How was the UNAIDS drug access initiative implemented in Chile?

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Abstract

In 1997, UNAIDS decided to implement Drug Access Initiatives (DAI) in four different pilot-countries. We studied the implementation of the DAI in Chile as part of the evaluation program conducted by the 'Agence Nationale de Recherche sur le SIDA' (ANRS/France). The objective was to understand how the politico-organizational dynamic influenced the implementation process of the DAI. Approximately 50 semi-directed interviews and observation activities were conducted with the actors who participated in the implementation of the DAI or who played a role in the HIV/AIDS context. The program theory models were established and their evolution analyzed. This article offers an original analysis of an international HIV/AIDS drug access program that was put in place at a time when such programs were seen as a priority by international and governmental institutions. It also offers some insights for the creation of international projects that will be locally implemented.

Keywords

Implementation evaluation; HIV-AIDS; International policy; UNAIDS; Pharmaceutical industry

1. Introduction

The first scientific results on the effect of tri-therapy were presented during the world conference on AIDS in Vancouver in July, 1996. It raised great hopes among patients, as it was the first treatment that really could improve their health-states for a significant length of time. The possibility of living with HIV became a reality. Associations of patients actively promoted an accelerated commercialization of the new drugs (Maguire, 2001). On the other hand, questions of equity were raised by different leaders, including political representatives of developing countries: how were we to accept treatments being unaffordable in developing countries where the majority of the people with HIV/AIDS lived?

At the end of 1997, two-thirds of those living with HIV/AIDS were in Sub-Saharan Africa. Adding South and Central America and South and South-east Asia gave us 90% of the

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persons living with HIV/AIDS (PLHA). 93% of the people affected by HIV and living in developing countries did not have access to antiretroviral (ARV) therapies (Forsythe, 1999). Prices of drugs for multi-therapies constituted 86–91% of total annual therapy costs (Floyd & Gilks, 1998). Pharmaceutical products, as any commercial product, are subject to international trade agreement regulations. Among the multilateral agreements ratified during the Uruguay Round in 1994, the TRIPS, Trade-Related Aspects of Intellectual Property Rights (Bulard, 2001; Bond, 1999; Demenet, 2001; Rivière, 2001a, b; World Health Organization, 1998), is the one that has had the greatest impact on the pharmaceutical industry (World Health Organization, 1998). According to the TRIPS, the state members of the World Trade Organization (WTO) shall guarantee patent protection for at least 20 years for all products. Some exemptions exist for patented inventions that are subject to commercial exploitation that threatens ‘public order and morality’ (art.27.2 cited in World Health Organization 1998:21). First, a country can decide to import a product, without the agreement of the patent holder, if the price in a foreign country is lower than the price offered on the local market (parallel imports) (Consumer Product Technology-a). Secondly, the government can impose compulsory licenses that allow the production of generic products, without the agreement of the patent holder, on the condition that he is paid a right (Consumer Product Technology, 1999; World Health Organization, 1998). Yet, the countries of the South that have tried to use these exemptions had to face pressures from the United States, the World Bank, some European countries, and pharmaceutical lobbyists (Demenet, 2001). Such was the particularly well-known case in South Africa when 39 pharmaceutical companies sued the government because it wanted to encourage the local production of generic ARVs (see <http://cptech.org/ip/health/sa/>). At the beginning of 2001, the Brazilian government was brought before the WTO by the American government for locally producing HIV/AIDS generic drugs (Rivière, 2001b). Similar examples are numerous and our objective is not to list them all. Using the parallel imports and compulsory licenses exemptions for HIV/AIDS therapies can have great consequences on international trade. This may create a precedent that could be applied to other diseases or in other countries, but it can also contaminate other sectors where international agreements are contested such as computers and agribusiness (Rivière, 2001a).

The joint United Nations program for HIV/AIDS (UNAIDS) was created in 1996 by bringing together six UN organizations: UNICEF, UNDP, UNESCO, WHO, World Bank, and UNFPA (UNAIDS-a). The United States is the main contributor as it finances one quarter of UNAIDS’ 60 million \$US annual budget. In 2000, UNAIDS developed the ‘Accelerating Access’ initiative (UNAIDS-b, c)—a new initiative which associates the private sector (the main pharmaceutical companies) and international and governmental institutions. The objective is still to support the countries in their decision to increase access to treatment for people living with HIV/AIDS. UNAIDS proposes an alternative to the use of trade agreement exemptions which UNAIDS does not seem to consider as a possibility even in situations of sanitary emergency. UNAIDS largely encourages negotiated agreements between the main pharmaceutical companies and the governments.

In 1997, before the ‘Accelerating Access’ initiative, UNAIDS decided to set up an experimental treatment access project for HIV/AIDS in developing countries as a first step for a wider strategy. UNAIDS decided to implement pilot-projects in four countries: Ivory

Coast, Uganda, Vietnam, and Chile. At that time, HIV prevalence in Ivory Coast and Uganda was high, 10.06 and 9.51%, respectively (UNAIDS/WHO, 1998). HIV prevalence in Vietnam and Chile was much smaller: 2% (UNAIDS/WHO, 1998). To be selected, countries had to present political and social stability, demonstrate their political engagement in combating HIV, have a national AIDS program, present good evaluation conditions, and have a high HIV infection prevalence or a high incidence. Disposition of medical equipment and location in diverse geographical zones also constituted selection criteria (UNAIDS, Background Document). The objective was to widen access to HIV/AIDS therapies, which implied negotiating drug prices corresponding to the economic reality of the country, and creating rational conditions for treatment access. The Drug Access Initiative was based on the assumption that drugs should be affordable, that is, adapted to the country's ability to pay (UNAIDS, Background Document). The idea was to convince pharmaceutical companies, who pay off the development costs of drugs in rich countries, to offer these same drugs at a subsidized price in developing countries. This would offer them the advantage of keeping their profit margins in rich countries, yet increasing their sales by penetrating new markets.

