

For the new AIDS policy to be sustainable: Old and new challenges

On last December 1, World AIDS Day, the Health Ministry announced new measures to cope with the epidemic, which are part of the new Clinical Protocol for Adult Treatment with HIV and AIDS. Among the new measures it is included the expansion of antiretroviral drugs in the public system for all adults with HIV, regardless of the defense cell body count - CD4. In accordance with the previous guideline, only patients with less than 500 CD4 per cubic millimeter of blood were eligible to the treatment. The new guidelines are in line with the new international treatment guidelines recommended by the World Health Organization (WHO) and scientific studies that show that early use of antiretrovirals reduces by 96% the rate of HIV transmission. However, the response to HIV/AIDS is not merely scientific but also social and political. One must address the serious social and political retrocession's of the response to the epidemic in the country, which are characterized not only by old challenges but they are deeper into the context of new challenges.

It is estimated that at least 718,000 people live with HIV in Brazil, among which 150,000 do not know they have the virus. Lack of knowledge about the infection itself is quite serious and the late start of treatment causes many people to die in the first year after diagnosis. Deaths that could be avoided if people were diagnosed timely and if treatment was initiated earlier, always accompanied by the support of health services.

Scientific progress cannot blind the political and social challenges of the HIV epidemic

The "test and treat" policy, which aims to expand access to diagnosis and treatment, is welcome. However, some concerns should be taken into consideration so that its implementation can be made to ensure human rights, and not to promote its violation. It is worth remembering that a policy based on human rights and with the continuing involvement of civil society in all stages of preparation and implementation is what has made the Brazilian program to fight AIDS to be seen, in the past, as a successful policy across the world. Without this, the setbacks that have already begun to appear may put all success achieved at risk.

Government initiatives to test HIV still exclude the groups most affected by the epidemic, which go on without access to testing. Many are afraid to take the test for fear of prejudice that often accompanies a diagnosis. The closure of several reference centers of care to people with HIV/AIDS, forcing them to seek care at the nearest health service to their home, as well as recent criticisms of campaigns and prevention materials are a serious sign that the government is regressing in fighting discrimination and social stigma related to AIDS. **Fighting prejudice** is central in the fight against AIDS; this is a lesson that cannot be lost.

The increased supply of diagnostic test should be done within ethical, social and scientifically established parameters, providing counseling pre and post testing, and always **voluntarily and with full confidentiality and privacy**. Thus, initiatives such as testing in mega events and availability of low cost testing in pharmacies are troubling, insofar as they are not accompanied by an interdisciplinary



health team trained for the case of a positive test result. Moreover, it does little good to receive a positive diagnosis and not have access to the necessary health services to treatment. The long waiting time for the first medical consultation and the lack of specialized care within the public health system are unacceptable.

Still, we believe that treatment with antiretroviral drugs should be available to all people living with HIV, but the decision on the beginning of treatment is only up to the person herself, after receiving all available information about the benefits and risks of the treatment. The approach of "treatment as prevention" should always target the clinical benefit **for the person** and the consequent increase in her quality of life. A person living with HIV cannot be treated as a transmitter of the virus. Thus, the decision on the beginning of antiretroviral treatment, especially in cases of asymptomatic people with CD4 counts greater than 500 or seronegative, must respect the autonomy of the individual, without coercion or moral judgment on their decision.

Furthermore, antiretroviral treatment cannot be seen as the only mean of prevention. **The prevention policy should be combined** with other forms to reduce transmission of the virus, such as using condoms. The combined prevention should not have only a biomedical approach, but also include cultural, social and structural dimensions of the epidemic.

The financial sustainability of the response to the HIV epidemic in the context of "Test and Treat"

In addition to all the concerns mentioned, we believe that another question should be made: is the new AIDS treatment policy sustainable? If all eligible people to the treatment opt for starting immediately the use of antiretroviral drugs, will we have funds available to ensure access to universal treatment and free of charge for all?

A major challenge for the sustainability of the public health system has been the increase in the costs of treatments due to the use of new drugs protected by patents. Patents provide exclusive rights to their holders. Thus, the patent holder can sell the product in a monopoly situation at high prices, hampering the viability of public policies on access to medicines.

