionals. The patients who were enrolled were highly motivated, since they were aware of their good fortune in being among the first people to benefit from subsidised HAART in Senegal. The health professionals were equally motivated by their involvement in an experience which aroused interest among the scientific community worldwide.

The desire for high-quality assessment that could help in monitoring the pilot programme lay behind the launching of operational research projects on various subjects related to fundamental virology, clinical research, and economic and social sciences. The financial support for various research projects provided funding for repeated immunological and virological tests, for the training of several clinical and biological staff, and to strengthen teams for adherence-support. The participation of researchers in the various committees from the very beginning of the programme added to the multidisciplinary spirit of the programme. Scientific consultations continued to be active over strategic decisions and organisational set-up. Evaluation sessions were organised during these first three years: a first internal assessment of the programme was made in January 2000; indications for ARV multi-drug therapy and therapeutic protocols were revised in October 2000,[3] and a study on the social aspects of treating PLWA with HAART in Africa was conducted in October 2001.[4] In addition, annual scientific councils were held under the aegis of the PNLS and of ANRS. These provided further opportunities to discuss the results of the on-going research projects, and to define new areas of research that would be of interest for the development of the ISAARV programme.

ISAARV differs from other current African initiatives in the following ways:

– the government's commitment, which lay at the origin of the initiative, and its political and financial support, contrasting with the very slight involvement of the non-governmental sector (see Chapter IV.1);

– the capacity for adaptation and the ability of those involved to react to external changes: the price of ARV drugs in the international market, the results of the initial evaluation of treatment adherence and accessibility, the evolution of international scientific knowledge about treatment regimens (i.e., early rejection

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[3] Africa. Use of antiretroviral drugs in the management of HIV-infected persons. Updated recommandations, October 2000. ANRS, IMEA, IRD, Société africaine contre le sida, UNAIDS, PNLS-Sénégal, PNLS-Côte-d'Ivoire, International AIDS Society.

[4] Place des antirétroviraux dans la prise en charge des personnes infectées par le VIH en Afrique. Aspects sciences de l'homme et de la société. Atelier de Gorée, octobre 2001.

of two-drug regimens as initial treatment, and inclusion of NNRTI). This pragmatic character of the programme was linked to its modest scale; the small number and geographical concentration of those involved; the dynamism of those in charge; the closeness of health teams, operational research teams and decision-makers, and also to the common contribution of them all to the development of the operation; and the increased funds that were made available, which reduced fears about the programme's sustainability;

– the limited numbers of patients included during the first three years;
– the support of operational research covering widely different subjects (a situation resembling that of Côte d'Ivoire);
– a planned expansion, based on the financial resources that were made available;
– continuous stock of ARVs in the dispensing pharmacies.

The Programme's Limitations and Difficulties

To consider the difficulties encountered, we shall use the classic criteria for evaluating health programmes.

Accessibility of HAART

The accessibility of treatment depends on several factors: access to awareness of one's HIV status, access to knowledge about the existence of ARVs and of a treatment programme, geographical accessibility of health centres offering HAART, and economic accessibility of HAART.

Concerning accessibility, the ISAARV programme was set up as a pilot project for its first three years, and did not set out to cover a wide geographical area (only two centres were involved, both in Dakar, treating limited numbers of patients — nearly 300 people over these three years). According to estimates made at the end of 2000,[5] 77,000 adults were infected with HIV in Senegal, and 20% of the infected adults (some 15,000 people) had reached the state of AIDS.[6] The coverage of the HAART access programme was thus very limited (500 out of 15,000, or 3.3% in April 2002), and the impact of the programme on public health, in terms of reducing morbidity and mortality, was thus very small. Access to testing was not directly developed within the ISAARV programme, but it was assumed that making HAART available in regional centres would necessitate the setting up of counselling and testing centres. Communication strategies about the availability of new therapies were relatively limited and did little to make known the offer of treatment outside certain health organisations.

