Expanding Access to Antiretroviral Therapies in Chile: Economic and Financial Issues for Patients and the Health System

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Key words: Chile; financing; scaling up; health system; health insurance; HIV/AIDS care.

Abstract

Chile’s experience of scaling-up access to antiretroviral treatment (ART) is relevant to identify main problems related to such a process and to assess their consequences for the patients and their caregivers as well as for the health system. Two data sources are used: a quantitative survey of people living with HIV/AIDS (PLWA) (12/2000-03/2001) and two series of structured interviews with key actors of the Chilean Health System (mid-2001 and mid-2002). The main results concern:

1) criteria for accessing ART in a context of limited resources: apart from medical criteria, socioeconomic factors introduce a significant bias in the selection of patients;

2) the transfer from private to public health system: due to better cover, 30% patients switched to the Public Health System before accessing ART;

3) the financial burden for patients: patients have to use different strategies in order to access ART, including paying for treatment out-of-pocket and taking out loans;

4) distribution of ART: due to the complexity of the distribution process, stocks frequently run out, with consequences on the patients’ health status and the quality of work in the health centers, as well as creating tension among the various health institutions involved.
Lessons drawn from the Chilean experience should be useful for other countries with intermediate levels of development and HIV/AIDS prevalence which have a well-established health system.

Résumé

L’expérience du Chili en matière d’élargissement de l’accès aux antirétroviraux (ARV) permet d’identifier les problèmes liés à un tel processus et d’évaluer leurs conséquences à la fois pour les patients et leur entourage et pour le système de santé. Deux sources de données sont utilisées : une enquête quantitative auprès des personnes vivant avec le VIH/sida (12/2000-03/2001) et deux séries d’entretiens semi-structurés auprès des acteurs clés du système de santé chilien (mi 2001 et mi 2002). Les principaux résultats ont trait :

1) aux critères d’accès aux ARV : dans un contexte de ressources limitées ; à côté des critères médicaux, les facteurs socio-économiques constituent un biais significatif dans la sélection des personnes qui ont accès aux traitements ;

2) aux migrations de patients des systèmes privés vers le système public de santé : du fait d’une meilleure couverture, 30 % des patients ont changé de système avant d’avoir accès aux ARV ;

3) à la charge financière pour les patients : les patients mobilisent différentes stratégies pour accéder aux traitements, depuis l’achat sur leurs propres ressources jusqu’à l’endettement ;

4) à la distribution des ARV : du fait de la complexité du processus de distribution, de nombreuses ruptures de stock se sont produites, menaçant la santé des patients et la qualité du travail dans les services, et créant des tensions entre les acteurs du système de soins.

Les leçons tirées de l’expérience chilienne doivent être utiles aux autres pays à niveau intermédiaire de développement économique et d’épidémie qui disposent d’un système de santé bien organisé.

Introduction

As the epidemic in Chile is relatively limited, the country’s experience of Antiretroviral Therapies (ART) delivery in the public health sector, especially in the initial period of scaling up access to ART (1998-2001), constitutes a good example of the difficulties that many countries will have to face when implementing such a process.

These difficulties are related to two main features:
– first, the scarcity of resources in the Public Health System (PHS) that limits its ability to offer public subsidies for ART cover for all medically eligible patients;
– second, the presence of a mixed health system combining public and private health insurance\(^1\) but where the private sector does not provide cover for ART expenditures.

These features pose a serious challenge to the public health system (PHS) that has to respond alone to the HIV/AIDS pandemic with an insufficient budget.

The main goal of this paper is to describe the Chilean experience in improving the accessibility to ART, in order to identify the problems more clearly and to assess the consequences both for patients and their caregivers and for the health system. The paper will specifically study 4 key issues:

1) the selection of the patients having access to ART in a context of limited resources;
2) the transfer of the patients from the private system to the PHS;
3) the financial burden for patients;
4) the impact of expanding ART on the current organization of ART distribution.

Lessons from the Chilean experience should be useful not only for the Chilean health authorities in their efforts to develop evidence-based interventions to fight HIV/AIDS, but also for other countries of Latin-America, Eastern Europe and Asia that may share similar epidemiological, economic and social characteristics.

**Background**

With a Gross Domestic Product (GDP) per capita of US$4,289\(^1\) in 2001, Chile is an intermediate country in terms of economic development with a relatively low public health expenditure that accounted for 2.4\(\%\) of the GDP (US$65 billion) in the same year\(^2\).

The Chilean health system is funded by a monthly contribution of 7\(\%\) of the workers’ income\(^2\). Individuals are free to choose between the private and the public insurance health system\(^3\). Those in a precarious economic situation and people over 65 are covered by the PHS free of charge.

