

# The PrEP recommendation: the inscribed disease in a healthy body

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In July 2014, the World Health Organization (WHO) recommended that all gay men join the “pre-exposural medication Truvada” as a valid resource to prevent HIV. The PrEP, prophylaxis consists in taking a combination of antiretroviral medication once a day, in order to prevent HIV infection. The WHO promotion of a policy that recommends all HIV negative gay men to join the PrEP, may be seen, in the context of contemporary biopolitical techniques and strategies, as a form of control and medicalization of homosexual bodies and practices. It’s important to explicit the life-related effects linked to a measure like the PrEP program, considering this as a paradigm shift in HIV/Aids strategies. The shift involves the gradual substitution of the “condom use” recommendations for the use of permanent prophylactic medications, and may be understood as a move away from the abstinence paradigm – sexual behavior control – to a more contemporary form of individual medicalized body biocontrol, as outlined by Foucault in his later texts.

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This measure also exposes a delicate aspect of the social conduction of the HIV/Aids epidemics: the stigmatization related to the gay community as the ultimate risk group. Affirming that every homosexual should take the PrEP pill, may have the effect of perpetuating the idea that gay men are the main vector of this disease. Among the misconceptions that this may involve are the perpetuation of prejudice related to Aids and gay men, leading heterosexual populations to believe that they are not connected in the epidemic chain. **Keywords:** HIV/Aids, Pre exposure prophylaxis, homosexuality, biocontrol, male body, biopower

## **1- Introduction**

The main goal of this article is to explore the possibilities and consequences of the PrEP<sup>1</sup> recommendation, (pre-exposure prophylaxis for HIV) through the analysis of media discourse, literature and scientific articles related to this subject, that have been published in the last couple of years. The PrEP prophylaxis is a therapeutic hypothesis, concerning the prevention/treatment of HIV, that consists in taking one pill of a specific antiretroviral as an alternative prevention form for HIV/Aids. Some double blind studies are being conducted in countries of South America and Africa, with serodiscordant couples. Gilead, the pharmaceutical industry that manufactures this medicine, actually sponsors most of these studies, in partnership with some research institutes like US NIH and the Bill and Melinda Gates Foundation. The PrEP protocol has been used as an official public health policy in the United States since 2014<sup>2</sup> supported by the government and the

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<sup>1</sup> Short for Pre-exposural prophylaxis

<sup>2</sup> CDC means Center for Disease Control, it’s the US govern agency that establishes the rules for the control

CDC. In 2014 there were about 3253 people using PrEP therapy in different parts of the United States.

In the course of our argument we will seek to examine some aspects connected to the usage of the PrEP as a public health policy, exposing some of the possible reasons that led to the emergence of this method of prevention, and discuss some of the issues that can be related to this prophylaxis. In the middle of July 2014 the World Health Organization (WHO) recommended that all HIV-negative, sexually active "men who have sex with men" or "MSM" and transgender women should consider joining in a permanent basis the pre-exposure prophylaxis (PrEP), which consists in the daily use of Truvada, an antiretroviral drug combination, in order to prevent HIV infections.

“Clinical Study Data Sources. Clinical data are now available from several relevant human studies on ART PrEP for sexual transmission of HIV-1. All studies of ART PrEP were conducted in the public health setting and sponsored by one or more non-industry organizations. All of the studies evaluated ART PrEP concurrent with a background of HIV-1 risk-reduction counseling and provision of conventional HIV-1 prevention methods. For each of the studies, Gilead provided study drug (ie, Truvada or Viread) but did not participate in protocol design, study administration, or data collection. (...) Study sites are located in 6 countries: 3 in Peru, 1 in Ecuador, 3 in Brazil, 2 in the United States, 1 in Thailand, and 1 in South Africa.” (Gilead 2012 p.8)

## 2- Methodology

This article is part of the initial and exploratory stage of a postdoctoral research in which the activities are to be conducted bilaterally, in Brazil and France. Its main goal is to investigate the similarities and differences of PrEP in these two countries. The information that is used in this article was obtained from two different sources: one consists mainly in participant observation in Brazilian, north American and French online groups for PrEP discussion, and informal conversation with participants of both nationalities in actions related to PrEP protocol, either as

and prevention for the infectious diseases in the United States and all its territories.