The main area where ISAARV produced results was financial accessibility. The provision of subsidies, according to the patient's resources, showed a desire for social justice. It emerged that most of the patients had very limited financial resources and thus qualified for the minimum level of financial contribution set out in successive price settings (see Chapters I.1 and I.2). This minimum contribution can be regarded as the measure of equity in the programme, since hardly

[5] Bulletin épidémiologique VIH no. 8, Comité national de prévention du sida, décembre 2000.
[6] Plan stratégique 2002–2006 de lutte contre le sida, 2001. Idem.

any of the patients could count on any help from any health insurance organisation to pay for HAART (see Chapter IV.2). The 24-month social follow-up of 164 patients revealed how low patients' incomes were (nearly half had no income at all); the impact of disease on families (a quarter of households had more than one patient to look after); the particular socioeconomic vulnerability of women; and the high share of ARV costs in family budgets and the efforts made to raise money to pay for them (see Chapters I.1 and I.2). The parallel follow-up of treatment adherence revealed the negative impact of the financial contribution on HAART adherence (see Chapter II.1). During ISAARV's first three years, ARV prices were reduced, in keeping with the price reduction agreed upon by the pharmaceutical firms. As soon as more affordable prices had been introduced, patients with lower incomes were enrolled. The 100% subsidy, recently introduced, was obviously a key element in making ARVs available to the majority of patients. It is the only way to allow most patients to regularly renew their prescriptions.

Availability of Qualified Human Resources, Medicines, and Reagents

In its three clinical centres in Dakar, the ISAARV programme mainly involved health-care professionals and social workers. In contrast with other countries, such as Côte d'Ivoire and Mali, the involvement of associations in care for patients under HAART was marginal, although it has developed a little in the past year (see Chapter IV.1). Biomedical care depended on the commitment of prescribing doctors and of qualified biologists (thanks to additional training given before the start of the ISAARV programme and to refresher training courses on the use of ARVs). For social follow-up and adherence monitoring, nurses and social workers received no formal training and had no defined framework or tools for follow-up. Knowledge and practices were worked out in each centre or within research projects. The pool of professionals involved in the ISAARV programme in Dakar organised trainings in some of the regional centres expected to offer HAART at a later date.

Various aspects of medico-biological follow-up were defined and adapted to fit with a fairly modest technical level. Psychological follow-up, on the other hand, remained somewhat vague, reflecting the lack of precise instructions on the use of "light tools" that were developed on the basis of research project results. In addition to this problem of transferring a functioning model, the lack of human resources must also be emphasised, especially in the social sector, in some of the centres in Dakar and in the regions. Moreover, the teams looking after the patients also complained of having too much work and no extra staff to handle it. Resources (office equipment, means of communication or transport) were also insufficient to cope with the additional activities.

There was no shortage of stocks of ARV products during the first three years of the ISAARV programme. The supply system will be adapted when the programme is expanded beyond Dakar. Whereas the two dispensation centres in Dakar are both stocked from a hospital pharmacy, which is itself supplied by the National Supply Pharmacy (Pharmacie nationale d'approvisionnement; PNA), regional centres will be supplied by the regional branches of the PNA. The evaluation of local needs and stocks should then be followed up at the central level to ensure that orders are properly co-ordinated.

There were repeated shortages of biological reagents for quantifying viral loads and CD4 counts, which sometimes led to a delay or even to a loss of information concerning patients on HAART or a delay in assessments for patients about to be enrolled. The evaluation of needs and ordering and payment procedures should be improved to handle an increasing number of patients.

Efficacy Within the ISAARV Programme and Its Impact on Public Health

Although the immunovirological results were generally satisfactory, the clinical impact, in terms of a reduction in mortality, was limited, compared with results shown in developed countries. The high mortality rate (11.6 per 100 person-years) reported for patients treated for 30 months emphasises the reduced impact of HAART on strongly immunodeficient patients, and the problems related to treatment of intercurrent infections in patients in bad condition (see Chapter III.1). CD4 counts at enrolment were very low for many patients. Clearly an ARV treatment should be initiated as early as possible, once the clinical and biological criteria are met. This calls for the creation of a standardised and documented system of follow-up for patients, from the moment they are diagnosed. Although this is recommended by the PNLS, this follow-up is not yet effective for all the people who have just been diagnosed. The availability of ARVs should be accompanied by a high capacity for treating opportunistic and other infections to optimise the impact of HAART. The rate of definitive abandonment of treatment remained very low (1 for 100 person-years for the first 180 patients enrolled).

