

# HATiP

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## Why Brazil's HIV/AIDS programme is a model for the rest of the world

### Brazil's strong leadership role

By Theo Smart

A comprehensive and balanced approach to prevention and treatment helped to stabilise Brazil's HIV prevalence, according to Dr. Pedro Chequer, Co-Founder and Director of the Brazil's National AIDS Programme. "Although today's overarching theme is prevention, there is no prevention without treatment, and neither is possible without political will, financial resources, and technical expertise" Dr. Chequer said at a plenary session at the 3rd International AIDS Society (IAS) Conference on HIV Pathogenesis and Treatment held this week in Rio de Janeiro, Brazil.

IAS selected Brazil as the host country for the conference at least partly because of the strong leadership role that Brazil has played in ensuring universal (and free) access to HIV treatment at the same time as aggressively promoting HIV prevention.

Over the course of the four day meeting, Dr. Chequer and other experts described the history of Brazil's HIV/AIDS control programme as well as some of its current success stories. But the future holds formidable challenges for the HIV/AIDS control programme including the high cost of second-line antiretroviral therapies, and, according to some researchers, the emergence of HIV-1C – the same subtype of virus responsible for the heterosexual HIV epidemic in southern Africa – which has gained a firm foothold among heterosexuals in the south of Brazil.

### Constructing a model HIV/AIDS programme

At the end of 2003, there were an estimated 600,000 Brazilians living with HIV – but according to World Bank estimates in the early 1990s, there should have been at least twice as many infected by now. Brazil seems to have stemmed the rise in new infections and Dr. Chequer gives the credit to the country's public health system and its comprehensive approach to healthcare. "I consider the conception of the public health system – and the universal access model – to be the structural "backbone" around which the Brazilian AIDS control policy emerged."

The Brazilian Constitution of 1988 stipulates that access to health is a basic right of every Brazilian citizen that must be guaranteed by the State. Brazil's public health system thus strives to provide universal and equitable access to healthcare. And in order to provide this access to health, the public health system was decentralized so as to reach people in the communities where they live.

Dr. Chequer said this model was "heavily supported by the strong leadership of public health professionals and had, as its main founding principles, a comprehensive approach to health and a constant dialogue with communities and civil society, especially as a means to enhance civil society participation over governmental policies." These features would be of critical importance in shaping the current care and treatment policies towards HIV/AIDS. Despite scarce financial resources, AIDS advocates and a committed professional healthcare community acted as a catalyst to, Dr. Chequer said "move the State machinery to appropriately confront the AIDS epidemic and to tackle both prevention and treatment."

"I am certain that none of our accomplishments would have been achieved without embracing a balanced prevention and treatment approach and the firm advocacy of the human rights of people affected by HIV/AIDS. If anything, it is this framework, coupled with strong civil society participation in all decision levels and a multisectoral mobilisation, that laid the seeds of the successes observed today. Our limited financial resources did not prevent us from adopting a pro-active and aggressive attitude against the epidemic."

### Brazil's prevention and treatment campaigns

As a result of these strategies, Brazil launched extensive and targeted safer sex and harm reduction campaigns, and has implemented a universal treatment program including treatment to prevent mother to child transmission (PMTCT).

Brazil's safer sex campaigns dramatically increased condom usage among the population. Dr. Chequer reported on data suggested that condom use among young people during their first sexual encounter increased from a low 4% in 1986 at the beginning of the epidemic up to 63% in 2003 – a thirteen-fold increase. These figures are similar to those reported by other wealthier developed countries. Reported condom-use for casual sex is also relatively high among younger-sexually active individuals.

### Percentage of condom use among sexually-active population according to age group, Brazil 2004

Condom Use	15-24 yrs	25-39 yrs	40-54 yrs	Total
Last sexual intercourse	57.3	36.6	22.3	38.4
Last sexual intercourse with casual partner	74.1	66.5	51.2	67.0
Regular use, (any partners)	39.0	22.0	16.1	25.3
Fixed partner	38.8	21.9	16.2	24.9
Casual partner	58.4	48.7	41.5	51.5

Harm reduction (targeting injection drug users or IDUs) is another pillar of the Brazilian prevention strategy. Introduced in the late 1980s, "it was increasingly adopted in other parts of Brazil throughout the 1990s as its efficacy became increasingly clear," said Dr. Chequer. Between 1999 and 2004, Brazil invested around 7.5 million dollars (US) into 391 IDU harm reduction projects.