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1. And a countrywide network of public and private providers.
2. An additional budget may be allocated by the State to the PHS in order to fund specific programs, such as ART drugs.
3. Ability to pay is the barrier to access since co-payment in the private system may rise to 40\(\%\). When registered with the PHS, people may choose to get part of their health care from the network of private providers.
In 2001, the Public Health System (FONASA) covered 67.4% of the whole population [3]. The remainder was covered either by the private-for-profit sector (Isapres) (19%) [4] or by other population-specific not-for-profit insurance systems such as the Defense insurance (Capredena) [5].

Private schemes do not fund drug-related expenses, including ART. Except in cases of hospitalization, people in need of ART who are insured in the private sector will either have to pay drug-related expenses themselves, or move from the private to the PHS.

Since the first cases of HIV/AIDS were detected in the country in the mid-80s, HIV/AIDS has become a major source of concern for the Chilean health authorities. On the one hand, the pace at which the pandemic is evolving has serious medical and social consequences, while on the other hand, HIV/AIDS treatment puts heavy financial pressure on the health system as well as on the patients and their caregivers [6].

Between 1984 and 2001, the total number of reported AIDS cases in Chile was 4,646 individuals [7]. During the same period, 5,228 non-AIDS HIV infected cases were reported. In 1999, the incidence rate of AIDS was 4.1 per 100,000. In 2002, UNAIDS estimated the number of people living with HIV/AIDS (PLWA) in Chile at some 21,000 individuals, with a prevalence rate of 0.3% among the adult population [8].

Chile thus appears to be an intermediate country both in terms of the level of the HIV/AIDS epidemic and of economic development.

A landmark in the national strategy to fight HIV/AIDS in Chile was the creation in 1990 of the National Commission on HIV/AIDS (Conasida). This Commission is a technical unit of the Chilean Ministry of Health (Minsal) responsible for providing a coherent social response to the HIV/AIDS pandemic in the country [7]. Amongst other responsibilities, Conasida allocates the resources available to provide access to ART to individuals registered in the PHS who may require it. But the problem is the same as in many other countries of the region: available public financial resources are often insufficient to cover the needs.

In 1993, Zidovudine (ZDV) was the first antiretroviral drug offered to patients registered in the PHS. With a total cost of less than US$300,000, there was 100% cover of ZDV needs at the time. The situation in terms of ART cover has changed under the pressure of two factors. First, the course of the pandemic has increased the number of patients requiring ART, and
second, new expensive molecules have to be used in order to improve signifi-
cantly the clinical status of patients and to cope with therapeutic failures.

In 1996, Conasida started to supply ZDV in combination with 3TC. However,
while the public budget available for ART in 1997 was US$1.5 million, the
standard bi-therapy in Latin America (AZT+3TC) was estimated to cost
US$4,800 per year [9]. Thus, with such a limited budget the PHS would have
been able to fund around 300 patients while the expected number of patients
in need of treatment at the time was certainly much higher (according to
Conasida, the number of AIDS patients in 1996 was 422).

The clinical and biological successes following the introduction of highly
active antiretroviral therapies (HAART) in 1996 exacerbated this situation by
imposing new standards for the treatment of HIV-infection. The year 2000 was
a milestone in the effort to take into account these new clinical standards and to
improve the level of access to ART in the Chilean PHS. At that time, national
therapeutic guidelines for the PHS distinguished 3 categories of patients:

– no use of ART was recommended for patients with low probability of
  progression: asymptomatic, CD4 count >500/cc/mm$^3$ and viral load < 10,000/ml;

– for patients with intermediate probability of progression: asymptomatic;
  CD4 count <350/mm$^3$ and viral load <30,000/ml, prescription of a bitherapy
  was recommended and HAART was also recommended provided that the
  patient was able to pay for the third additional drug in the combination;

– HAART was recommended for patients with high probability of progres-
  sion: symptomatic; CD4 count <350/mm$^3$ and viral load >30,000/ml: prescription
  of a tritherapy.

On the basis of these criteria, 750 bitherapies and 750 tritherapies were
provided to PHS patients, representing approximately 46% of the estimated
needs [10]. This improvement in access to ART was partly due to Chile’s parti-
cipation as one of the four pilot countries$^5$ in the UNAIDS Drug Access
Initiative (DAI) [11]. With the support of the United Nations Development
Program (UNDP), who agreed to be the official ART importer, DAI allowed a
dramatic reduction of the import-taxes on ART. Such tax cuts represented
savings of approximately 21% on the price of ART provided to PHS patients [12].

Nevertheless, HAART were, and remain, very expensive and the ressources
insufficient to provide a 100% access. In 2000, the public budget available for
ART reached US$6.5 million. The situation remained approximately the
same until 2001.

5. Other countries were: Côte d’Ivoire, Uganda and Vietnam.
Because of the risks of therapeutic failures and the development of resistant strains, physicians soon became reluctant to prescribe bitherapies. Patients had to procure the third molecule themselves: either through other public or non-profit institutions (Municipalities, NGOs, Foundations), or from their own or their family’s resources, on the private market or even on the informal market [13].