volunteers, or as researchers. The other significant source is a collection of textual data gathered from a variety of sources such as PrEP manuals and study protocols, institutional online sites, mass media vehicles and scientific journals, commenting on different aspects of the prophylaxis. From these sources of information we have gathered observations on several important aspects of the PrEP usage, such as the different regimen choices in the multiple studies that are conducted and their consequences, the point of view of those who support the prophylaxis and of those who look at it more cautiously, and some of the most common issues related to this form of prophylaxis, such as cumulative toxicity and the possibilities of a widespread relaxation in safer sex practices.

## 3- A little bit more about the PrEP

PrEP, short for pre-exposure prophylaxis, are a series of studies to assess whether the use of a pill that combines two antiretroviral drugs, tenofovir (TDF) and emtricitabine (FTC) - marketed as Truvada - can significantly reduce the spread of HIV virus in seronegative people. The site of the French National Agency for Health describes several benefits of PrEP such as that it "may be effective in preventing HIV infection in men who have sex with men and transvestites." In France, the study is conducted by ANRS (National Agency for Research on AIDS and Viral Hepatitis). In Brazil, the study is conducted by the National Institute of Infectious Diseases Evandro Chagas - Oswaldo Cruz Foundation.

The prophylaxis, in most sources, is usually presented as a new form of HIV/Aids prevention, and often described as quite revolutionary, in a universe that for nearly three decades was populated mainly by messages of "safer sex"<sup>3</sup> and condom usage.

Emerging from a very restricted universe, with quite limited prevention options regarding an incurable condition, PrEP's popularity has grown

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<sup>3</sup> Safer sex messages can be taken as "the status quo" of the prevention since de 1990's and it consists in the condom usage recommendation advertisements that are commonly displayed in HIV/Aids prevention campaigns.

widely, mostly for accomplishing good results in most researches, and due to the 2014<sup>th</sup> WHO's recommendation. The prophylaxis reputation seems impeccable, and lots of people are interested in joining the therapy that is much acclaimed among certain social groups; in fact it is not uncommon to see news about the PrEP in the news and in discussion groups in social networks.

That said, it is also absolutely necessary to put the PrEP in perspective: issues related to its practice should be raised and a questioning of the all aspects of the therapy should be exposed and discussed. From the perspective of human and social sciences, this can be done in different ways. In this research, we are combining the analysis of the study protocols and manuals for the implementation of PrEP and its results, with information from program researchers and volunteers, as well as textual data derived from various sources, and crossing these data with the current literature related to the issues of public health, sociology of health and social medicine.

Most PrEP protocols that are currently underway, involve the use of a daily pill of Truvada – an antiretroviral drug used in the treatment of patients with HIV – to prevent infection by the HIV virus. A series of double-blind studies using the protocol of a daily dose of Truvada in medium and long term basis, are carried out in Latin America, Africa and Asia with serodiscordant couples, transsexuals, men who have sex with men and sex workers. Most of these studies are sponsored by Gilead, a pharmaceutical company that manufactures the drug, in partnership with research institutes such as the US NIH and the Bill and Melinda Gates Foundation. According to the disclosure of the company:

"All PrEP studies were conducted as part of Public Health Issues and sponsored by one or more non-industrial organizations. The PrEP studies are being conducted with HIV-1 counseling funds and supply of conventional methods of preventing reduction risks. For each study, Gilead supplied the study drug (Truvada or Viread), but was not involved in protocol design, administration of the study or data collection (...) There are study sites in six countries. Peru, Ecuador, Brazil, the US, Thailand and South Africa "(2012, Gilead p.8)

Today, in 2015, it's been about a year since the first research related to the pre-exposure prophylaxis has been applied in Brazil. This research is conducted by Fiocruz in Rio de Janeiro. Currently, there is more than one type of PrEP protocol under development in Brazil and from what one may infer about the prevailing attitude in user, media and scientific discourse, mostly related to the North American experience, it seems well on its way to being integrated into Brazilian public health policies in the near future. Currently, the main Brazilian research is the iPrEx<sup>4</sup> Protocol, which has about 650 volunteers. What we have observed so far is that this increase of PrEP studies is gradually changing the focus of prevention. Since the beginning of the 1990's most of the HIV/Aids prevention actions were based almost exclusively in the promotion of safe sex practices. Now, we seem to be facing a very significant shift from the safe sex paradigm to a new, almost entirely medicalized form of prevention.