Recent data from Brazil's Ministry of Health suggest that these investments paid off. There are around 193,000 IDUs in Brazil but about 76% of them now report that they do not share syringes or needles. The percentage of AIDS cases due to injection drug use dropped significantly as the coverage of projects aimed at this specific population expanded, from nearly 28% in 1993 down to 10% of all AIDS cases reported ten years later – a 65% drop.

### Effects on HIV prevalence

According to recent data compiled by the Brazilian Ministry of Health, HIV prevalence has remained stable or dropped "in strategic segments of the population, especially among the most vulnerable

groups,” said Dr. Chequer. He said that studies conducted with 20,000 pregnant women during delivery in 2000 and 2004 indicate that the estimated HIV prevalence rate has remained stable around 0.4%. The same pattern was observed among army conscripts, and there were also significant reductions among IDUs.

Other research presented at the conference by Dr. Wayne Shandera of Baylor College of Medicine in Texas independently corroborated the impact of Brazil’s harm reduction initiatives on HIV prevalence among IDUs in most of Brazil’s major cities. Most markedly, in Rio de Janeiro, Sao Paolo and Salvador there has been a continuous decrease in HIV prevalence among IDUs over the last decade. However, the HIV prevalence among IDUs in the city of Santos (a port city near Sao Paolo), which also has the highest general HIV prevalence in the country, and Itajai, (another port city in the far south of Brazil) remains very high at around 60%.

In another poster at the conference, Dr. Shandera reported on an analysis of more than a thousand Brazilian epidemiological studies to assess the history of AIDS in the country among different at-risk populations and geographic areas, and “to determine parameters associated with successful containment” of HIV. He reported that “the highest HIV seroprevalence values for Brazil were registered in 1991,” but that since that time there has been “significant improvement in prevalence rates among a number of groups.”

The risk factor groups with highest prevalence historically were hemophiliacs (54.7%, 48%, median, mean prevalence), followed by transgendered individuals (49%, 53.1%), IDUs (38.3%, 37.8%), and sex partners of the infected (33.5%, 28.2%). Infection has significantly declined among hemophiliacs/transfusion recipients (as a result of blood screening), infants in PMTCT studies, drug users, street youth/gang members, hospitalized patients and prisoners. Less significant changes or stable rates of infection have been seen among partners of the HIV-infected, commercial sex workers, patients in STD clinics and gay men.

## PMTCT

Free PMTCT programmes were implemented in Brazil from 1995 onward, and two studies presented at the IAS meeting described the experience of the programme over ten years in Belo Horizonte (Melo et al) and Rio de Janeiro (Rubini et al). In Belo Horizonte, mother to child transmission among women/child pairs fell from a high of 60% between from 1994 to 1996 (before PMTCT), to 28.5% between 1997 and 1998 and down to 0.84% amongst PMTCT recipients since 1999. Meanwhile in Rio, researchers report an increase in the proportion of mothers who received PMTCT or ART between the period from 1995-1999 and the period 1999-2004 – from 30% to 75% ( $p < 0.001$ ). The main barriers to access were lack of an HIV test during pre-natal care and the lack of pre-natal care. When the mother received PMTCT or ART (and standard treatment for PMTCT has improved measurably over the course of the last ten years), the rate of HIV vertical transmission was 2.6%.

## Treatment

Although Brazil’s targeted prevention initiatives have been largely credited for containing the spread of HIV in the country, it is likely that Brazil’s universal treatment programme has also had a significant impact on HIV transmission.

The potential impact of ART on HIV prevalence was reviewed in an opening plenary session talk on Tuesday morning, by Professor Salim Karim, Director of the Centre for AIDS Programme of Research in South Africa (CAPRISA). First, there are the biological effects of ART on viral load that have been demonstrated in the

blood, semen and female genital tract – and a low viral load is associated with a lower risk of transmission. Second, access to ART gives people an incentive to be tested for HIV and to seek care, thus providing multiple opportunities for behavioural interventions encouraging people living with HIV/AIDS to practice safer sex. Finally, Dr. Karim said, providing ART “strengthens health systems” and thus has “operational health system effects by changing perceptions, improving morale in health services and actually improving health systems, for example, improving the treatment of sexually transmitted diseases... Even in the absence of trial data [of ART’s impact on prevention], the evidence for integrated prevention and treatment is compelling.”

With 160,000 Brazilians currently receiving free ART from the national public health system, the effects of Brazil’s treatment programme on HIV prevention must be great indeed. Additionally, the mortality rate has dropped from 9.7 in 1995 to 6.4 AIDS-related death per 100,000 inhabitants in 2003.

