



CONSEIL NATIONAL DU SIDA
39-43 QUAI ANDRE CITROËN
75902 PARIS CEDEX 15
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OPINION AND RECOMMENDATIONS
REGARDING THE POTENTIAL FOR
TREATMENT AS AN INNOVATIVE TOOL FOR
FIGHTING THE HIV EPIDEMIC

MEMBERS OF THE « TREATMENT AND PREVENTION » COMMITTEE

FRANÇOIS BOURDILLON

BRUNO CADORE

JEAN-PIERRE DOZON

PHILIPPE GAUDIN

NICOLE HESNAULT-PRUNIAUX

CATHERINE KAPUSTA-PALMER

WILLY ROZENBAUM

RAPPORTEURS

MICHEL CELSE

MARC DIXNEUF

LAURENT GEFFROY

ADOPTED BY THE FRENCH NATIONAL AIDS COUNCIL, IN PLENARY SESSION, 9 APRIL 2009.

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OPINION AND RECOMMENDATIONS REGARDING THE POTENTIAL FOR TREATMENT AS AN INNOVATIVE TOOL FOR FIGHTING THE HIV EPIDEMIC

Considerable efforts have been deployed for many years to prevent the sexual transmission of HIV, but although these efforts have made it possible to hinder the spread of the epidemic, it has not been contained. Despite significant improvement in access to treatment around the world, the pace of contamination continues to grow faster still: in 2007, for every person in the world who commenced treatment, 2.5 new contaminations occurred. Although the rate of spread varies, depending on epidemiological situation and conditions of care, the epidemic continues to grow dynamically, even in countries such as France, which feature what is termed a "concentrated epidemic" and which offer the highest standards of therapeutic care. Our aim cannot be simply to stabilize the number of new contaminations, since that necessarily leads, by the simple effect of arithmetic, to an increase in the total number of people contaminated. To reduce the prevalence of HIV, our goal should be a clear *decrease* in the number of new contaminations to reduce prevalence in the long term. Reducing the rate of transmission is thus a crucial goal, in developed as well as developing countries, in order for the epidemic to be controlled, but the current tools of prevention have demonstrated their limits in this respect.

Scientific data indicates that providing treatment to infected persons sharply reduces the risk that they will sexually transmit the virus. This opens new perspectives for the control of the epidemic. In addition to the individual therapeutic benefits which have motivated and guided its prescription so far, treatment could now also be deployed to impact transmission, thus becoming a useful tool for curbing the dynamics of the epidemic on a macro level.

In the past year, there has been much debate (and, often, controversy) both in France and abroad regarding the importance of this issue for the future outcome of the fight against the HIV pandemic, as well as discussion of the implications and complexity of such a change in the status of treatment, both for individuals and for their communities. It is incumbent on the National AIDS Council to report on these debates, and to propose a critical and organized understanding of it which may contribute to the necessary repositioning of the various actors who are engaged in the fight against AIDS, as we together face what appears to be a shift of paradigm. Operating in a democratic society that is founded on equal access to knowledge, the National AIDS Council strongly wishes to promote the sharing of information with all concerned persons, and particularly persons living with HIV, whom it considers to be fully capable of understanding the importance and the limitations of such information.

PART I REDUCTION OF TRANSMISSION THROUGH TREATMENT: POTENTIAL BENEFITS AND LIMITATIONS

I.1 TREATMENT MAY CONSTITUTE A POWERFUL TOOL FOR CONTROLLING THE HIV EPIDEMIC

I.1.1 SCIENTIFIC BASIS FOR USING TREATMENT TO REDUCE THE EPIDEMIC

In 1996, when the first effective antiretroviral multitherapies (ARVs) arrived in the developed world, they profoundly altered the course of the epidemic of HIV infection by causing a drastic reduction in mortality and morbidity. ARV therapies work by blocking the replication of the virus, thus decreasing viral load to an undetectable level and preserving long-term immunity. However, the virus is not eradicated from the organism but remains within reservoirs, and lifelong treatment is necessary in order to keep viral load under control.

In the last ten years, progress in terms of diversification, heightened effectiveness and tolerance of these molecules has meant that infected persons can enjoy life expectancy similar to that of uninfected persons, provided that treatment is initiated and followed under optimal conditions. Thus the primary target of treatment is therapeutic. In addition, we observe a strong correlation between levels of viral load in the blood and the risk of transmitting the virus during sexual intercourse. We also note that treatment is already being deployed under certain circumstances in order to prevent transmission.

Thus treatment could additionally be deployed for its ability to reduce the risk of sexual transmission of HIV. But in order for the effect of reducing risk of transmission to be large enough to change the dynamic of the epidemic, several conditions must first be met.