Some aspects of patient care need to be strengthened and harmonised for proper psychosocial follow-up. For example, support for adherence should involve various actors in the health-care system (doctors, pharmacists, social workers, or nurses) and in the associations, through individual counselling (in medical consultations, at medicine dispensation, or interviews), as well as in discussion groups. For the moment, only one centre for patient care is running regular support groups. Contact with patients gone missing is often hampered by the lack of means for transport. Adherence follow-up by the pharmacist was sometimes difficult to manage, outside any research project, since it often seemed an additional burden, without an obvious benefit. The motivation of those involved in such an operation depends on the recognition of the value of their contribution, and on their acknowledgement in frequent meetings with other involved health-care workers. Local co-ordination at every clinical centre has, in this context, an important role in validating the contributions made by every team member (see Chapter II.3). As for the need for psychological support, both quantitative and qualitative studies have drawn attention to how often patients encounter psychological and relational problems. However, spontaneous demands for specialised care from patients or from clinicians or social workers are still relatively infrequent. Weekly sessions with psychiatrists were provided in one of the three clinical care centres, but few attended them. It seems necessary to develop a system of psychological care and support, directed by a central specialised team that could support on a regular basis the various actors for the benefit of the patients, their families, and also the health-care team (see Chapter III.3).

Acceptability of Treatment in ISAARV

Most patients, for whom clinical treatment has been effective, have regained a precious quality of life, because of the disappearance of physical problems and the removal of the clinical signs of the illness that had stigmatised them (serious weight loss, marks on the skin). These signs had attracted criticism, made them feel guilty, or even led to conflicts. Treatment enabled them to resume work and undertake normal daily activities, and once more to make a contribution to family life, notably with children. The return to good health did not, however, remove completely the psychological burden of the illness. It signified the loss of the condition of being "a sick person," which, within certain limits, allowed patients to benefit from "family solidarity." Health rendered them once again liable to "social obligations," without, however, enabling them to meet their financial obligations, because of the direct or indirect costs associated with their treatment. Health did not remove the fear of being a danger to one's partner or to one's family circle, though it tended to revive questions about having children. These problems did not devalue HAART for patients, but they did lead them to change their priorities and join in new social networks, formed with people who shared their concerns (see Chapter III.2).

As in other socio-cultural contexts, HAART is a treatment that carries restrictions. This is due less to the actions it necessitates for the patient than to the way these actions "mark" the patient's illness and to the changes they make in a patient's relationships once treatment obliges him or her to disclose his or her seropositivity.

Patients showed considerable confidence in HAART, articulating their feelings of being privileged, and later the feeling that access to treatment was their right, to statements about the efficacy and effects of the molecules fixed in their bodily perceptions. Adherence still demanded, however, that patients adapt, integrating medicines into their daily lives and integrating awareness of seropositivity into close relationships. Most patients found the relational aspect of the treatment harder to cope with than the material requirements and restrictions that went with their prescriptions, particularly during the early years of the ISAARV programme. The need to rely on family solidarity subjected the patients to a moral or financial "debt law," which sometimes led to conflicts, while possibly endangering familial economic stability without even a guarantee of sustained treatment access. From this point of view, the reduction of the cost of medicines helped adherence, since it reduced the impact of treatment on relationships with the extended family and gave people the chance to keep their seropositivity to themselves, if disclosing it would spark conflict. The high level of patient confidence in treatment was probably also due to the involvement of ISAARV health professionals: the patients saw the desire of the team to establish coherent arrangements to help meet and resolve their problems. The reduction in prices made the ISAARV programme and then the ARVs more acceptable because it enabled patients in precarious financial situations to obtain high-quality health care. The patients were themselves aware of these efforts and appreciated the nature of the therapeutic relationship built up with most of ISAARV's health professionals, even if they often found them authoritarian. The high rate of acceptance of HAART noted in Dakar can only be understood in the context of these therapeutic relationships and a programme that was widely acceptable to the patients.

Programme Sustainability

State financing of HAART, which caused concern in its first years, was never cut back, and on the contrary has been increased. Other sources of funds appeared in 2000 (the EU), in 2001 (the IDA) and in 2002 (The Global Fund for the Fight against AIDS, Tuberculosis and Malaria). The 2002–2006 Strategic AIDS Control Plan established 2006 as a target for the provision of HAART to 7000 patients. The main problem will be to get the resources that have been promised. This will depend on the complicated financial procedures of the various donors involved and on the management capacity of the Senegalese institutions concerned.