This research was part of the evaluation program of the UNAIDS Drug Access Initiative (DAI) in Chile, coordinated by the National Agency of Research on AIDS in France (ANRS). In particular, the objective of this implementation evaluation research was to examine how the politico-organizational dynamic explained the development of the project, with the aim of identifying factors that helped or impeded its implementation. The goal of this research was, first, to help countries with the implementation of the project; secondly, to create information for countries interested in offering ARV treatment at large. We examined negotiation and decisional processes using the strategic analysis model (Crozier & Friedberg [1977] 1992; Friedberg, 1993, 1994) as a conceptual framework.

In this article, we present our theoretical framework and methodology. Then, we explain the evolution of the DAI through three logic models (McLaughlin & Jordan, 1999; Rowan, 2000; Weiss, 1998). The first represents the DAI as it was conceived before its implementation. The second represents the adaptation of the DAI to the Chilean context. The third presents its implementation, highlighting the strengths and difficulties associated with the politico-organizational dynamics (Figs. 1–3).

2. Theoretical framework and methods

The work we realized is a process evaluation (Sheirer, 1994; Weiss, 1998) or an implementation evaluation (Patton, 1997) depending on the terminology and definition used. Our study addresses questions of program objectives, design and delivery with the objective of understanding what was going on. As a theoretical framework we used the model of strategic analysis developed by Crozier and Friedberg in their book *Actors and Systems* ([1977] 1992). It is a good model for grasping the organizational dynamic of a particular context. This model can be interpreted as a component of the movement of process analysis of political networks (Crozier & Friedberg [1977] 1992] 1993; Gervais, 1998; Kingdon, 1984; Klijn, Koppenjan & Termeer 1995; Klijn, 1996), political networks being

characterized by the interdependence of multiple actors having multiple rationalities (Marsh et Rhodes 1992; Kickert, 1993).

The theoretical framework cannot be dissociated from the research data collection process, as it does not pose a priori relations between variables. It promotes the utilization of an hypothetico-inductive strategy (Crozier & Friedberg [1977] 1992). Based on the approach Crozier and Friedberg propose, we designed the specific objectives of our study: (1) documenting the history of the DAI; (2) identifying important themes related to the implementation of the DAI; (3) documenting the history of each decisional process chosen and identifying facilitating factors and difficulties actors meet; (4) examining how the intra-theme dynamic influences the orientation of decisions; (5) investigating the politico-organizational dynamic of the whole system, so as to explain how the DAI was implemented in Chile.

The initial project was designed in 1997 and different activities took place up to the official inauguration of the DAI in Chile in January 2000. We consider these official and informal activities at least as significant as the media-covered ones. In collaboration with the director of the National Commission on AIDS in Chile, we chose different games (Crozier & Friedberg) or issues (Langley, Mintzberg, Pitcher, Posada, & Saint-Marcary, 1995) to be studied. We centered our data collection around the Advisory Board and the drugs import/distribution process. We also documented the context of HIV/AIDS in Chile.

Data were collected between September and December, 1999. The data collection took place in Santiago where the majority of PLHA lived. Our data collection was limited to the metropolitan region even if regional health care centers treating patients with HIV/AIDS were concerned by the DAI. In that sense, we don't offer a complete portrait of the situation in Chile.

We used several sources of information. First, semi-structured interviews were conducted with about fifty actors, who could be divided into two groups. The first group was composed of people who effectively played a role in the development of the DAI. The second group consisted of people who did not participate directly in the UNAIDS project, but who appeared to be essential, in order for us to have a complete portrait of the HIV thematic in Chile. As the DAI had a participatory mandate, it gathered many actors dedicated to daily activities different from those of the DAI. We interviewed actors from CONASIDA (the National Commission on AIDS), Vivo Positivo (the national association of people living with HIV), people working in the health system, patients, managers of pharmaceutical companies, representatives of UNAIDS, people working for FONASA (the public health insurance fund) and for ISAPRES (private health insurance funds), actors from UNDP, and people working for NGOs and foundations. The same researcher conducted all the interviews. The actors were guaranteed that the information would be kept confidential. The interviews were recorded with the actors' consent and transcribed. The text was coded twice and NUD*IST 6.0 Software was used to classify the different themes.

Second, numerous ethnological observation activities were conducted in different health care centers (including hospitals) and associations of patients, in various official and informal

meetings, etc. Although information about the functioning of health care centers was mainly collected through interviews, we also observed directly the process of care for PLHA in one hospital in the metropolitan region.

Third, information was gathered by reading the press releases compiled by CONASIDA from 1996 to 1999.

As a single researcher collected and analyzed raw data, there was a risk of misinterpretation. To minimize this bias, we carefully triangulated information contained in the different sources of data. We also discussed, during all the evaluation process, particular points with a member of the CONASIDA. Finally, the evaluation report was submitted to the ANRS and to the CONASIDA in order to validate our analysis. The report was sent to all interviewees.

3. Results

3.1. The initial logic model (see Fig. 1)

The pilot-project had three main objectives: to give access to HIV-related therapies in developing countries, to create optimal conditions of access, and to collect information for generalizing the program to other developing countries. A selected number of patients would be eligible for the program.

At the structural level, the mission of an advisory board, made up of representatives of the different groups that participated in the HIV thematic, would be to guide the Health Department in all aspects concerning implementation and functioning of the DAI. Secondly, a non-profit company would be created with the objective of negotiating with the pharmaceutical companies and ensuring the proper management of drug stocks. Auditing experts would verify its functioning annually. Should a similar company exist in the country, its use would take priority. Finally, centres of care (primary and referral centres) would be selected. UNAIDS' mission was to give the pilot-countries technical support to help them obtain preferential prices and to give rational access to drugs. No financial support for buying drugs was considered. UNAIDS also wanted to evaluate the DAI.

This model was the original implementation plan that was to be applied to all pilot-countries. This plan was described in official UNAIDS documents and constituted the guidelines for implementing the DAI in each country.

3.2. Adaptation of this model to the Chilean context

The initial model of the DAI we have just described was adapted in response to national characteristics. To explain the evolution of the design of the DAI, we must first explain the Chilean context of the HIV/AIDS issue, which refers to the environment in which the actors had to manage. Then we must present the governmental response offered to the increasing incidence of HIV infection and of AIDS cases.