### **3.1 – The implications on WHO<sup>5</sup> recommendation.**

The WHO recommendation in July 2014, stimulated several movements around the advent of PrEP: "WHO recommends that men who have sex with men consider the possibility of taking antiretroviral medication as an additional method to prevent HIV infection". (WHO, 2014) Perhaps the most expressive implication here is the transformation of pre-exposure prophylaxis in a consolidated public health policy in the United States. Currently people living in serodiscordant relationships or who feel otherwise vulnerable to HIV infection, may apply in counseling centers, or their family doctor, to join the PrEP therapy. This can be done free of charge from the insertion in a PrEP study, or by funding the drugs through health insurance or paying for the prescribed drugs in a pharmacy.

Another consequence of the WHO recommendation is the popularization of PrEP. In the US is not unusual to see debates about PrEP on TV, and on social networking, the facebook group

<sup>4</sup> IpREX is the PrEP protocol that consists in taking one pill of Truvada daily.

<sup>5</sup> WHO short for World Health Organization

“PrEP Facts” has over 10.000 followers. In France the health minister Marisol Touraine, announced the adoption of PrEP as a health policy in the near future. In Brazil, information about the FIOCRUZ study is gradually becoming more widespread especially among LGBTT people. Brazilian mass media started disseminating news about the success rates related to PrEP studies, and called on recruiting volunteers to take part in research. News headlines related to PrEP proliferated in the international media after July 2014. The Fio Cruz Brazil PrEP project gained ground in social networks and currently in 2015 has over two thousand followers on Facebook.

#### **4- A real shift in the prevention paradigm?**

As said in the previous section, the WHO recommendation was widely reported by the media in different parts of the world, marking the entry of PrEP as a central device for the prevention of HIV/Aids, and thus, as observed in our research, promoting a paradigm shift in the previously consolidated scheme of prevention that was in operation since the 1990s, almost exclusively focused on safer sex messages. In Brazil most preventive campaigns that have been promoted over the last two decades essentially emphasize in different ways the recommendation to use condoms. Thus, after almost two decades of this basically 'safe sex' approach and its accompanying effects on sexual practices, quite suddenly a new feature related to prevention has just appeared: the prevention based on drug therapies.

This movement shows as a paradigmatic change in the practical field of risk management concerning the HIV virus – the use of a chemical molecule to avoid contamination – that can drastically change the whole conceptualization and application of prevention. This is associated with a shift in the very idea of prevention itself, with the displacement of abstinence practices in favor of a form of medicalization closely related to the risk management model that characterizes biopolitics. By contrast, the safer sex model may be seen as more closely related to abstinence practices and/or the direct control of sexual behavior through discipline, due to the mandatory imperatives of condom usage. A shift from disciplined bodies to

biomedical control – the Foucauldian model provides us with a conceptual matrix which may help us to clarify and to outline some of the most important implications of the PrEP model adoption.

Seen from this perspective, the adoption of PrEP may be understood as a contemporary form of health management, where security mechanisms and risk management, based on individual biocontrol and medicalization, rise to the surface. For the time being, the previous preventive model will probably not be discarded and will coexist with the new one; what we see today is arguably the beginning of a coexistence between the two strategies; discipline strategies and abstinence policies in HIV/Aids prevention are gradually being associated with the use of medicines to prevent new infections in specific populations. According to Foucault, it is precisely from inside the disciplinary forms that the new biopolitical forms of social management emerge.