Since 2001, Chile’s participation in the new UNAIDS Accelerated Initiative to Access to ART has enabled the health authorities to successfully negotiate prices for ART with industry, obtaining an average reduction of 50% [8, 12]. In 2002, 2,600 ART were provided, representing 86% of the patients meeting the national guidelines criteria followed by the PHS. The main factors contributing to this increase in cover were the new lower prices and a 33% increase of the public budget for ART. Finally, the level of cover is expected to rise to 3,600 ART in the first half of 2003, and when the extra-resources from the Global Fund to Fight AIDS, Tuberculosis and Malaria become available, 4,200 treatments will be distributed, approaching the goal of 100% cover. It is worth pointing out that so far no antiretroviral generics have been used in the Chilean PHS [14].

In summary, Chile’s access to ART at the very beginning of the century was that of a country with significantly expanding access but still with insufficient resources to afford universal ART cover. We analyzed the consequences of this increased but limited access, both for the persons living with HIV/AIDS and for the health system. We focused on 4 main issues:

– first, how patients were selected for access to ART: in a context of limited resources the selection process raises questions of equity that need to be explored in order to develop interventions aimed at reducing the social and economic inequalities that may result from such a process;

– second, to what extent PLWA not-covered (or poorly covered) by the private system have moved to the PHS: as the private insurance programs do not cover for ART, patients get better access to ART if they register with the PHS. Such a phenomenon could undermine the long-term sustainability of the public policy for access to ART;

– third, how the health-related financial burden on patients has evolved within the new context of access to ART: most PLWA are in a precarious

6. Thanks to a multi-sector project presented by a partnership including the health authorities and representatives of the patients. The funding of this project is US$ 36 million over a five year period. Nevertheless, the Global Fund project has been approved only for the first two years (US$13 million). After that, continuity will depend on the evaluation and availability of funds from the Global Fund.
socio-economic situation [15], and due to the limited resources of the PHS, they are often asked to contribute substantially to the purchase of their treatment. This could jeopardize the patient’s long-term follow-up treatment;
– fourth, what are the individual and organizational consequences of ART supplies running out related to scaling up access? This issue challenges the management of the ART distribution process in the PHS.

III
METHODS

To answer these questions, two different data sources from the Evaluation of the Chilean UNAIDS Drug Access Initiative\(^7\) were used: one quantitative and the other qualitative\(^8\).

Quantitative survey of PLWA

The first data source is a survey of public sector patients that was carried out between December 2000 and March 2001. The survey was of PLWA in six public hospitals in the Metropolitan District of Santiago and two in the v\(^{th}\) District of Valparaiso. These eight hospitals treat over 70\% of national PHS patients. Participants were randomly selected from the hospital databases of HIV/AIDS patients on the basis of 1 out of 3. People were approached and informed of the survey by a member of the medical or nursing staff in the hospital department, and when the person consented to participate, he or she was interviewed by a member of the research team.

In-depth data about the patients’ sociological, economic and psychological characteristics were obtained by means of a face-to-face questionnaire. It included questions on the following topics: current ART treatment, changes in the social security system, level of health expenditures, sources of ART funding.

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7. In Spanish, the Chilean participation in this UNAIDS-Initiative is called Iniciativa ONU-SIDA-CONASIDA para Facilitar el Acceso a los Antiretrovirales. The evaluation of this initiative was funded by the ANRS (French National Agency for Aids Research) on behalf of UNAIDS and in collaboration with Conasida and the Chilean Health Ministry.
8. Combination of both methods is particularly appropriate to study complex interventions such as expanding ART cover in a developing country. While the quantitative techniques are relevant to studying the main tendencies and the statistical relationships between different variables, the qualitative techniques allow more in depth insight into the underlying relationships of the phenomena studied and contribute to implementing actions intended to address the issues [16, 17].
Biological data, in particular CD4 counts, were obtained from medical files. Biological data going back more than 6 months before the survey were not taken into consideration.

Data were treated with EPI-Info and SAS and the unit of analysis was the patient.

Semi-structured interviews with key-actors

The second source of data was two sets of semi-structured interviews with key-players involved in HIV/AIDS [18]. These were aimed at highlighting the key players’ roles and perceptions regarding the issues of the study [19]. In this type of survey, the criterion allowing adequate analysis of the data is saturation. It requires getting a sufficiently representative sample of key actors involved in the fight against HIV/AIDS to cover the whole range of opinions. The quotations used in the Results section are not anecdotal since they reflect convergent arguments expressed by various interviewees; they complement the interpretation of the statistical survey.

Two settings were represented in the sample:
– three large urban centers with high HIV prevalence (Santiago, Valparaiso and Viña del Mar);
– two small urban areas with low HIV prevalence (Valdivia and Osorno).