3.2.1. A brief epidemiological history—The first case of AIDS had been notified in 1984. Up to 1999, 3150 ill people and 3857 asymptomatic people were notified, of which 2112 people died. 90% of AIDS cases were male, and 10% were female. People between 20

and 49 years of age constituted 85.3% of all cases of infection. Exposure had been sexual for 92.8% of the cases, through blood contact for 5.5% of the cases, and from mother to child for the remainder (1.5% of the cases). The sensitivity of the vigilance system was estimated at 86% in 1997, thanks to the revision system of the death certificates initiated in 1991 (Ministerio de Salud 1999a).

3.2.2. The social context of the HIV/AIDS issue—There are three major determining influences for the governance of any political decision on appropriate care for people living with HIV in Chile. First, homophobia was still strong in Chile. Sodomy among adults was decriminalized in 1999. Although the epidemic affects the heterosexual population more and more, 67% of those living with HIV contracted it during homosexual relations (UNAIDS/WHO, 1998). This form of discrimination might complicate relations between the patient and the health care professionals or with his family circle, which has known effects on prevention, on treatment observance, or simply on HIV screening. Some NGOs or community groups decided to mitigate this influence by creating greater access to professional resources. Furthermore, CONASIDA, in association with some health care centers and some NGOs, was trying to lessen homophobia, ignorance, and associated discrimination, so as to reduce the impact this could have on access or quality of care.

The second important influence is discrimination against people living with HIV. For example, at the time of our research, employers often required proof that they were HIV negative before hiring someone. In the same way, some patients stated they had difficulties finding housing once people knew they were HIV-positive; others claimed that they lost the support of their family. This kind of discrimination accentuated the social precariousness in which many patients live, and added difficulty to the problems already associated with the acceptance of their serologic status. People living with HIV/AIDS often said they experienced social death before experiencing physical death. We noted that when we asked patients to introduce themselves at the beginning of the interview, they generally gave the year they were diagnosed, their number of CD4 lymphocytes, and that of their viral load, exactly as if it had become their new identity.

The third notable characteristic is the influence of the Catholic Church, which still determined moral values and greatly influenced social actions. For example, in 1997, CONASIDA decided to broadcast prevention messages on television, to sensitize the population to the risks of transmission. Television channels refused to broadcast the message. This campaign created an incredible outcry. Personalities such as the President of the Republic, ministers, and the President of the Senate had to take position for or against this message. At issue was the apparent governmental approval given by CONASIDA to the use of condoms, which was rejected by the Catholic Church. The Church was also very present in the patients' surroundings. Some religious foundations offer support for access to drugs, for lodging, for food, etc. Volunteers offer moral support. We attended the blessing of an association of patients in a health care center during its inauguration. The church is still very influential in the social structuration process and seems to be all the more present, given that people living with HIV are socially isolated.

In this context, the association of people living with HIV/AIDS, Vivo Positivo, played a particularly important role. This association was created in 1997 when patients had to stop their treatments due to an interruption in the drug supply. Some patients decided to take the lead, and to bring together local patient associations and CAPVIH, a self-support association, in order to create a unique political interlocutor. As with its counterparts in other countries, this AIDS activists' association was a dynamic and proactive player in the political field, one that used clever communication strategies in order to promote the interests of its members. Its main goals were to modify the legislative and social context of the HIV issue and to increase the access patients have to HIV/AIDS therapies through periodic demonstrative action, the development of political support at the national and international levels and the close and proactive monitoring of governmental actions. As far as we could see, Vivo Positivo seemed partially able to compensate for its limited formal resources by the dedication and cleverness of its members. For example, one of the observable measures of its efficacy is the fact that CONASIDA developed participative relations with Vivo Positivo but, at the same time, kept a watchful eye on the possible actions and declarations of the association. Vivo Positivo also played a significant role in the adoption of the non-discrimination law.

This general context placed great pressures on the CONASIDA, the governmental institution dealing with the HIV/AIDS thematic. It had to deal with social pressures that complicated the everyday management of the different epidemic aspects. It required a high political sensibility and strategies to comply with the requirements of its mandate, while satisfying popular values.

3.2.3. The Chilean answer to the HIV/AIDS issue—The National Commission on AIDS (CONASIDA) was created by the Chilean government in 1990 as a component of the Department of Health, but one with a particular structure. Whereas the majority of departments have a matricial structure, CONASIDA had the advantage of having an autonomous structure, one where all thematic programs and resources (administrative control, control of communications, care, and prevention, responsibility for sexually transmissible diseases, and control over epidemiological and sociological studies) were grouped together. The hierarchical structure was also particular, with CONASIDA answering directly to the Department of Health Under Secretary. This form of organization indicated the government's determination to develop specific responsibilities and skills to face the HIV issue.

At the time of our study, CONASIDA financed drugs for opportunistic diseases and antiretroviral treatment for the population covered by the public insurance fund (FONASA). Other treatment costs were the responsibility of FONASA. It is important to note that the majority of patients were covered by the public insurance fund. In fact, most private insurance companies (ISAPRES) did not cover diseases whose treatment was terribly expensive (certain cancers, AIDS, etc.). Due to the importance of their treatment costs and of the co-payments requested by their private insurers, the majority of people living with HIV were forced to move to the public system soon after their diagnosis had been made.

CONASIDA financed AZT as a monotherapy in 1992 (Ministerio de Salud, 1999a). In 1997, bitherapy was introduced (Ministerio de Salud, 1999a). The increase in the cost of the therapy, associated with increased needs, put a great strain on financial resources. While the Department of Health decided to increase CONASIDA's budget, it remained insufficient for covering all the needs. Since then, not all patients in need of treatment had been able to receive therapy. This is when CONASIDA began to consider involvement in UNAIDS' DAI.