“La encore, d’ailleurs, il suffit de voir l’ensemble législatif, les obligations disciplinaires que les mécanismes de sécurité modernes incluent pour voir qu’il n’y a pas une succession : loi, puis discipline, puis sécurité, mais la sécurité est une certaine manière d’ajouter, de faire fonctionner, en plus les mécanismes proprement de sécurité dans l’ordre de la médecine et on pourrait multiplier les exemples (...) il s’agit de l’émergence de technologies de sécurité à l’intérieur soit de mécanismes qui sont proprement mécanismes de contrôle social, soit des mécanismes qui ont pour fonction de modifier quelque chose au destin biologique de l’espèce.” (Foucault, 2004 p12)

Both the WHO recommendation about PrEP and its use as a public health policy by the US government, present themselves as a move towards risk management through medicalization, based on the adoption of a "security technology" as a mean of protection and risk mitigation. In this operation, the guarantee of an apparently healthy body, through the ingestion of a chemical particle, can bring advantages and disadvantages; the promises of additional protection combined with possible side effects, cumulative toxicity, etc.

According to LeBreton (2003 p65), this is a psychopharmacological, chemical modulation of behavior and affection – or in the case of PrEP, eroticism – "which demonstrates a fundamental question about the body that should be maintained captive through the appropriate molecule." We can think of PrEP, also as a mechanism of "social control" and a new event in prevention policies that promotes a leveling or a reduction in the complexities and specificities involved in its older, more disciplinary form.

In this context, one may observe that the widespread educational system connected to the HIV/Aids, which was at least ideally intended to promote awareness and dialogue between the research centers and the population, may be reduced to the ingestion of a drug, in a prophylactic measure, that most of the times suppresses additional information concerning prevention and self-awareness regarding HIV. The advent of prevention is passing from the behavioral prescription – always use a condom – which implies a certain minimum level of dialogue and participation – to the simpler form of the drug prescription: one tablet daily can prevent Aids. Thus the new form may exclude an entire subjective dynamics linked to the social status of the HIV/Aids epidemic.

### **5- Some reasons for PrEP: the inscribed disease in a healthy body**

Why does the WHO recommendation emphasize certain groups of society instead of others? The main target seems to be the men in LGBTT groups rather than the sexually active population as a whole. The official discourse that concerns this choice, passes through economy, as regards the high costs of such treatment, and an epidemiological belief that the incidence of the disease is higher among men who have sex with men, than in the rest of the population. However, the annual Aids/STD report of 2013, issued by the Brazilian government shows a different scenario, in which heterosexual contact is accounted for over 40% of male contaminations, while contamination linked to homosexual and bisexual sexual interactions are around 30 %:

"As for ways of transmission among people over 13 years old, there's a sexual prevailing. In women, 86.8% of cases

registered in 2012 resulted from heterosexual sex with HIV-infected people. Among men, 43.5% of the cases are given by heterosexual contact, 24.5% by homosexual and 7.7% for bisexual." (Brazil, 2014B)

This kind of recommendation, targeting specific populations for the prophylaxis, has to be carefully considered while developing a preventive strategy anchored in PrEP, specially in order not to encourage the stigma attached to HIV/Aids that is currently one of the major trouble factors for prevention policies, since it feeds the belief that only the GLBTT people would be susceptible to infection by HIV. Furthermore, PrEP involves medicating a healthy population, and every medication has its pros and cons, mostly every molecule that we ingest have an effect over our bodies.

### **5.1 – The two point of views**

Despite the fact that antiretroviral drugs usage for HIV prevention is considered to be a relatively recent option, the use of this artifice arouses different opinions; some people think it's a liberating initiative and others look at it with a little bit more caution.

It's possible to say that there are two main opinions on PrEP. On one hand, we have organizations that are in favor of the WHO recommendation, supported by physicians and researchers, in addition to pharmaceutical companies that make this kind of study possible. The WHO, claims that PrEP is a fast and secure way of improving the healthcare services concerning HIV/Aids prevention among "vulnerable social groups" such as sex workers, male homosexuals, and transgender communities. They affirm that these populations aren't getting the specialized health services that they need, so, using a drug such as Truvada would lower the risk of contamination among these social groups. "These people are most at risk of HIV infection yet are least likely to have access to HIV prevention, testing and treatment services. In many countries they are left out of national HIV plans, and discriminatory laws and policies are major barriers to access." (WHO, Media Center 2014)

The majority of the reasons claimed by those who support PrEP are similar to those given by the WHO, such as the sensitivity and vulnerability of socially marginalized groups and the lack of support for targeted prevention, or that the prophylaxis is a simple way to prevent HIV with a single pill a day.