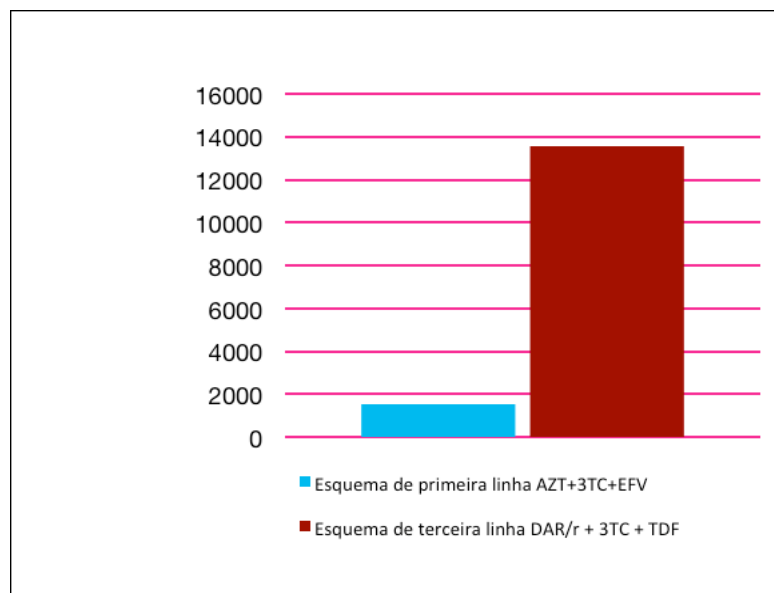
According to the Ministry of Health data, currently 313,000 people receive antiretroviral drugs in Brazil. According to estimates, some 100,000 should start treatment in 2014, an increase of 32%. However, the increase in the total budget of the Ministry of Health for the AIDS program will be less than 20%, from R\$ 1.1 to R\$ 1.3 billion. In 2013, R\$ 770 million (66% of the STD/AIDS and Viral Hepatitis Department budget) were intended only for the purchase of medicines. In 2005, when drug spending reached R\$ 986 million, mainly due to the incorporation of patented drugs at high prices, the Ministry of Health publicly declared that the AIDS policy was at risk in Brazil.

The Brazilian experience proves, therefore, that increasing the supply of treatment should always be accompanied by strategies for price reduction and fighting abusive patenting practices. Otherwise, in the medium term, we risk seeing the sustainability of the program threatened, as in the past. However, the debate on fair price and the political will to use legal mechanisms for the protection of health have been lost, just at a time when new patent barriers stand between patients and new therapeutic options.

Moreover, among the 313,000 patients already on treatment, many have already begun to acquire resistance to the virus and need to migrate to other treatment regimens. Currently the price of drugs, especially those of second and third line, is back at very high levels, with treatment reaching some R\$20.000,00 per patient per year, leading us to the scenario we faced at the beginning of the epidemics. Thus, we must consider that new patients will need in the medium term, high-cost drugs protected by patents. This trend will bring challenges to the sustainability of the universal access policy, if the patent issue is not subject to policies that prioritize human rights, against commercial rights of large laboratories.

We bring the chart below to illustrate the difference in prices between a first-line regimen consisting of generic versions produced in Brazil (zidovudine, lamivudine and efavirenz), and third-line regimen (darunavir, ritonavir, tenofovir and lamivudine), in which there is a medication under monopoly, darunavir.

Chart 1. Difference between the price of first and third line antiretroviral treatment in Brazil, in R\$, 2012



Source: Proprietary preparation with 2012 data from the Ministry of Health

At the beginning of the AIDS outbreak, Brazil had a leading role in proving to the world that the treatment of people with HIV/AIDS was possible. Access to antiretroviral treatment was largely made possible by the domestic manufacture of drugs at much lower prices than those charged by multinational laboratories. But also in 1996, Brazil changed its industrial property law and the newest medicines became protected by patents, which prevents local production or import of generic drugs at lower prices.

Some measures could have been adopted by the government to minimize the negative impact of patents on access to medicines and to ensure the sustainability of public policies on access to health, but currently little has been done in this regard.

In 2007 it was issued a compulsory license for efavirenz, an antiretroviral drug, the first and only compulsory license in Brazil. With this measure, Brazil saved in 5 years more than R\$ 200 million, with the import of generic medicine from India and subsequent domestic production by public laboratory Farmanguinhos. Despite the success of the compulsory license, the government chose to set aside the use of this measure to protect public health and adopt a trading strategy based on the negotiation of voluntary licenses with the patent holders, through the Partnerships for Productive Development (PDPs). Despite the good intentions declared, the benefits of PDPs for health policies are still a bet, surrounded by government promises, contrasting with the immediate results brought by the compulsory license.

Still, different bills are under way at the House of Representatives aimed at a revision of the patent law from the perspective of the public interest. The approval of these amendments would provide Brazil with measures that, as well as the compulsory license, could benefit access to medicines and the sustainability of public health policies. The reform of the patent law is an important step, but adopting a new legislation is pointless if there is no real political will to use those measures.

The availability of treatment for all who want to start it is a laudable initiative, but must be accompanied by other measures to be effective and sustainable, such as strengthening of primary health care, timely diagnosis, consultation with a qualified health care team, and the performance of other tests within the required period of time. On access to medicines, it is worth remembering that the international intellectual property system allows countries to adopt measures to protect the right to health. The international human rights system imposes the countries the obligation to use them. On the World AIDS Day, we hope that the government remembers that only a policy based on human rights, respecting the principles of the national health system (SUS), including social control, can be effective in fighting the epidemic.

The Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/Rebrip) is a group of civil society organizations, researchers and activists who for 10 years have defended a public interest perspective in the debate on access to medicines. Since 2003, it has developed activities turned to reducing the negative impacts of patents on public health policies in Brazil and in the Global South. Learn more about our work at: www.deolhonaspateentes.org.br .