Seventeen different antiretrovirals are now distributed through the public health system, including new drugs such as atazanavir, tenofovir and enfuvirtide. Brazil has set up a national network of more than 70 laboratories equipped to perform viral load and CD4 cell testing for patient monitoring. Fourteen laboratories even carry out genotypic resistance tests (which remain inaccessible in most other resource-limited countries). Dr. Chequer said that “the sharp drop in AIDS mortality and the very low level of primary resistance, which, according to a 2003 survey, stands at 8.3%, represent very successful results of our national policy.”

Eight of the 17 antiretrovirals are locally manufactured generic drugs. And according to another oral presentation on Monday, ART treatment is quite effective in Brazil, irrespective of whether the drugs are generic or brand name or whether treatment is delivered in a public health or private practice setting. May et al conducted a retrospective analysis by reviewing the charts of drug-naïve patients who had started ART in Rio de Janeiro between 1996-2004 and who had information on plasma viral load after 6 months on treatment.

485 patients were included from three settings: 354 (73%) from a public health outpatient unit (PHU), 76 (16%) from a clinical trials unit (CTU) and 55 (11%) from a private practice (PP). Mean CD4 count and median plasma viral load at baseline were 185 cells (SD=129) and 82,550 copies/ml, respectively. Initial treatment regimens were anchored by a non-nucleoside reverse transcriptase inhibitor (NNRTI) in 258 (53%), a protease inhibitor (PI) in 211 (44%), triple nucleoside analogues in 10 (2%), and PI/NNRTI in 6 (2%).

Virologic failure was observed in 119 (25%) of the subjects but many of the failures were associated with starting therapy before the year 2000 (OR=2.71, 95% CI =1.75-4.2) and use of a PI-based rather than an NNRTI based regimen (OR=1.48; 95% CI=1.2-1.8). Failure was also associated with having a lower baseline CD4 count (median 114 vs. 193,  $p < 0.01$ ), a higher baseline viral load (mean 5.02 vs. 4.50,  $p < 0.01$ ). There was also a statistically non-significant trend towards more failure at the public health clinic however the public health clinic also tended to see patients with more advanced disease.

## Sustainable costs

According to Dr. Chequer, such a large treatment programme has been sustainable only because Brazil has been able to substantially reduce the average cost of ART per patient/year from 1997 through 2001. “It has been possible by a three-fold

strategy; firstly, investments made by the Ministry of Health to set up national producers, such as public laboratories; secondly, the gains obtained from large scale procurement; and thirdly, price negotiations with pharmaceutical companies holders of patent rights.”

“This strategy, however, has shown signs of exhaustion,” said Dr. Chequer. Since 2002, the average cost per patient/year decreased only marginally, as the prices of patented second-line drugs stopped falling substantially. In 2005, for the first time since 2001, the average cost per patient per year will actually rise, and is expected to go back to its pre-2001 level.”

Although the rate of transmission is stable, the number of people on treatment is actually growing steadily because the mortality rate has dropped. And the Brazilian ART programme has “matured.” Not only have more patients in Brazil been on therapy for longer than in most other resource limited settings (with more chances for failure) but the patients being enrolled in the programme today are not as desperate for therapy as the highly adherent patients being enrolled into the new ART programmes in Africa.

As a result, rates of adherence do not seem to be as high. According to one poster (Bonolo et al), the cumulative incidence of non-adherence was 36.9% among 306 patients receiving their first ART prescription in public referral centers in Belo Horizonte, Brazil. (Nonadherence was self-reported and defined as the intake of less than 95% of the prescribed dose in the three day period prior to follow-up interviews).

According to the researchers “multivariate analysis (p<0.05) showed that being unemployed (RH=2.17), alcohol use (RH=2.27), self-report of three or more adverse reactions (RH=1.64), number of pills per day (RH=2.04), having switched ARV regimen (RH=2.72), and having a longer time between HIV test result and first ARV prescription (RH=2.27) were associated with increased risk of non-adherence.”

Thus the number of people using second-line therapies in Brazil has and will continue to increase significantly.

But new drugs used for second-line treatment tend to be much more expensive than older drugs. So in 2005, expenditures for ART will rise to their highest level ever. Dr. Chequer said that 62.5% of the 310 million dollars Brazil has budgeted for brand name antiretroviral drugs in 2005, will be spent on the procurement of only three drugs: efavirenz (*Stocrin*), lopinavir/ritonavir (*Kaletra*) and tenofovir (*Viread*).