The interviews were carried out in July 2001 and August 2002, a previous round of interviews having been completed during the pre-implementation phase in late 1999 [12]. As the 2002 round of interviews was aimed at updating the earlier information, only a subset of these organizations was selected to participate.

Overall, the organizations and institutions selected were as follows:
– 5 central institutions: Conasida, Fonasa, UNDP, Cenabast9, and, ISP10; with a total of 18 persons interviewed (12 in 2001 and 6 in 2002);
– 9 health centers: seven in large urban areas and two in small urban areas; with a total of 28 persons interviewed (22 in 2001 and 6 in 2002);

9. Cenabast is an autonomous public body in charge of grouping purchases of drugs and medical equipment for the public health centres. Before the involvement of UNDP in purchasing ART, Cenabast was in charge of the purchase and distribution of ART. Cenabast was included only in the 2001 round of interviews.
10. The Institute of Public Health (ISP) is in charge of controlling the quality of imported ART and the viral load kits. As a biological laboratory, ISP is currently the national reference laboratory for the HIV tests. ISP was included only in the 2001 round of interviews.
– 4 pharmaceutical companies: Glaxo-Smith-Klein, Merk-Sharp&Dohme, Boehringer and Roche; with a total of 9 persons interviewed (6 in 2001 and 3 in 2002);
– 5 patient organizations: Vivo positivo (the federation of PLWA organizations) and four local patient organizations; with a total of 10 persons interviewed (5 in 2001 and 2002).

The mean time of the interviews was 35 minutes and more than one thousand pages of transcriptions were produced.

Data were treated with QSR-NUD*IST discourse analysis software package; the unit of analysis was the key-players involved in the health system.

IV
RESULTS

Description of the population of PLWA (quantitative survey)

929 persons were selected for the survey. 50 could not be contacted and 80 refused to participate. 799 persons completed the questionnaire (answer rate = 85.5%).

Overall, 20% of respondents were women (N = 160); 80% were men (N = 639), including 481 homo/bisexual men (60%). Mean age was 36.6 years (sd = 9.5). 22.5% were under 30 (N = 180) and 30.4% were over 40 (N = 242).

CD4 counts taken within the last 6 months were available for 672 persons. There was no statistical difference between people with and without CD4 counts for demographic and socio-economic factors (gender, age, sexual identity, family per capita income, marital status, schooling, membership of a voluntary organization, employment). Mean CD4 count was 257.7 (sd = 200.3).

The proportion of individuals having access to ART in the sample was 62.5% (N = 499). 44% had been on ART for less than one year (N = 180). This proportion of people on ART is higher than the 46% cover in the PHS estimated by CONASIDA at the time. This relative overrepresentation of individuals receiving ART is probably related to the recruitment in large hospitals of major urban areas. These areas are known to have higher rates of HIV prevalence [7], and probably deal with a larger number of individuals in more advanced stages of the disease.

11. Only in the 2001 round of interviews.
Access to ART

Patients eligible for ART must be registered with the PHS and meet the medical criteria defined in the national guidelines. But as long as there is no full cover, some individuals will not receive ART even when their medical condition requires it.

The health centers have to define their own additional criteria, resulting in a wide variety of approaches in selecting the patients who receive ART. These criteria may include the length of time on the hospital waiting list, lifestyle, social support, socioeconomic situation (i.e. the ability to pay for a third molecule), and sometimes random selection by lottery. The quotations below, from the semi-structured interviews, illustrate the diversity of approaches that exist in the various health centers:

[...] At that point (when it is time to choose) we are God and the Devil. God for those who get the therapy and the Devil for the others... As I cannot choose because one patient is nicer or has blue or brown eyes or is big or small... Then (I choose) by the order of arrival. (Key informer: physician, small urban area, 2001-free translation).

[...] To choose between two individuals with the same urgency for treatment, we consider who is expected to be more adherent, who is more motivated by the therapy, who has better support from their family network, and who is not an alcoholic or drug addict. (Key informer: physician, major urban area, 2001-free translation).

[...] Once the criterion of being affiliated to the public system is met, there are some 50% of the patients left... How to decide who will get ART and who will not? We choose to not discriminate by sex, age or lifestyle, so facing the same clinical needs it will be a lottery that will decide who will receive the ART. (Key informer: physician, major urban area, 2001-free translation).

Some interviewees expressed concern about the fact that informal networks may favor an individual and give him/her access to ART before another with the same indication for treatment and medical need.

[...] Also there is the issue of the pitutos (relationships)... I entered the system because of who I know... At that point I told the physician I will come back...
Even if I have to talk with the president... I won’t move and if you don’t treat me I will find another hospital... I won’t die without a fight. (Key informer: patients’ advocate, major urban area, 2001 -free translation).