3.2.4. The UNAIDS drug access initiative in Chile: the revised model (see Fig. 2)—The opportunity to participate in UNAIDS' DAI coincided with the moment the Health Department envisaged offering tri-therapy. The DAI appeared as a means for CONASIDA to reduce the cost of drugs and to increase the number of patients who would have access to treatment. In September of 1999, CONASIDA, in addition to the 750 bi-therapies already financed, added 700 tri-therapies—which was still not enough to cover all needs. In February 2000, fifty salvage therapies were added.

In Chile, the DAI did not involve a cohort of patients as in other pilot-projects. It was directly integrated into the national policy of access to HIV/AIDS therapies. Eligible patients were those covered by FONASA, the public health insurance system. The DAI did not involve patients covered by private insurance, except for pregnant women who were admissible to treatment protocol for vertical transmission (ACTG076).

It was not necessary to create a new health care infrastructure, as there were health centers that had treated patients with HIV/AIDS for many years, with access to all facilities for laboratory tests (ELISA, viral load, etc.).

One way to increase the number of therapies offered by CONASIDA was to reduce drug prices. In Chile, a structure of negotiation and importation already existed, so it was not useful to adopt the structure which UNAIDS conceived in its official documents. CONASIDA evaluated the needs for ARV and negotiated directly with the pharmaceutical companies. It transmitted its purchase order to CENABAST (Central purchasing department), which invited bids. CENABAST bought from pharmaceutical companies, which distributed drugs directly to the hospitals. Usually, a 6% commission was paid to CENABAST to finance administrative costs, but in the case of ARV, CENABAST agreed to forego this commission. However, drug prices had increased by 31% due to importation and value-added taxes. A new path for the importation of drugs was considered. Pharmaceutical companies accepted a reduction of drug prices on the condition that they be allowed to bypass the importation and value-added taxes. The proposition consisted of buying the drugs, not through CENABAST, but through UNDP, international organizations being exempt from national taxes. There was a 4-year convention between UNDP and the Health Department for importing medical equipment without paying taxes. As this convention expired the same year, UNAIDS and CONASIDA tried to integrate the import of drugs into the new convention. This would let them increase the budget for drug purchases by 25% (31% in taxes—6% UNDP commission). This importation process was considered temporary until the government solved this issue. The convention was approved by the Chilean government at the end of June, which was much later than anticipated. It was agreed that UNAIDS would give UNDP the financing for the support activities for observance and

for the salary of the UNAIDS coordinator, and that CONASIDA would transfer the financing for drug purchases to UNDP, and would give 6% of the total amount to UNDP for administrative costs. To bypass the various taxes, it was arranged that the drugs would be purchased from head offices, but that subsidiary companies would be in charge of distribution and would continue to receive their commissions. The 'Contraloria', an independent organization in charge of validating all agreements between the government and other institutions, had to ratify this agreement to make it completely legal.

The Advisory Board first met in July 1998. It was directed by the Under Secretary of the Health Department, responsible for CONASIDA, and brought together representatives of medical staffs, patients' associations, of ISAPRES, of FONASA, and of diverse organizations involved in the HIV/AIDS issue. Some forty people participated in the first meetings. The Advisory Board was divided into four work groups specializing in ethics, mobilization of resources, psychosocial support, and therapeutic protocols. Each group worked independently and presented their work during the UNAIDS representative's visit in May, 1999.

The UNAIDS representative wanted to nominate a coordinator for the project in order to help resolve the tense relationships between CONASIDA and some actors (in particular, doctors). This coordinator would be remunerated by UNAIDS and would be UNAIDS-appointed, so as to have plenty of scope to act. In fact, the coordinator was nominated by CONASIDA in May, during the UNAIDS representative's visit. The Advisory Board deplored the fact that it had not been consulted.

The National Agency of research on AIDS in France (ANRS) would be responsible for the evaluation of the DAI. UNAIDS would keep its role as negotiator with the head offices of the pharmaceutical companies.

We see that UNAIDS' DAI in Chile was far removed from the characteristics of the pilot-project defined in the official documents. It was much more like a generalized common action, integrated into the existing care system, with, however, exploratory project characteristics. No specific institution was created, but the pilot aspects can be noticed in different elements which would probably not have been assembled if the project had been led only by the national authorities. The design of the DAI in Chile—in particular, the fact that it was not a separate exploratory project but one integrated into the national system—gave a larger responsibility to the national organization for HIV/AIDS, CONASIDA.

3.3. UNAIDS drug access initiative implementation in Chile (see Fig. 3)

The model we have just described presents the DAI as it was conceived in May, 1999, when the UNAIDS representative went to Chile. Project implementation obviously differed from its design because of the appropriation of different constitutive elements by the actors. We present a third logic model that represents implementation of the DAI, emphasizing the non-realization of some components or the difficulties (gray zones on the graph) met when the actors put the theoretical project into action. In fact, these gray zones are of two kinds. First, some are zones of negotiation—that is, places where uncertainty in the final avenue existed because of the confrontation of different actors' power relations. These zones of uncertainty

are particularly significant for the observation of actors' strategies, interests, and power relations. The second type of gray zones are the ones that indicate the non-realization of some objectives due to a previous gray zone in the process leading to the development of the planned strategy. We will examine these gray zones in a longitudinal manner in order to avoid repetitions. The explanation of these 'gray zones' will highlight the organizational dynamics and will constitute different elements for the understanding of the general dynamics of the project.

3.3.1. The role of the advisory board in the initiative—The Advisory Board was constituted in July, 1998 and was divided in four independent groups in order to concretize different elements necessary for the development of the DAI. Each work group brought together representatives of different actor groups participating in the HIV/AIDS environment, that is, members of CONASIDA, Vivo Positivo, NGOs, FONASA, ISAPRES, but also nurses, doctors, etc. Vivo Positivo was present in the different groups and helped in the functioning by translating the official documents into Spanish.

3.3.1.1. The group on ethics: This group decided not to orient its work on the DAI, but rather to work with the aim of defining the ethical references of action. In a few pages, the preliminary document raised critical points for an integral and coherent answer to the HIV/AIDS issue but, at the same time, questioned founding principles of Chilean society. This document was never completed.