“In a world with limited resources and competing demands,” Dr. Chequer insists “this trend is unsustainable over time.”

Contrary to earlier published reports, Brazil’s Ministry of Health has yet to conclude negotiations with Abbott Laboratories over the price of *Kaletra*. Abbott has offered a set price to supply all the *Kaletra* that Brazil needs. That means that the price of the drug per patient would fall as more patients begin to take it. According to Abbott, Brazil would be receiving the lowest price anywhere outside of Africa. However, Dr. Chequer believes that – given the number of people who might actually need the *Kaletra* in the next few years – the price will still be too high.

If an agreement cannot be reached, Brazil has threatened to issue a compulsory license to a local generic manufacturer that claims that it could supply the drug more cheaply within the next year. However, it is important to point out that the generic drug would not be stable at high temperatures as the new formulation of *Kaletra* that Abbott will soon be distributing; (<http://www.aidsmap.com/en/news/a3ce4f01-eaee-45ef-9201-545205c8daba.asp>) – which is an important consideration, given Brazil’s climate. The new heat stable formulation is made possible by proprietary technology that Abbott

is unlikely to simply give away anytime soon.

To date, its not clear yet how this will all play out. To this writer, it seemed that Dr. Chequer and other Brazilian experts at the meeting are determined to negotiate a better price with Abbott – negotiate being the operative word. It is possible that Brazil may still reach an arrangement with Abbott. But, as the largest market amongst the middle-income countries, whatever Brazil chooses to do will likely impact all other middle-income and lesser-resourced countries.

### A more transmissible virus

Another threat to Brazil’s HIV/AIDS control programme could be the recent establishment in the south of the country of HIV-1C, a subtype of HIV-1 that is potentially more easily transmitted by the largest part of the population, heterosexuals. Like the US and Western Europe, Brazil has, until very recently, been fighting an epidemic predominated by HIV-1 subtype B, which is more commonly associated with men who have sex with men, and to a lesser extent, with transmission amongst IDUs in the West. While it is possible for a person with HIV-1 subtype B to transmit the virus to their heterosexual partner, heterosexual epidemics caused by HIV-1B simply have not taken off in the same way as with other HIV-1 subtypes.

The same cannot be said for HIV-1 subtype C, currently the most prevalent virus subtype. It is found in at least 50% of HIV-1 infections worldwide and affects men and women equally. It is the predominant strain in sub-Saharan Africa, especially southern Africa, has subsequently spread to India and recent data suggest that subtype C is also becoming the most prevalent subtype in China.

The evolving pattern of HIV worldwide was the topic of a plenary lecture by Dr. Francine E. McCutchan, who leads the Global Molecular Epidemiology Program for the US Military HIV Research Program. “HIV is the most genetically variable of human pathogens,” she said, “with a rapid replication rate, a high mutation rate and the capacity for recombination” (coinfection generating a hybrid virus).

To start with, there are HIV-1 and HIV-2. HIV-1 is divided into at least three types but only group M type viruses that have spread significantly outside of West Equatorial Africa. HIV-1 (group M type) viruses are divided into 9 genetically distinct subtypes; there are at least 21 circulating recombinant forms (CRFs) of the virus and countless unique recombinant forms (URFs). Said, Dr. McCutchan “the distribution of HIV-1’s subtype and recombinants is as dynamic as its human host.” The virus, she pointed out, likes to travel.

She listed as examples of the changing global epidemic:

- CRF01\_AE was a minor recombinant strain in Central Africa, but it gained global importance once it was introduced into Southeast Asia
- Two new BC recombinant CRFs are circulating in China along different drug trafficking routes
- A subtype A strain with low diversity (meaning it was probably only recently introduced into the region) and a new CRF, CRF03\_AB, have emerged in former Soviet Republics after the dissolution of the Soviet Union
- CRF14\_BG has arisen among IDUs in Spain and Portugal in recent years

Finally Brazil’s HIV epidemic has not actually been as homogenous as in the US (though subtype B has been the predominant strain). For example, subtype F has apparently been present in Brazil since sometime early in the epidemic, and has

spread to several other nations in Latin America. Subtype F is more commonly observed in heterosexuals but it remains quite rare globally (with the exception of Romania, where it was spread primarily by contaminated blood products given to institutionalised children).

According to a number of posters at the conference (Sanabani, Munerato, Leal, Chequer Fernandez, Guimarães, Ambrosioni Czyrko) recombinants of subtype F and subtype B have also been observed in recent years in Brazil and Argentina. But these BF recombinants may not be any more infectious than subtype F and seem to be a stable minority population in the Brazilian epidemic.