From the quantitative survey [Table 1], we compared individuals with and without ART. Then we took into account that the category ‘without ART’ is heterogeneous, as it refers to both clinical and biological criteria, and therefore includes both people not in need of ART and people in need of ART but without access. In order to reduce the heterogeneity, we focused on the individuals medically eligible for ART according to the national guidelines and compared them with people under treatment. As relevant data on viral loads and clinical status were not available, we used CD4 counts to separate the people without ART into two categories of people ‘in need of ART’:

- group 1 (N = 163): people without ART and with a CD4 count under 350 (threshold at which a patient is considered to present a high probability of disease progression, according to the national therapeutic guidelines);
- group 2 (N = 96): people without ART and with a CD4 count under 200 (threshold at which there is a world-wide consensus among experts that immediate ART initiation is essential [20]).

Comparison of people with ART and people without ART

Individuals without ART are significantly younger than individuals with ART. There is no relationship between access to ART and gender or sexual identity.

Mean CD4 count is significantly lower for ART-treated patients. This result probably reflects the relatively recent access to ART for a large proportion of the sample: mean CD4 for people with access to ART within the last year (44% of people with ART) is 185.

Access to ART is also positively correlated with socioeconomic and behavioral factors: people with monthly family income per capita of more than US$100 are more often treated with ART. Conversely, people not treated with ART are more frequently alcohol and drug users.
Table 1: Characteristics of people with and without ARV treatment*

<table>
<thead>
<tr>
<th></th>
<th>With ART</th>
<th>Without ART</th>
<th>Without ART (\text{and (cd4&lt;350)}) (Group 1)</th>
<th>Without ART (\text{and (cd4&lt;200)}) (Group 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(N)</td>
<td>499</td>
<td>300</td>
<td>163</td>
<td>96</td>
</tr>
<tr>
<td>(\text{Mean (sd)})</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(\text{AGE})</td>
<td>37.8 (9.3)</td>
<td>34.7 (9.5)</td>
<td>35.8 (9.1) (p&lt;0.02)</td>
<td>36 (8.4) (\text{NS})</td>
</tr>
<tr>
<td>(\text{CD4})</td>
<td>238 (184)((N=672))</td>
<td>291 (222)((N=425))</td>
<td>162 (106)</td>
<td>86 (64)</td>
</tr>
<tr>
<td>(\text{% women})</td>
<td>21</td>
<td>17</td>
<td>18</td>
<td>17</td>
</tr>
<tr>
<td>(\text{Homosexual men})</td>
<td>59</td>
<td>62</td>
<td>62</td>
<td>59</td>
</tr>
<tr>
<td>(\text{Family income per capita &lt; 100 US$})</td>
<td>45.1</td>
<td>54.3 (p&lt;0.01)</td>
<td>53.8 (p&lt;0.05)</td>
<td>58.5 (p&lt;0.02)</td>
</tr>
<tr>
<td>(\text{Member of voluntary organization})</td>
<td>24.7</td>
<td>24.4 (\text{NS})</td>
<td>21.5</td>
<td>20.8 (p&lt;0.02)</td>
</tr>
<tr>
<td>(\text{Alcohol consumption (at least once a month)})</td>
<td>46.1</td>
<td>54.7 (p&lt;0.02)</td>
<td>51.5</td>
<td>44.8 (\text{NS})</td>
</tr>
<tr>
<td>(\text{Drug consumption last month})</td>
<td>10.2</td>
<td>15 (p&lt;0.05)</td>
<td>14.1 (\text{NS})</td>
<td>13.5 (\text{NS})</td>
</tr>
</tbody>
</table>

* Each comparison is with column 1 (with ART).

Comparison of people with ART and people ‘in need of ART’

People ‘in need of ART’ are younger than people with ART. The difference is significant for Group 1.

Behavioral variables (alcohol and drug consumption) are not significantly different between people with ART and people in need of ART (Groups 1 and 2).

Conversely, economic and social support variables are significant: the proportion of people with low family income per capita is significantly higher in the 2 groups of people ‘in need of ART’ than in the group of treated patients. Belonging to an AIDS voluntary organization is more frequent among persons with treatment; the difference is significant for Group 2.

Thus our data provide evidence that in addition to medical criteria, socioeconomic factors introduce a significant bias in selecting patients for access to ART [21, 22].
Transfer from the private to public health system

Table 2 documents the phenomenon of transfer from the private health system to the PHS for patients with HIV/AIDS once they have been informed of their serological status.

This phenomenon is far from being anecdotal: among the 794 individuals who answered the questionnaire, 29% (n = 233) declared that they had moved from the private to the public system. The proportion was even higher for people with ART (32 vs 25%), but the difference was not statistically significant.