3.3.1.2. The group on mobilization of resources: The objective was to find new ways to mobilize resources to increase access to treatments for people living with HIV. Different possibilities were considered for encouraging joint action between private and public health insurance systems. The creation of a special fund for the treatment of people living with HIV was considered but, legally, it required that three sources of funding (for example, a government institution, employers, and users) participate. This idea was soon put aside. The second solution considered was concerning only the public sector. This possibility was based on the idea that offering tri-therapies reduces the burden on the health care system (FONASA) and that the cost of ARV (paid by CONASIDA) should be part of a joint action. The third possibility considered was to define AIDS as a 'catastrophic disease'. The government considers 'catastrophic' diseases for which treatment is extremely expensive and offers full insurance coverage for these patients. This idea was not considered in the short term.

While the group did not meet from June to November, 1999, discussion continued periodically between FONASA and CONASIDA to contemplate a united action.

3.3.1.3. The group on psychosocial support and observance of treatment: This group elaborated three main projects. The first one consisted in creating different information documents for the drugs, treatment characteristics, and observance. The second project consisted in establishing information workshops for health professionals. The third one was a training project for people living with HIV, to encourage support and advice from peers. These projects were approved by the UNAIDS representative in May, 1999 and funding was allowed. Yet, funds were not received before October, after long negotiations between

CONA-SIDA and UNAIDS in Geneva. There was a change of management in UNAIDS and there was no representative from Geneva during five months. CONASIDA then decided to postpone the development of the activities of this group until it received the funds. While some particularly motivated people transferred their new skills to their health centers, these kinds of external developments remained rare. Whereas tri-therapy was introduced at the end of September, none of the activities elaborated in the groups had been implemented by then.

3.3.1.4. The group on therapeutic protocols: Different protocols were elaborated: the protocol for adults, the protocol concerning vertical transmission, and the protocol for treatment of children. The last two protocols were elaborated by physicians expert in maternal and pediatric treatment, and were distributed to all specialists in this field. 100% of the drug needs for pregnant women and children were covered.

The major difficulty encountered by the group working on the definition of the therapeutic protocol for adults concerned the type of therapy CONASIDA should offer. Since the beginning, it was clear that resources were not sufficient to cover all the needs. The question was whether CONASIDA would only recommend the initiation of tri-therapy and offer fewer therapies, or whether it would encourage bitherapy for some patients, in accordance with their clinical state, and increase the number of patients receiving treatment. This dissension caused several physicians to leave the group, claiming their disagreement over offering a therapy, less efficient in the long term, that increased the risk of development of resistance. While the coordinator, with a role of mediator, was nominated, CONASIDA never brought the physicians and the coordinator together.

Finally, it was decided that bitherapy would be recommended under certain conditions: it would be proposed for patients with an intermediate probability of progression to AIDS—i.e. asymptomatic patients with CD4 between 350 and 499/mm³ and a viral load of 10,000–50,000 copies/ml. It was suggested that patients with sufficient financial resources to buy one of the three drugs should immediately start tritherapy. If bitherapy were not efficient enough and if it were not due to a problem of observance, the patient should be given tritherapy (Ministerio de Salud 1999a).

The members of the Advisory Board, while finding the experience interesting, deplored the fact that this activity was so time-consuming, it being really an over-time activity for which they received no compensation. Furthermore, some events led to the feeling that they were being manipulated by CONASIDA. First, they found CONASIDA reluctant to distribute information on the UNAIDS project. Secondly, in November, 1999, the participants had still not received information on what came out of their work, nor on the development of the DAI. The groups did not meet after June, and their work remained, in general, incomplete. Whereas the mission of the Advisory Board was to guide CONASIDA throughout the DAI, the continuity of its role, as defined in official documents, was not maintained. While the Advisory Board did have an initiating effect at the beginning, it was CONASIDA that largely led the project.

3.3.2. UNAIDS Representation in Chile—Different actors claimed to be UNAIDS representatives in Chile and put forward their legitimacy for the management of the project

or a part of the project. The legitimacy of the manager of UNAIDS- Geneva was never questioned. Yet he resigned in June, 1999 and there was no regular communication between CONASIDA and UNAIDS until the new manager was named in October, 1999. At the local level, UNAIDS representation was a source of ambiguity and tensions either involving the designation of legitimate actors or the definition of its functions. The analysis of this theme was particularly relevant for understanding the relationships between some actors and the systems' rules.

3.3.2.1. The coordinator of the project: The role of the coordinator consisted in facilitating the implementation of the DAI. According to the manager from Geneva, the coordinator had to be the link between some actors reluctant to participate, and CONASIDA, in order to facilitate their collaboration. The manager wanted the coordinator to work closely with CONASIDA but to have the label of UNAIDS. CONASIDA, on the other hand, declared that since the beginning it had wanted the coordinator to be part of CONASIDA, the DAI being led by CONASIDA.

UNAIDS had to remunerate the coordinator but no funds arrived before October, 1999. Until that date, CONASIDA remunerated the coordinator. Furthermore, no contract was signed ratifying the nomination of the coordinator or defining its role. This delay constituted a breach in the legitimacy of the coordinator at the level of CONASIDA. In October, when UNAIDS 'reappeared', communications with UNAIDS were reestablished with CONASIDA, but not with the coordinator. CONASIDA apparently did not wish that sort of relationship to be established without its intervention. The coordinator's status was, in the long run, only dependent on the will of CONASIDA to integrate him into the project. With time, the coordinator lost the independence Geneva had had in mind.

The status of the coordinator, as seen initially by UNAIDS, constituted by nature an external source of power independent from the authority of CONASIDA. On the other hand, CONASIDA considered the coordinator as part of CONASIDA, and did not recognize its legitimacy as an independent actor. This situation shows the necessity of quickly ratifying agreements between institutions, so as to minimize misunderstandings or post-hoc interpretations. This situation also seems to reveal CONASIDA's wish to be the prime contractor of a project that inscribes itself in the continuity of its action.