Obviously, WHO, did not decided to recommend PrEP without any research and study to support this decision. Since 2006 some of the major pharmaceutical companies have been developing studies on PrEP and PEP (the initials for Post Exposition Prophylaxis). PEP<sup>6</sup> has actually been used for a while now, and it's the current prophylaxis for healthcare providers who get hurt in their professional duties with contaminated needles, or as part of the "rape kit" and in some countries it's part of a harm reduction strategy being used in serodiscordant couples.

"A half-dozen studies are happening now. The trials all focus on tenofovir (marketed under the brand name Viread), a drug that appears safer than the other Aids medications on the market. Placebo-controlled trials are enrolling 5,000 people on four continents who are in high-risk groups, including gay and bisexual men, sex workers and injecting drug users" (COHEN, 2006)

The double blind studies made by some research institutes, mostly financially supported by some of the biggest pharmaceutical companies through the last 10 years, ended up leading some governmental agencies like the USA CDC to adopt PrEP as a health care intervention towards HIV/Aids. "The FDA approved Truvada for this intervention in July 2012, and the CDC earlier this year released new clinical guidance for PrEP which also cites the efficacy of everyday use of PrEP in preventing infection"(Heywood 2014)

Other countries like Brazil are running tests with some antiretroviral for PrEP use, and seriously considering the possibility of making this

a real opportunity towards its adoption as a public health policy. In Fiocruz webpage, where information about the Brazilian study is available, the welcome message is displayed below.

"Since 2010 the results of several studies have proved that daily use of one pill that combines two antiretroviral drugs, tenofovir (TDF) and emtricitabine (FTC) , marketed under the name Truvada is effective in preventing HIV acquisition among men who have sex with men (MSM) and transvestites, the efficiency can reach 99% if the individual makes regular use of the drug , that is , if you take one pill every day of the week. The studies also showed that daily use of Truvada is safe because the most common side effects were mild and temporary without causing serious side effects. (...)In Brazil, this study is conducted by the National Institute of Infectious Diseases Evandro Chagas - Oswaldo Cruz Foundation" (<http://prebrasil.com.br/sobre-nos/>)

There are some related factors that also end up supporting a decision for adopting Truvada as a prevention tool, such as the positive experiences with PEP standard medical protocol for health care professionals who are injured with contaminating material, or as part of "rape kit". In some countries PEP is part of a harm reduction strategy used in people who may have been exposed to the virus, with a very high success rate. "The success rate of PEP sex therapy was 78%, while the healthcare providers who used the PEP after a labor accident have success rates between 45% and 68%" (Salvador, 2013). It should be noted here that the PEP is applied after a suspected contact with HIV virus and it is not used continuously for more than 2 consecutive months.

### 5.1 – The stigma factor

However, it remains to be known if indeed PrEP is effectively a way to "quickly and safely improve health services in the prevention of HIV/Aids among vulnerable groups", as stated by the WHO. Is it really as simple as that? Is the "one pill a day can prevent Aids" message the ultimate prevention tool with zero risks? Does it not simply conceal and strengthen certain issues at the heart of the social conduction of HIV/Aids such as

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<sup>6</sup> Short for Post Exposure Prophylaxis, it consists in taking antiretrovirals for a period of time after being in contact with the virus. It is very common in the medical field in case of accidents with needles or scalpels. But it has been used among serodiscordant couples, in case of condom breaks for a while in Europe, US and Brasil.

stigma, strengthening the notion of risk groups, or the belief that Aids is a disease limited to certain segments of the population, like homosexuals, transgenders and sex workers?

### **5.2 – The treatment adherence factor**

Another question that should be made, beyond the levels of success of PrEP as an effective prevention method, are the practical problems of PrEP, and the most expressive of them is probably medication adherence. That is a known issue among HIV positive patients who take medication, and is a reality shown in some PrEP studies. There is not a safe way to establish effectiveness if the volunteers do not take the drug as prescribed by researchers. The FEM-PrEP study is a concrete example of it.

A decrease medication adherence was a real problem found in the FEM-PrEP protocol, where the study was severely jeopardized due to the difficulty of the volunteers with the daily medication regimen; originally the FEM-PrEP study was unable to reach conclusive results on the reduction of cases related to the use of Truvada among women.