Table 2: Transfer from the private to the public health system following notification of diagnosis of HIV-infection

<table>
<thead>
<tr>
<th></th>
<th>WITH ART</th>
<th>WITHOUT ART</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not change system</td>
<td>314 (63%)</td>
<td>202 (68%)</td>
<td>516 (65%)</td>
</tr>
<tr>
<td>Changed system</td>
<td>157 (32%)</td>
<td>76 (25%)</td>
<td>233 (29%)</td>
</tr>
<tr>
<td>Not concerned</td>
<td>24 (5%)</td>
<td>21 (7%)</td>
<td>45 (6%)</td>
</tr>
<tr>
<td>Total</td>
<td>495 (100%)</td>
<td>299 (100%)</td>
<td>794</td>
</tr>
</tbody>
</table>

Reasons for such transfers were documented for 206 individuals:

- 55% (n = 125) perceived that they would have better health cover in the public health system;
- 22% (n = 50) could no longer afford the cost of their insurance premiums;
- 8% (n = 18) were obliged to transfer in order to have access to the support of a private or public foundation;
- 6% (n = 13) were explicitly excluded from their private insurance program because of their HIV serostatus.

These results raise the issue of the sustainability of the public supply of ART, especially if the epidemic continues to grow. To what extent such an issue could undermine the process of universal access to ART is nevertheless difficult to assess due to the absence of relevant data on the number of HIV/AIDS patients in the private sector. In addition, they highlight the private sector’s lack of involvement in the fight against AIDS.
Financial burden to the patients and their caregivers

Table 3 shows the magnitude of the financial burden reported by PLWA in the questionnaire.

While the mean monthly health expenditure for patients treated with ART is US$98, it is only US$33 for patients without access to ART. The difference is highly significant. Persons treated with ART declared monthly health expenditures of over US$84 in more than 40% of the cases. This proportion fell to 20% for the non-treated individuals. On the other hand, only 26% of individuals treated with ART declared monthly health expenses of US$17 or less, against 42% for the non-treated individuals. These differences are statistically significant.

Thirty two per cent of individuals treated with ART (N = 159) said they had taken out a loan in order to cover their health budget, against 22% of non-treated individuals (N = 62). The difference is significant.

Main reasons for such differences in health expenses and loans between people with and without ART are the following:

– first, in 2000 a large proportion of patients treated with bitherapy were asked to provide the third molecule to complete their treatment;

Table 3: Individual health expenses and indebtedness

<table>
<thead>
<tr>
<th></th>
<th>WITHOUT ART</th>
<th>WITH ART</th>
<th>p&lt;0.01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly health expenses (means)</td>
<td>US$33 (sd = 38; N = 285)</td>
<td>US$98 (sd = 104; N = 485)</td>
<td></td>
</tr>
<tr>
<td>Proportion of individuals with health expenses &lt; US$7 (10,000 pesos)</td>
<td>42%</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>Proportion of individuals with health expenses of US$7-84 (10,000-50,000 pesos)</td>
<td>38%</td>
<td>32%</td>
<td>p&lt;0.02</td>
</tr>
<tr>
<td>Proportion of individuals with health expenses of &gt; US$84 (50,000 pesos)</td>
<td>20%</td>
<td>42%</td>
<td></td>
</tr>
<tr>
<td>Proportion of patients having contracted a debt in order to cover their health expenses</td>
<td>22%</td>
<td>32%</td>
<td>p&lt;0.00</td>
</tr>
</tbody>
</table>

Note: US$ of 2001 (1US$ = 526 chilean pesos).

12. Given the precarious socioeconomic status of most patients, different mechanisms are used to meet the health expenses. These mechanisms include contracting mainly short-term debts with family and friends, but also mid- and long-term debts when they have access to the credit market (credit cards, consumer credits, etc.)
The bitherapies we prescribe are prescribed on the condition that the patients, with or without our support, are able to obtain the other molecules elsewhere... (Key informant: Physician, major urban area, 2001.)

– second, access to ART was partially determined by the time that individuals spent on the waiting list: when they finally had access, their health status could have become more serious, incurring higher health expenses;
– third, due to occasional breakdown in the distribution of ART, some patients may have been forced to obtain their ART themselves on the formal or the informal private market.

Besides, there is the dramatic case of persons who due to their precarious economic conditions sell their ART, as it is a transaction good: if they don’t have pesos for food, they sell it on the market and they can eat. (Key informer: patients’ advocate, major urban area, 2001-free translation)

Both the survey and the semi-structured interviews identified the following sources of funding for ART: the PHS, clinical trials, municipalities, some other non-profit sources (foundations, NGOs), and the patients’ family and caregivers. Of the 499 individuals receiving ART in our sample, the type of treatment was documented for 495 (91 under bitherapy and 404 tri- or quadri-therapy).

Overall 73% (n = 362) were fully covered by the PHS: 96% for people with bitherapies (n = 97) and 69% for people with tri/quadritherapies (n = 275).