Receipts from patients, originally envisaged as a possible source for buying medicines, were not in the end used for this purpose, and they would not have covered more than 10% of the costs of the products on the international market (see Chapter I.4). It is thus mainly public funds and international aid that will secure the programme's development and sustainability.

Organisational and Operational Aspects of Running the Programme

Several things went wrong in the programme's pilot phase, due to the complexity of some of the procedures (access procedure, attribution of subsidies), financial or material constraints (regarding medicines, reagents, office equipment, and communications), or the fact that some of those involved were not sufficiently available for the work (because of limited human resources, sometimes little motivation, or overwork). Some of these points have been dealt with in the preceding paragraphs.

The access system, described in Chapter I.1, seemed poorly adapted to a continuous increase in the number of patients and centres. The procedures need to be simplified, as do also the procedures for attribution of patient subsidies. A two-level pricing system for ARVs is ideal, especially in the regions, with guaranteed free treatment access for the very poorest and another modest level of contribution — 2500 CFAF a month, for example. Rather than having the contribution depend on an assessment of the patient’s and her or his family's resources, it would be preferable to fix objective criteria of need, which would be clear to patients. These might consist of making a 100% grant for “those under 18, those without any personal income, those with someone else in the family infected,” etc. This procedure could be applied by any of the staff involved, and the patients could thus start their treatment once the diagnosis and the treatment regimen had been approved by the Medical Committee (Comité médical technique). To permit regular enrolments in the programme, committee meetings should be held once a month without fail. Missions and membership of other committees, in particular that of the “central” committees, should certainly change, due to the increase in the number of centres and of the staff involved. Their timetable should involve meetings once every two or three months.

Conclusion

In 1998, the Senegalese government decided to meet the challenge of treating HIV infection with HAART in African health-care structures. The present work highlights the positive experience of the first three years of this HAART programme, an experience limited to three centres in Dakar and to a few hundred beneficiaries. The next challenge to the Senegalese health-care system lies in providing HAART in the country's regional capitals. The project's pilot phase has enabled many gains to be registered, notably in the field of biological and clinical follow-up. It has also drawn attention to the system's limitations, particularly in treatment access and adherence support. Actions in the psychosocial field need to be more clearly defined, taking into account the potential support of actors from the private sector or associations. Restructuring the central core of the programme with a view to decentralising training, supervision, evaluation, and co-ordination procedures, also seems to be a necessary precondition to running the programme on a national scale. Additional human, financial, and material resources are required. Operational research should contribute to the process, with the objective of providing evaluation and help for decision-taking and action. The results achieved in the pilot phase can only be obtained on a greater scale if these conditions are taken into account.

Perspectives

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Senegal was the first African country to put forward the idea of access to highly active antiretroviral therapy (HAART) through a public programme — thus demonstrating an unprecedented commitment from an African government. The pilot project began in 1998, against a backdrop of low HIV prevalence rates and under the sceptical eyes of public-health experts of the international community. Apart from a small group of scientific experts, public-health officials, and political leaders who had explored the question of how antiretrovirals (ARVs) could be used in Africa and had supported their introduction here, this kind of health care was considered beyond the capacity of countries with limited resources and thus not a priority for them.

While positive results were being obtained from the introduction of triple therapies with protease inhibitors in developed countries, the difference in access to HAART between developed and developing countries was arousing increasing indignation, particularly in the activist movement in both North and South. The fight to make HAART available in less developed countries met a major obstacle: the price at which patented pharmaceutical products were being sold. In this international setting of questioning how strategies for care could be devised in developing countries and of tensions with the pharmaceutical companies who held production licences, Senegal introduced an experiment that provided positive results, which was soon taken up in international circles as a model for consideration for further HAART programmes in Africa.