3.3.2.2. The UNAIDS thematic group: This group brings together representatives of the different United Nations organizations in Chile: UNESCO, UNICEF, and UNDP, but also PAHO/WHO and CONASIDA, the community network that includes NGOs and associations involved in the VIH/AIDS issue in Chile, such as Vivo Positivo. The objective was to develop a concerted action plan for AIDS in Chile. The Thematic group had to sign documents for agreements between CONASIDA and UNAIDS-Geneva. It played no role in the implementation of the DAI. The UNAIDS manager of the DAI kept the thematic group informed but the group never mobilized to get involved. The thematic group got a new director in March, 1999. The new director decided to play a major role in various activities concerning the issue. Yet he was poorly informed about the implementation of the DAI and he did not even know of the existence of the coordinator. The presence of two people with a

mandate from UNAIDS in Chile created, on various occasions, ambiguities as to the role of each in UNAIDS representation and delegation of authority.

3.3.2.3. UNDP: UNDP was the organization in charge of importing drugs through the agreement ratified in June by the government and approved by the 'Contraloría' in October, 1999. It was also the intermediary for the transfer of funds from UNAIDS expected by CONASIDA. The people in charge of the DAI at UNDP considered themselves to be the administrative and operational representatives of UNAIDS in Chile. They recognized and supported the role of the local coordinator.

The multiplication of people and institutions claiming a legitimacy for UNAIDS representation may appear anecdotal. But it is symptomatic of the political dynamic of the context studied. The absence of an officially recognized determination of the roles of different actors, with no distribution of up-to-date information creates an undefined zone that sets the stage for power games for the control of zones of uncertain authority.

The only actor that had regular contacts with each representative was CONASIDA, where information from every actor was centralized. This favorable position was preserved through control of interactions that might occur between some of these actors. This situation was typical of the preponderance of the role CONASIDA had amongst different actors in Chile. The situation concerning the roles of different representatives gave a strategic advantage to CONASIDA. The management of the DAI was very centralized, which posed a dilemma for leadership of the project. Quite quickly, and throughout the implementation of the DAI, the role of UNAIDS as the initiator of the project became difficult to reconcile with the place CONASIDA occupied as the body responsible for the national program against HIV/AIDS. Difficulties or disagreements represented occasions for the CONASIDA to take the lead in the project and to establish new game rules. Let us remember that CONASIDA's context of action was particularly political and tense.

3.3.3. The drug negotiations and imports process

3.3.3.1. The negotiations process with pharmaceutical companies: According to CONASIDA, the pharmaceutical companies reduced their prices by 25–30% between 1996 and 1998, i.e. before the UNDP importation process became effective, an agreement that would represent an increase in the number of therapies sold. At the time data was collected, the pharmaceutical companies told us they would not reduce further their prices: they accorded reductions on the base that the UNDP agreement would be ratified, and applied these reductions prior to its use. It is important to specify that the price reductions took various forms. Some companies proposed a true price reduction (e.g. Glaxo-Wellcome). Others did not modify their prices, but offered, for example, three viral load exams each year for all patients who took their company's drugs (e.g. Merck and Co.). Some maintained their prices but proposed bonuses (e.g. Boehringer Ingelheim), which meant they added a given number of drugs to the quantity bought at full price. If this formula meant a reduction in the average price, it was not equivalent to a real price reduction. As a matter of fact, this solution offered companies the chance to increase patients' dependence on their products. While CONASIDA could initiate more therapies, nothing obliges the laboratory to keep on offering

these bonuses. This position in fact looks like a strategy for market penetration. Negotiations between CONASIDA and the companies were going on, but no negotiation strategy seemed to exist at the UNAIDS level from the time the UNAIDS manager left the project onwards.

3.3.3.2. The UNDP importation process: Generally, the actors had little information about the agreement with UNDP. There seemed to have been no new developments since the last visit of the UNAIDS DAI Manager in June. UNAIDS was absent from negotiations during all this period. CONASIDA continued its own negotiations with the pharmaceutical companies, whereas UNDP thought negotiations to be its responsibility.

The agreement was signed at the end of June, 1999. Legally, the agreement had to be approved by the 'Contraloria' to be effective. Yet imports via UNDP began as early as July, 1999 for all products except drugs, CONASIDA refusing to use this import structure until the 'Contraloria' had approved it. This convention was neither used in August nor at the beginning of the year 2000, when CONASIDA bought new drugs. The first imports through this process came in May, 2000. The approval by the 'Contraloria' justifies why CONASIDA did not use the agreement with UNDP. Yet it is probably not the only reason, as other units of the Health Department began to use it as soon as the agreement was ratified and UNDP affirmed it was ready to start. CONASIDA declared that they waited for the approval by the 'Contraloria' and that they would not use the agreement until the funds from UNAIDS arrived. Yet the agreement was not used at the beginning of the year 2000 even if the funds were paid.

Between September and December of 1999, CONA-SIDA began to appropriate the project:

'The project of access to tri-therapy is not a project of UNAIDS but a CONASIDA project (...) The pilot-project has not begun yet' (CONASIDA informant).

In fact, the official inauguration of the pilot-project was set for January, 2000. CONASIDA explained that ARV were financed by the Health Department so it should be considered a project of the Chilean government and not of UNAIDS. As CONASIDA strongly associated the UNDP agreement with the DAI, they might have refused to use it until the pilot-project was officially inaugurated, in order to emphasize the fact that, until the inauguration, tri-therapy was offered through the Chilean program of access to ARV and not through the DAI. We also noted that CONASIDA announced an increase in therapies distributed in order to cover approximately 30% more of the needs (El Mercurio 13 January 2000) a few days only before the presidential elections (16 January 2000).

The agreement was valid for four years. There was no guarantee it would be renewed. This import channel perpetuated a system originally perceived as a temporary solution to increase the coverage of needs in therapies.

3.3.4. Implementation of the therapeutic protocol—The Advisory Board group on the elaboration of therapeutic protocols ended with the formulation of guidelines for clinical practice and for the selection of patients. We examined how the protocol for adults was implemented in the health care centers. As we shall see, difficulties were encountered in both fields.