The distribution of funding sources among the individuals not fully covered by the PHS was the following:

  . 8% (n = 40) from a mix of public, non-profit and protocol sources (10% of tri/quadritherapies and 1% of bitherapies);
  . 17% (n = 86) from a mix of private and public sources (21% of tri/quadritherapies and 2% of bitherapies);
  . and only 1% (n = 3) from an exclusive private source.

Municipalities were involved in the full or partial funding of drugs for 25 individuals (5%); other non profit sources (foundations, NGOs), for 19 (4%). Eight people (2%) participated in clinical trials, and consequently they received their drugs from the protocol sponsors.

13. The phenomenon of the informal market is not yet well-documented but many key actors of the Chilean health system interviewed in the framework of the research have acknowledged its reality [13]. In the quantitative survey, 13.5 per cent of people treated with ART said they had been obliged to buy drugs from other patients at least once because the health center was out of stock. (n=67).
Finally, 89 individuals (18% of people with ART) had to pay costs for accessing ART out of their own pocket.

**Distribution of ART**

Access to ART is not only an issue of availability of financial resources but also involves the organization of the drug distribution process. In the perspective of scaling up access to ART, any dysfunction of this process may have a negative impact on the patients’ health status, and even for public health in the event of the spread of resistant viral strains.

Due to the high number of possible therapeutic combinations and the need for a continuous supply of each drug, the antiretroviral schemes are especially difficult to manage.

These issues require the health authorities to optimize efficiency of the distribution process. As shown in figure 1, this process is complex due to the diversity of the actors involved and their interrelationships. Seven main actors are involved:

– Conasida: evaluates the needs, defines the purchasing strategy, negotiates prices with industry and coordinates the whole process;
– Fonasa (PHS): funds drug purchases;
– UNDP: plays an intermediary role in the purchase of ART allowing a tax exemption for imported ART;
– pharmaceutical companies: provide and distribute drugs at the local level (Health services or health centers), following the instructions of Conasida;
– National Institute of Public Health (ISP): controls the quality of the imported drugs;
– regional health services: coordinate the distribution to the hospitals;
– hospitals (health centers): assess local needs and, of course, provide ART to the patients.

The usual time between evaluation of the needs by Conasida and distribution of ART to the patients in the health centers is 3 months.

Problems may obviously arise at each step of this process. For instance, an insufficient access to viral loads and CD4 tests will challenge the ability to carry out accurate medical assessment of the patients’ status; the lack of human resources will undermine the quality of the data transmitted to Conasida and will prevent an accurate assessment of the needs.

Such planning problems have occasionally led to purchases of drugs close to their expiry date. Lack of coordination also results in extra delays and in conflicts between the public health authorities and the industry: for example,
when the local branch of a company is not able to fulfill the demand due to the short deadline of the purchase order (incompatible with the rigid supply requirements of the company’s headquarters). Any such mismanagement may lead to supply problems.

[...] (supply problems) have occurred five times in the last year... Now we have a lot of cooperation from patients... when you explain to them that we have not received any AZT they understand better. (Key informer: pharmacist 2001).

**Figure 1: The process of distribution of ART**
In the survey, 52 persons (10.4%) with ART declared that they had been forced to give up their treatments at least once because the drugs were not available at their hospitals.

The consequences of such situations were documented in the semi-structured interviews. They concern the patients and the different actors and players involved in the distribution process.

For patients, the consequences of running out of stock are financial (due to unexpected expenses), work-related (due to absenteeism) and health-related (anxiety, stress and risk of therapeutic failures)

*We have had this problem (supply problems) twice this year... It is a mess because we give the patients 5 caps for 5 days when the usual doses are monthly... So, they have to come back more often to the hospital, they have to spend more money on transport... (also) they become stressed and even desperate, they tell you that if it (the ART) does not arrive they will stop the therapy... it happened for instance with Combivir.* (Key informer: Physician 2002).

In some extreme cases, supply problems may even lead to interruptions in the patient’s treatment.

For the health centers the consequences of disruptions concern the quality and quantity of work (increase in the work-load, diverting time from patient care to administrative duties, deterioration of the work atmosphere), stress and burn-out (coping with patient frustration and dealing with bureaucracy).

[...]*It is very stressful and I have a difficult time because of Conasida but I know that I will eventually be lucky and I will obtain what I need... But it is painful and difficult... Everything is in the hands of the professionals (at the health center)... I waste hours that I could be using on the other many tasks I have.* (Key informer: pharmacist, major urban area, 2002 – free translation).

For the different institutions and organizations involved in the ART distribution process, the consequences of running out of stock are potential tension, conflicts and a deterioration of the atmosphere of trust.

[...]*Of course, it (the ART) arrives bit by bit and it's a disaster... We never know when to expect it (the ART), Conasida blames the industry that doesn't deliver on time, the industry blames Conasida claiming that they don't pay.* (Key informer: physician major urban area, 2001-free translation).
Conclusion

When examining the Chilean experience it appears that even in a country with a relatively low epidemic and an intermediate level of development, the economic and organizational consequences of scaling up access to ART are far from minor at both the individual and the community level. While some of the consequences regard the limited covering of needs, others concern the access expansion process itself.