Now that the feasibility and the efficacy of HAART in an urban African context have been demonstrated during the pilot period, the challenge facing the ISAARV programme is to demonstrate that the impact on public health can be extended to a national level, in particular by reducing mortality among PLWA in Senegal. This goal entails increasing the number of people who are receiving HAART in Dakar, as well as in the regions, and maintaining the level of effectiveness attained in the pilot phase. This future development is the objective of a five-year plan, which includes establishing care centres in the regional capitals. The donors (the International Development Association and the Global Fund to Fight AIDS, Tuberculosis and Malaria) have undertaken to support the will and financial investment of the Senegalese government. An ambitious target–treating 7000 patients–has been fixed for 2006. If this target is reached, the coverage of patients with symptoms will be 46%, assuming that prevalence levels remain comparable. This change of programme scale should have a major public-health impact.

Though the experience gained in the pilot phase has informed consideration of how to provide treatment in decentralised areas, questions remain concerning the various points described below. These questions are valuable for the formation and comparative analysis of other HAART programmes in countries of the South.

Decentralising Care and HAART Access for PLWA

The choice was made to integrate HAART into existing hospital services, rather than develop a specific new vertical programme (based on the model of the TB national programme). It follows that existing health care teams will be implicated, the medicine-distribution services in place will deliver ARVs, and existing hospital laboratories will be used for immunological checks-ups. To increase the demand for health care, information, counselling, and voluntary testing centres will be set up near treatment centres.

In the regional centres, a single committee, the "Enrolment and Follow-up Committee," will coordinate the activities of the centre. This committee will include the health and the social staff, as well as association members or patient representatives. The level of consultation and cooperation in these small multidisciplinary teams, all focusing on the same target of beneficiaries, will determine how dynamic the centres will be. Following the same model, multidisciplinary committees for each care centre will be formed in due course in Dakar along with the increase in activity.

The increased workload resulting from introducing HAART into existing clinical centres should be offset by additional staff and extra means and equipment (office equipment, travel expenses, tools for communication such as telephones, Internet, etc.). The provision of additional resources should be made in proportion to the centre's extra activity. This is particularly important for health structures that depend on limited means and are supposed to "balance their budgets," so that patients who are "big health-care consumers" but "small payers" can be properly treated. These patients, with their own very limited resources, can hardly make any serious contribution that could be circulated to provide an income to staff. The commitment of the health-care system's staff and of associations that might be involved must be sustained by providing proper resources for their work.

Protocols and tools for clinical, biological, and social follow-up to be used in the decentralised sites will require adaptation for contexts with fewer medical, paramedical, and social staff. Strategies for overall care, including its biomedical and psychosocial aspects, have yet to be defined. The treatment regimen will incorporate first-line simplified schemes, which besides being effective and well tolerated, are often better accepted. The rhythm of follow-up and the writing-up of medical records will be standardised, so as to allow for retrieval of essential information. Biological follow-up will adhere to methods that can be used with reduced technical equipment (for example, CD4 count by immunofluorescence microscope), and more sophisticated techniques in case of unsatisfactory clinical or biological developments should be provided for: samples could be sent to the reference laboratory in Dakar to determine viral load or to research major mutations that could explain resistance to HAART.

Psychosocial care should be organised at different levels: support when patients face social problems in accessing or following HAART (financial problems or relational difficulties with the health-care system, problems with adherence, negative perceptions about the treatment, etc.); support regarding more general social and relational problems (economic hardships, provision of food, jobs, discrimination, sexual life, married or family life, a wish to have children,

etc.); and psychological care of patients with acute problems. Identification of roles within the health-care system (psychologists and psychiatrists, social workers, etc.) and also outside it (association members, contributors from the private sector, etc.) is vital for the provision of social care close to the patient, based on community support. An effort to consider and formalise the strategies for action that are to be contained in this overall care scheme (and to provide the tools for its practical application — reference guides, documents for following up on actions taken) is indispensable for HAART to be introduced in new places, allowing for high-quality initial training. This training will particularly concern associations and NGOs involved in adherence support, through support groups, information groups, and groups for specific actions (adherence clubs). Community support for adherence can thus be connected to self-help actions. The participation of all concerned in the initial training and in the launch of activities is vital for the establishment of proper working practices. A database managed at the central level and the collection of essential data on medical and social follow-up will enable regular evaluation of patient confidence in the programme, immunovirological efficacy, and consistency of follow-up.