The same may not be the case for subtype C, as indicated by several studies presented at the conference. According to Dr. Esmeralda Soares of the Universidade Federal do Rio de Janeiro, subtype C is spreading rapidly in southern Brazil.

Around 1997, de Martinez et al identified subtype C in 22% of 107 blood samples (compared to 75% subtype B and 3% subtype F) from patients in Rio Grande do Sul (RS), the southern-most state of the country. RS's economy is primarily based on port activity with ships from Africa and Asia frequently arriving at the local harbours.

Dr. Soares has performed a number of subsequent studies to see how viral diversity had evolved in the state. Blood samples were drawn from 281 HIV-positive patients from the cities of Porto Alegre and Rio Grande (both located in RS) between January and December 2002. HIV RNA was sequenced, genotyped and subtyped. Most viruses were either subtype B (42%) or C (45%). No risk behaviour, sexual orientation or laboratory parameter was associated with any specific subtype but subtype C tended to be more frequently found in women ( $p=0.06$ ).

Dr. Soares also presented data showing that the frequency of subtype C has increased over time, and accounted for almost 60% of new cases diagnosed in 2002 (compared to around 30% with subtype B, and smaller proportions of subtype F and recombinants). A poster presentation study by Stella et al corroborated these findings among ~100 consecutive patients attending HIV testing clinics in Porto Alegre, RS, 62% of whom were found to have subtype C.

Dr. Soares said that a new study by de Martinez has found that subtype C accounted for 72% of the HIV infections diagnosed in pregnant women from 1998-2004 in the city of Rio Grande. Subtype C has also been observed in the countries (including Uruguay, Argentina and Paraguay) neighbouring southern Brazil. Still another poster presented at the conference reported on findings in a study of patients attending a VCT clinic in Itajaí, a port city in the northern part of Santa Catarina State (just north of RS). Researchers reported subtype C in 41.7%, subtype B in 33%, subtype F in 8.3% and recombinants combining subtype C and B.

"HIV-1 subtype C is expanding and is already the predominant form in Southern Brazil," said Dr. Soares, "which is corroborated by diverse sets of data. Although there is anecdotal documentation of subtype C in other South American countries, that subtype was not detected previously in those countries, and data points out a recent spread in the southern cone. A scenario where subtype C expands and predominates in Latin America, like what has happened in African countries cannot be ruled out."

### Nipping it in the bud

The allusion to the sub-Saharan Africa experience is sobering indeed. Its important to remember HIV-1B was present in southern Africa, for example, in the early 1980's but due to that subtype's predilection for gay men, HIV was perceived to be a gay disease in

southern Africa. Once HIV-1C was introduced into the region, it spread swiftly and silently until the point where the average sexually active heterosexual would be regularly exposed to the virus. But early detection and management might have allowed southern Africa to nip it in the bud.

Of course, an exact repetition of the experience of southern Africa should not be expected in Brazil or Latin America. For one thing, Dr. Soares and her colleagues have sounded an alert. In addition, host factors such as inherited characteristics, differences in immune function, environmental and social factors and risk behaviours are completely different. So, HIV-1C may not spread as efficiently among heterosexuals in Brazil as in Africa.

But no one really knows and so far the preliminary data are frightening. And even if subtype C is not the best suited strain for transmission in Brazil, Dr. McCutcheon's findings indicate that, given time, HIV will find a way to exploit the weaknesses its finds, and that eventually a subtype or recombinant form of HIV could arise or be introduced that spreads in Brazil, or Latin America, or the US or Western Europe much more efficiently than HIV-1B has.

In that eventuality, we don't know whether the behavioural interventions that "we think" stemmed the spread of HIV-1B in the West will really work against HIV-1C. They don't really seem to be working in southern Africa (though that may be a function of HIV-1C having reached critical mass there).

But Brazil's national AIDS programme may be better equipped than most to deal with such a problem than most countries. Not so much their uptake in condom usage, per se, but the country's enlightened approach to comprehensive and equitable healthcare delivery to its citizens, and the public health service's engagement with civil society and the community — plus, the health programme's ability to "think on its feet" and react appropriately to challenges despite limited resources.

Brazil has done well so far, but this may represent a qualitatively different challenge. How Brazil handles this challenge could provide a model — not just for the lesser-resourced countries but for the entire world. Can new HIV epidemics be stopped? Brazil will be the test.

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## about HATIP

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