First of all, because of a lack of resources, there is probably no satisfactory way of selecting patients for ART treatment among those who meet the clinical and biological criteria. Nevertheless, our data clearly show that access to ART is dependent on socioeconomic factors. We do not know if these factors are used as a priori criteria, but the reference to patients adherence as a selection criteria is likely to include such socioeconomic factors. Such a criterion should be removed: it has been clearly demonstrated that patient adherence is a dynamic process that cannot be predicted reliably solely on the basis of a few a priori patient characteristics [23]. In order to decrease inequalities in access to ART in countries involved in a scaling-up process, it would be preferable to define the conditions of access better, either by strengthening biomedical criteria, or by prioritizing some specific sub-groups of the population.

Secondly, the lack of resources imposes a significant financial burden on a large proportion of the PLWA, especially those having to pay for the third molecule themselves, while only bitherapy is funded by the PHS. Thus, these conditions affect individual health status and equity.

Financial constraints could be a factor in stopping treatment either temporarily or even permanently. In other countries, it has been proved that disruption of the patient’s financial resources was the main obstacle to adherence to ART adherence [24].

As Evans [25] has clearly shown, any form of co-payment reduces the health system’s ability to redistribute financial resources. On the one hand, the more a system is funded by co-payments rather than taxes, the less it is able to redistribute from poor to rich individuals and achieve an equitable distribution. On the other hand, the more a system is funded by co-payments rather than by state-financed health insurance premiums, the less it is able to dissociate the risks related to the illness from the ability to pay and to redistribute resources from healthy to sick individuals.
Thirdly, the move of patients from the private health system to the PHS may undermine the sustainability of a policy aimed at improving access to ART if: the HIV pandemic continues to increase at the same pace; and/or the PHS experiences difficulties in maintaining an adequate level of funding.

Obviously, as long as the for-profit private sector does not accept a fair share of the collective responsibility to fight HIV/AIDS by including cover for out-patient ART treatment in insurance schemes, the long-term sustainability of the public strategy will continue to be challenged. This latter issue is currently under debate in the framework of the Chilean health reform\textsuperscript{14}. Another approach for strengthening the involvement of the private sector would be to give it the possibility of acquiring ART at the same reduced prices as the PHS.

Finally, the success of scaling up access to ART will depend not only on financial issues but also on issues regarding the organization of the health system itself, especially the drug distribution process. Due to the complexity of this process, supply problems may occur, especially in a context of limited resources. The recent Chilean experience provides a good example. In order to improve the process, four main issues have been addressed, concerning:

1) management of information: implementation of an online information system allowing patient needs to be monitored in real time;

2) improvement of the medical decision-making process: creation of an advisory committee to manage the prescription of ART and therapeutic changes;

3) improvement of the coordination and planning of the negotiation process with companies: design of a yearly programmed schedule for the purchase of ART and of a fixed calendar of negotiation rounds with the industry;

4) reduction of the number of stakeholders in order to raise the efficiency of the process: substitution of the artificial mechanism of drug purchasing involving the UNDP by a permanent tax exemption for the purchase of ART\textsuperscript{15}. Such a measure would not only improve the ART distribution process, but would also bring about a 21 percent price reduction.

Recently, the Chilean situation in terms of access to ART has evolved significantly. Today, the needs are almost completely met, and in the near future.
future, implementation of the Chilean health reform project (AUGE)'s proposals, predicting the inclusion of HIV/AIDS as one of the 56 national health priorities with universal and comprehensive cover in the country, will bring even further improvements\textsuperscript{16}. This dramatic expansion of access to ART will of course improve the health status of patients and probably, at least in the short- and mid-term, reduce the global HIV-related health expenditures due to a decrease in the number of hospitalizations, as has been documented in the case of Brazil [26]. Expansion of ART cover will also reduce the negative effects induced by partial cover: socioeconomic inequalities in access to treatment and risk of disrupting treatment due to lack of individual resources.

Success in effectively maintaining this strategy of universal cover will further depend on the appropriateness of the needs assessment, on the involvement of the private sector, on the efficiency of the distribution process and, above all, on the ability of the PHS to mobilize funds. Mobilization of national funds will be the key to substituting in the mid-term those recently obtained from the Global Fund to Fight AIDS, Malaria and Tuberculosis and also to sustaining future therapeutic guidelines regarding new generations of more expensive ART.

\textsuperscript{16} Auge proposals will be of benefit to patients registered in the private as well as in the public system and will include out-patient care and hospitalization.
REFERENCES

3. Available at www.fonasa.cl
communication at the xivth AIDS Conference, Barcelona July 7-12th 2002, ThOrE1423.