Enhancing Equity and Transparency, Reducing the Cost of Access Procedures

The experience of the first two years shows that any pricing system should incorporate the 100% subsidy to guarantee universal access. More than 90% of patients initiating HAART in 2002 received this subsidy. The question of maintaining a system of contributing to ARVs is debatable, since the present arrangements are clearly cumbersome, not very transparent, expensive in terms of human resources, and characterised by a subjective approach to taking decisions (see Chapter I.2). In addition, the costs of health care outside HAART are steep for patients, most of whom are symptomatic (see Chapter I.3). The arguments for making HAART available to all patients free of charge are based on: ethical considerations (a strict application of principles of equity and justice in a country where 60% of the people are living under the poverty line); public-health considerations (adherence — a guarantee of treatment efficacy — appears to be higher among patients receiving the drugs free of charge); considerations of efficiency (the present system for allocating subsidies and for collecting financial contributions is costly, and the sustainability of the programme cannot depend on financial contributions from patients); and finally, political considerations (the provision of free HAART in countries of the South was first called for by doctors and by activists in associations, was put into effect in Brazil, and now has the support of some European political leaders[1]). A wide and free provision of HAART would make HIV care closer to care systems already existing for “major endemic illnesses” such as tuberculosis, onchocerciasis, leprosy, or trypanosomiasis [5]. While the HAART programme should be integrated into existing health-care structures, it should also benefit from exceptional arrangements for charging fees; as a stigmatising pathology, this disease carries a heavy social cost which often involves whole families and demands a lifetime of treatment whose costs cannot be met by exceptional contributions based on the usual arrangements for “solidarity.”

[1] For example, Ms Wieczorek-Zeul, German Minister for Development, in *Frankfurter Allgemeine Zeitung*, 30 March 2001.

A large-scale supply of ARVs requires that the National Supply Pharmacy (Pharmacie nationale d'approvisionnement; PNA) be able to reduce the costs of medicines, which can be achieved by turning to generic drugs, by obtaining further reductions in the price of patented drugs, and by validating and generalising new treatment strategies. Securing fresh funds from international organisations, as well as maintaining the continuation of their existing financial support, will be necessary if the programme is to be expanded.

Adapting the Programme's Infrastructure to an Increased Number of Centres

The scaling-up of the programme should be accompanied by restructuring its organisation. At the "central" level, the programme must bring together sufficient human and material resources to provide for coordination, supervision, training, and evaluation in the different centres, as well as for their management. The present patient database is an essential tool for monitoring and evaluation. The structuring of this central "core" and its ability to intervene will be vital preconditions for the revitalisation of the decentralisation process and its follow-up. Five full-time staff members seem the minimum needed (a coordinator, a manager, a supervisor/trainer for biomedical aspects, a supervisor/trainer for social aspects, and a public-health doctor or an epidemiologist to run the database). Those who made up the ISAARV founding group did most of their work outside the programme. Some of them could make an important contribution to the process of decentralisation as coordinators, trainers, or in evaluation. Nevertheless, the scaling-up of the programme will call for full-time staff. The proposed structure at the central level should facilitate exchanges between the management of the programme and the decentralised groups and enable useful cross-fertilisation. This team would make regular visits to the regional centres, in order to set up the local teams and train them in procedures for selection and follow-up. They should carry out periodic evaluations of the level and quality of the work undertaken and confirm the presence of the minimum means (i.e., medicines, reagents, follow-up equipment, etc). Adequate means for communication and travel will be needed to carry out visits to the regions and ensure that regular exchanges take place.

The role of the "central" committees will change. The present Eligibility Committee will become a Steering Committee, concerned with the technical and financial evaluation of the programme, the choice or adaptation of strategies, and the study of particular cases. The central technical committees (the Medical Committee [Comité médical technique], the Welfare Committee [Comité pour les aspects sociaux], and the Drugs and Reagents Management and Supply Committee [Comité de gestion et d'approvisionnement en medicaments et réactifs]) will take on the tasks of coordinating, supervising, training, and evaluating and monitoring different aspects of the programme (access to treatment, the quality of the clinical and psychosocial care, its immunological and virological efficacy, and the provision of medicines and biological reagents). The directing staff from the regional centres will be encouraged to participate, so as to contribute to the evaluation of progress in each regional centre and the solutions for any problems encountered, to deepen reflection on certain technical aspects of care in each specific context, and to harmonise practice.