3.3.4.1. Implementation of the Therapeutic Protocol in Health Care Centers: The protocol was sent for validation to all physicians working with PLHA in the country. It is important to note that the Society of Infectiology of Chile did not recommend the same treatment protocol as did CONASIDA, particularly in terms of the possibility of initiating bitherapy. This situation questioned the legitimacy of scientific societies versus governmental ones for the elaboration of therapeutic guidelines. The Society of Infectiology felt that offering bitherapy could have important negative effects for patients who developed resistance. This would reduce the therapeutic choices at the level of the patient, but also at the epidemiological level by running the risk of resistant strains being transmitted (Comité Consultivo de SIDA, 1998). This situation contributed to reducing the applicability of the governmental protocol in the health care centers, with the potential risk of creating gaps in CONASIDA's estimated drug needs.

In two health care centers for adults we visited in the metropolitan region, no bitherapy had been initiated for several months. This did not respect the clinical protocol elaborated by CONASIDA. Two motives were put forward to explain the non-prescription of bi-therapies. First, there was too much disappointing experience of development of resistance with bi-therapies. Secondly, professionals were skeptical of the possibility of getting salvage therapies in case of therapeutic failure, as all tri-therapies had already been allocated to the health care centers.

According to CONASIDA, in the thirteen administrative regions, ARV were distributed, according to the proportion of 'active' patients in each health care center, active patients meaning those who came regularly for follow-up consultations. This meant that drugs were not allocated according to needs. Since the number of therapies distributed was generally not sufficient to cover all the needs, it is likely that all combinations of ARV have been allocated. But this system was not equitable for centers that had a great proportion of active patients in need of therapies, as the proportion of therapies related to the number of patients in need of therapy would be lower. With this system of allocation, the chances of survival were not equal for all patients.

Furthermore, as the drugs were bought according to the revised prescriptions as seen earlier, and not according to real practice, one ran considerable risk of drugs' remaining unused.

3.3.4.2. Selection of patients for access to treatment: Once the therapies were allocated to the health care centers, it was their responsibility to decide how to distribute them. As there were far more needs than therapies available, different strategies were used, at the discretion of the health care personnel, to decide who would have access to treatment. There was no homogeneity in the selection criteria used in the different centers (information was gathered through interviews with patients' representatives, doctors, nurses and social workers of different health care centers in Santiago). Some elaborated a standardized procedure for patient evaluation that included not only clinical criteria, but also criteria to evaluate the social support a patient could receive, his living conditions, etc. The patient who got the most points got the therapy. This system was elaborated in order to maximize the anticipated chances of observance of treatment. In other centers, priority was given to those who already had bitherapy via the government but did not respond to treatment. The remainder of

therapies was given to people who did not receive treatment and who were at an advanced stage. As there were not enough therapies for all, the staff used a lottery system. For the selection of patients, bio-clinical criteria were dominant, but they were necessarily completed with other methods of selection (social criteria, lottery). It was generally the nurse or the social worker, with the support of the medical staff, who determined who would have access to therapy and who would not. As most patients were at an advanced stage of disease, it was often a matter of determining survival or death, which amounted to a very painful decision for the staff that regularly saw these patients.

3.3.4.3. The fate of patients who could find funding to pay for one of the drugs: If a patient had enough financial resources to pay for one of the drugs, he could benefit from CONASIDA's joint program, joint because the Health Department financed the bi-therapy and the patient had to find another source of funding for the third drug. In most cases, the patient paid for it on his own, but as the cost of ARV was really high, in the long run, he could find it difficult to pay for his treatment. When a patient did not have enough resources, the social worker or the nurse contacted different organizations, such as municipalities, foundations, the First Lady Cabinet, for financial support.

When the patient had the resources to buy at least one of his drugs, he could go to the pharmacy, but they offered the more expensive products. The patient could go through the foundations that negotiated with the pharmaceutical companies to get cheaper prices. It was often the more advantageous legal solution. The patient could also get his drugs on the black market. It is difficult to know all the sources of supply and the extent of this phenomenon. One of the sources was the sale of drugs from the governmental access plan to ARV. Some penniless patients chose to sell their drugs, preferring to live less long but in better material conditions. This state of affairs could not last long: if the medical staff did not note an improvement in the patient's state of health, they stopped the treatment. This phenomenon was worrisome for those who bought their drugs on the black market, as they had no guarantee of the quality of the product and the supply could stop at any moment. Furthermore, there was a risk of patients taking treatment without being aware of the medical information. Finally, some patients used other sources of supply. Some traveled to other countries where they could benefit from other national or local NGO programs. Buying a plane ticket was often less expensive than several months of treatment. Other patients benefited from international solidarity. For example, some PLHA received drugs from international networks that send unused ARV after a patient died.

After the end of the evaluation process, we recommended, (1) for reasons of equity and efficiency, the revision of the mode of allocation of drugs to the health care centers by considering drug needs instead of the proportion of active patients; (2) that, CONASIDA made sure that drug purchases really matched prescriptions, as a way of minimizing the risk of having orphan drugs; (3) that objective selection criteria be developed to homogenize the chances of access to therapy in all health care centers (the fact that chances of survival are not the same for all was a source of discontent not only among patients but also among the staff, who had to bear the whole responsibility for these critical choices); (4) that the different sources of supply for ARV drugs be investigated, as some, more precarious, represented an important risk of development of viral resistance.

4. Conclusion

Implementation of the UNAIDS Drug Access Initiative was initially designed in accordance with a single scheme for four contrasted pilot-countries. The pilot project in Chile was considerably modified in order to adapt it to the national reality. The revised model rested essentially on CONASIDA, which was responsible for the drugs (evaluation of needs, negotiations), and which coordinated the project and the Advisory Board work groups. With time, this aspect was accentuated, CONASIDA having almost completely integrated the project into its activities. The implementation analysis shows two major evolutionary trends. First, the design moved from an experimental project to a project adapted and integrated to the national administrative functioning. Second, the leadership shifted from the hands of international managers to national administrators.