"Although specific advice and support was provided, the treatment adherence was low, suggesting that women in the population chosen by the clinical trial may have had difficulty in taking a pill in daily basis. Because of poor adherence, the study could not determine if the drug Truvada may reduce the risk of HIV infection, according to the latest analysis of the FEM-PrEP study, the researchers are still studying behaviors, clinical measures and health outcomes that may have contributed to the low adhesion between the study participants (The New England Journal of Medicine, 2012)

There are also some problems with the adhesion to the drug regimen presented in the PrEP studies, due to the unpleasant side effects and also the obligation of taking the pill daily in a disciplinary regimen that has to be followed in order to guarantee legitimate results in this kind of study. Side effects are a very important factor

affecting the decision to abandon or follow a treatment. Gilead, the manufacturer of the drug Truvada, has reported some side effects due to the continuous use of antiretroviral medication, among the most common are "Nausea, vomiting, diarrhea, headache, dizziness, sleep disorders, back pain, osteoporosis, thrombosis, skin discoloration on the palms or soles of the feet." (TRUVADA. Drug leaflet). The importance of these side effects in treatment adhesion cannot be discounted in considering the possible benefits and costs of the protocol.

### **5.3 – The possibility of a cultural condom dismissal**

Another relevant question regarding PrEP is the possibility of opening a breach in safe-sex practices, leading many people to believe that habits such as condom use are no longer necessary, since they would be replaced with Truvada as a new form of prevention. This may open the way for a premature cultural rejection of safe-sex practices, with no evidence yet of long-term side effects or the full effectiveness of medication used in PrEP. This is one of the main aspects that should be pointed while conceiving a PrEP related prevention project.

This possibility of "behavioral disinhibition" has been pointed out by some concerned researchers such as Dr. Susan Buchbinder, head of the HIV research section at the San Francisco Department of Public Health:

"Dr. Susan Buchbinder, (...) says she initially had "big reservations" about the research, because she worried about what psychologists call "behavioral disinhibition": what if fear of H.I.V. declined in people who took the drug, and they then skipped using condoms or increased their number of sex partners?" It's scary as an investigator, as a public-health official and as a person who has worked with the community for many years to think about doing something that could paradoxically make the epidemic worse rather than better," she says." (COHEN, 2006)

The recommendation of PrEP for certain target groups may have a huge impact on how people perceive the HIV/Aids issue. Approval and

dissémination of PrEP as a prevention tool, simply establishing that a significant portion of the GLBTT community should join PrEP, without further information and dialogue between health institutions and the population, may perpetuate the idea that gay men are the main vector of the disease, and the « behavioral disinhibition » effect of PrEP may backfire on epidemics prevention and control. The deconstruction of this kind of stigma, which reinforces the message that Aids is a "gay disease" is absolutely necessary to educate and make aware that anyone is vulnerable to HIV.

## 6- Conclusion

The discussion on PrEP must begin with a honest dialogue on its possibilities and limitations. If PrEP can prevent HIV infection during unprotected sex, it can be an interesting tool for those who are more vulnerable to HIV infection; but it should be discussed with the full disclosure of all the advantages and disadvantages of this strategy.

The PrEP strategy has a very high cost, it's a huge investment in research and application, and if the results end up showing it as an effective tool to prevent HIV, PrEP can be seen as an opportunity for prevention, in a field that counted basically with educational campaigns and safe-sex practices. However, that should be done and thought out carefully, thinking about the pros and cons of this decision.

Mostly the PrEP strategy is about the sale of a security concept to a population that is eager to have one; but this kind of information must be accurate in order to make those willing to adopt it aware of the risks involved in a program such as PrEP. Establishing a specific target for PrEP in LGBTT people can be a mistake that perpetuates the stigma bonded to HIV. Truvada is medication that can have severe side effects, some of them very harmful and health threatening ; healthy and productive people may get sick by taking it, with no certitude that he/she may risk viral exposure for

sure. A segmented and personalized orientation is absolutely necessary in this case in order to establish if PrEP is the best prevention tool for each individual. It has to be carefully discussed and directed towards the different realities between the populational groups.

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