Development of Operational Research for Evaluation Purposes

Operational research has produced crucial information during the pilot phase on: HAART effectiveness and feasibility, interest in using simplified treatments, follow-up of viral resistance, financial aspects of HAART access, HAART adherence, measures for adherence support, patients' experience of treatments and psychological needs, dynamics of the association movement, and finally, circulation of ARVs outside the ISAARV circuit.

To enhance consideration of the implementation of HAART programmes in Africa, it seems necessary to pursue the development of research projects in Senegal along two main axes:

– the long-term (over several years) effectiveness and efficacy of HAART: follow-up of the initial cohort beyond the first three years of enrolment will enable monitoring of viral strain sensitivity; clinical, immunological, and virological efficacy and tolerance of HAART (including the importance of side effects of metabolic origin); the progression of simultaneous infection by hepatitis B and C under HAART; the maintaining of adherence; interest in alternative or sequential treatments; and changes in patients' experience of infection and treatment over several years;

– the minimum provision for ensuring high-quality care in the regional structures: necessary strategies for biological, clinical, and social follow-up; definition of actors; procedures for financing various aspects of treatment; the way in which patients, health-care workers, and the community perceive this treatment; as well as issues relating to the cost-effectiveness of the treatment.

Conclusion

At the Extraordinary Session of the United Nations General Assembly in June 2001, heads of state and government representatives committed themselves "as a priority, to ensure progressively and in a sustainable way, the highest possible level of treatment for HIV, especially its prevention, the treatment of opportunistic infections and the effective utilisation of antiretroviral therapies...."[2] Later on, in April 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria chose the first programmes to be supported (including the one in Senegal). The main obstacles identified were economic and technical (relating to public health). Mr Peter Piot, the Executive Director for the UN Programme for HIV/AIDS, recently recalled the progress achieved during the previous year in developing a global response to the epidemic, but expressed concern about the lack of available resources [4].

This background of lacking resources, which one would have hoped to be less substantial after the unprecedented political activity during the past two years, requires consideration of how resources should best be allocated. Two studies that examined the cost-effectiveness ratio of different intervention strategies called for allocating the newly available funds to prevention measures and to care, excluding long-term multi-drug therapies [1, 3]. These analyses are based on patchy data and underestimate some of the benefits of structured pro-

[2] Resolution adopted by the UN General Assembly on 27 June 2001.

grammes for HAART access. They do not consider the value in diversifying activities and ignore the requests of PLWA and the individual and collective importance of keeping them in good health. Although in the North antiretroviral treatment did not require economic justification in relation to prevention activities to generalise its use, the provision of antiretroviral multi-drug therapies in "poor" countries is endlessly under threat from "appeals to common sense," based on arguments that are advanced as "scientific." Many scientists against the idea of imposing "the cost of the experiment" [2] on PLWA in countries of the South proposed at the International AIDS Conference in Barcelona that an end be called to this one-sided debate, which should henceforth be regarded as closed[3]: whatever the context, it cannot be disputed that prevention and care are complementary. The real economic questions concern reducing the cost of treatment and making the necessary funds available.

The technical arguments calling for the fulfilment of numerous prerequisites before creating HAART programmes in any country of the South are often relevant. The ISAARV programme has provided some original responses to them and has made available to decision-makers a number of pragmatic solutions or ones that have emerged from operational research. ISAARV's experiences, however, cannot be regarded as universally valid, unless its limitations are also taken into account, and if other countries adapt the Senegalese "model" to their own circumstances, improving it as necessary.

The social, economic, educational, and political consequences justify the replication of these programmes. This social necessity makes the "pilot" experiment that provided widespread HAART access in Senegal a beacon for the benefits and limitations of large-scale structured treatment programmes, within other strategies for fighting HIV.

[3] At the opening of the Barcelona Conference, P. Piot criticised the reports, based on cost-effectiveness arguments, that concentrate on prevention at the expense of setting up a HAART treatment system. He judged this debate outdated: "The only effective treatment at present is antiretrovirals.... Let's get the debates about cost-effectiveness and the need for treatment out of the way. Are we accountable against our promises?" XIVth International Conference on AIDS, Barcelona, 7–12 July 2002.

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