The adaptation of the experimental project to the national context eliminated the possibility of comparison of experiences with the other pilot-countries. Yet, it had many advantages. As it was remodeled by the national administrators, with the agreement of the UNAIDS manager, it showed a sensitivity to the national way of doing things, which is a condition for successful project design and management (Rondinelli, 1987), thus lessening the risk of project inadequacy. It also avoided a duplication of mobilized resources in a context where competent resources were in place.

The second evolutionary trend concerns the shift of leadership from the hands of international managers to national administrators. We have seen that, while the period of latency during which there was a change of managers at UNAIDS-Geneva created difficulties, this did favor the appropriation of the project by CONASIDA. It lead, at the DAI management level, to a 'shift from a top-down leadership to a bottom-up mode of leadership' (Canadian Center for Foreign Policy Development, 1999: 1). A local appropriation of the project is a good way to avoid the gap often observed between UN agendas and UN capabilities and commitments (Cooper in CCFPD, 1999). It is a good means of ensuring continuity in a project (Rondinelli, 1987). Yet, there is a risk of a project becoming subject to local organizational and political dynamics.

The fact that CONASIDA was responsible for implementation of the project had many advantages. As it had a long experience in project management and various competencies in HIV/AIDS fields, it could ensure a permanence no other organizational mechanism could guarantee. However, once the project was adopted by the local actors and integrated into their institutions, it was evident that the regulation logic was strongly influenced by local organizational dynamics, and that the implementation process depended on games and power relations that existed prior to the Initiative. Two aspects seemed especially characteristic of local organizational dynamics. First, the fact that CONASIDA had to operate in a controversial political context limited the scope of possibilities in its everyday management. CONASIDA did not entirely have the liberty to complete its mandate, as this was dependent upon public opinion. Furthermore, CONASIDA's ability to gather resources for drugs and other activities depended on the perceptions the government had of the health priorities for the Chilean population. Secondly, CONASIDA's way of functioning was very centralized, which had various advantages for the continuity of the project in a context

where UNAIDS could not be locally present throughout the project, and its position in the Health Department gave CONASIDA a good deal of autonomy. But this centralization lessened the possibility of creating new actors' networks, which in turn lessened the likelihood of coordinated actions or shared responsibilities that might have encouraged an opportunistic and political utilization of information.

Furthermore, the integration of the project into national policy put UNAIDS' role in question. Adjustments were made to adapt the project to the national reality, but the responsibilities and roles of each partner were still unclear and not completely defined. And once the local actors had appropriated the project, what was the role of the instigator to be? It is evident that CONASIDA derived prestige from an alliance with UNAIDS at international and national levels (media, credit for negotiations with governmental institutions, etc.). This clearly had an effect on negotiations with the pharmaceutical companies. Nonetheless, UNAIDS' local role should have been clearly defined to avoid conflicts in the division of responsibilities between CONASIDA and UNAIDS, and to go beyond the duality between the experimental project and the governmental program.

The transformation process from an international experimental project to a national program of access to ARV raises new questions. What should be the role of UNAIDS, and how does it fit into the picture (Cooper in CCFPD 1999)? Will the project suffer fragmented authority (Cooper in CCFPD 1999)? How can we bring about change if the project only runs in existing and local structures (Rondinelli, 1987)? More fundamentally, our analysis underlines a dilemma many international programs experience in their local adaptation: How can we conciliate program adequacy with local organizational and political innovations?

Our research offers some insights for the conception of international programs that will be nationally implemented, and for international support for drug access initiatives. UNAIDS, as a United Nations organization, has a great symbolic power that can be used in various activities. First, it can be the initiator of movements towards worldwide price reductions, and create norms regulating the commercialization of HIV/AIDS products. Secondly, it can support national actions in order to provoke change at governmental levels, and it can legitimize governmental policies. It seems better to encourage the implementation of drug access initiatives where a national policy for HIV/AIDS already exists, national institutions being the real prime contractor of the project and UNAIDS having only a counseling and support role. The project should be integrated into national policy, not separate from it, even if there is an interest in underlining UNAIDS contributions to policy developments, so as to benefit from its symbolic power. Rather than creating new structures, it is worth relying on and consolidating national resources in order to maximize the chances of project continuity. Furthermore, it is important that the roles of each organization and their relationships be clearly defined (Cooper in CCFPD, 1999) and made official. Still, in order to minimize the potential utilization of this symbolic power for opportunistic or political ends, there should be a constant UNAIDS presence, one making itself felt through coordination, complementary relationships, and partnership.

5. Lessons learned

Weiss said that ‘evaluation is a rational enterprise that takes place in a political context (...)’ (Weiss, 1987). In fact, we could say that evaluation is a rational but political enterprise that takes place in a political context. Two elements had a marked influence on this project. First, the fact that we used an inductive process of research. Second, the political context of the HIV/AIDS thematic in Chile. As for the design of the implementation evaluation, the choice of an hypothetico-inductive strategy had the advantage of maximizing the sensitivity of the evaluation to the dynamic of the DAI. Yet, it carried a great amount of uncertainty, especially for stakeholders, about what would be investigated. In order to compensate for this uncertainty, it was necessary to organize regular meetings with stakeholders. Due to the political context, CONASIDA wished to have a particular control on the evaluation process. We experienced at different moments important pressures from stakeholders. The culminating point was when members of the Chilean government opposed themselves to a presentation on the informal ARV market accepted at the XIV International AIDS Conference in Barcelona. The ANRS considered to cancel the presentation if no agreement was found. This project revealed the need to establish, prior to the evaluation, clear parameters to define the responsibilities and rights of every actor having a role in the evaluation. In our case, the fact that we had independent funds and that this research was done by academics provided us with enough legitimacy and independence to defend the respect of confidentiality of the interviewees, the validity of our research and the right to diffuse our results.

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Fig. 1.
Initial logic model of the UNAIDS drug access initiative.

Fig. 2.
Revised logic model of the UNAIDS drug access initiative in Chile, June 1999.

Fig. 3.
Revised logic model of the UNAIDS drug access initiative in Chile, September–December 1999.