TREATMENT REDUCES THE RISK OF TRANSMITTING HIV

Treatment has been used since 1994 in preventing mother-to-child transmission. Pregnant women infected by HIV may transmit the virus to their children during pregnancy, birth and breast-feeding: in the absence of treatment, the rate of transmission varies from 15% to 30% with no breast-feeding and reaches 30% to 45% with breast-feeding. In 1994 a trial demonstrated that mother-to-child virus transmission could be prevented by treatment with Zidovudin (AZT) during pregnancy. In developed countries, prophylactic courses of therapy nowadays use the same drug combinations that are deployed in therapeutic treatment, and the rate of virus transmission that ensues is less than 1%. It has also been established that prescribing preventive treatments to children can successfully prevent virus transmission during breast-feeding¹. Antiretrovirals have also been deployed since 1998 in post-exposure prophylaxis to avoid transmission. For example, health professionals exposed to HIV through accidents during injections are given a 4-week prophylactic treatment. People who have had unprotected sexual intercourse or who have used potentially infected needles and injection material may also be given access to such treatment within 48 hours. Based on expert recommendations, several ministerial circulars have defined the modalities of care modalities that should be applied to persons exposed to the risk of HIV transmission² and this treatment is available in all French casualty departments. In addition, there has been research regarding the use of ARVs to reduce the risk of HIV sexual transmission in pre-exposure treatment strategies³.

¹ Kumwenda NI, Hoover DR, Mofenson LM, Thigpen MC, Kafalufu G, Li Q, Mipando L, Nkanaunena K, Mebrahtu T, Bulterys M, Fowler MG, Taha TE. Extended antiretroviral prophylaxis to reduce breast-milk HIV-1 transmission. *N Engl J Med*. 2008 Jul 10;359(2):119-29.

² Circulaire n°DGS/R12/DHOS/DGT/DSS/2008/91 du 13 mars 2008 relative aux recommandations de prise en charge des personnes exposées à un risque de transmission du virus de l'immunodéficience humaine (VIH). Circulaire n°DGS/DH OS/DRT/DSS/2003/165 du 2 avril 2003 relative aux recommandations de mise en oeuvre d'un traitement antirétroviral après exposition au risque de transmission du VIH. Circulaire n°DGS/VS2/DH/DRT/99/680 du 8 décembre 1999 relative aux recommandations à mettre en oeuvre devant un risque de transmission du VHB et du VHC par le sang et les liquides biologiques. Yeni P [dir.], Recommandations du groupe d'experts, rapport 2008, Paris, Flammarion Médecine-Sciences, Ministère de la santé, 2008.

³ This kind of strategy, which to date has been proven effective only in animal models, consists in proposing that uninfected persons should follow antiretroviral treatment before they take any predictable risk. Research on the development of microbicides containing ARVs proceeds from the same logic: it aims to use their preventive effects for uninfected persons. Such applications of treatment are not in the scope of this current Statement, both because they have not yet been validated and because they belong to a different logic, i.e. the primary prevention of safe persons.

The correlation between the level of viral load in plasma and the risk of sexually transmitting HIV has been evidenced by data gathered in Uganda and published as early as 2000. This study observes that no transmission occurred with persons whose viral load was below the detection threshold⁴. A study in Thailand confirmed the observation⁵.

Studies of serodifferent couples have studied cases of virus transmission to the originally uninfected partner according to whether or not the originally infected partner was receiving effective treatment. A study in Spain showed that among 393 serodifferent couples observed between 1991 and 2003, no contamination occurred when the contaminated partner was under treatment⁶. The article concludes that ARVs will cause a significant decrease in transmission among stable heterosexual couples, independent of other factors possibly affecting transmission risk.

Certain studies have sought to assess the impact of treatment by comparing rates of transmission before and after the introduction of effective therapies to a given region. One study that reviewed surveillance data in Taiwan from 1984 to 2002, including HIV infection records and AIDS cases, estimated that the transmission rate decreased by 53% following the introduction of ARVs⁷. The authors concluded that this demonstrated the potential impact of treatment as a tool for controlling the epidemic.

More recently, new data gathered in Uganda, Rwanda and Zambia, from much larger cohorts of serodifferent couples, have made it possible to confirm that treatment reduces the risk of transmission⁸.

Equivalent data concerning transmission during homosexual intercourse is not available to date. However, data gathered in San Francisco from men who had sexual intercourse with other men indicated that a dramatic rise in syphilis – which is a marker for high-risk sex – was not accompanied by a rise in HIV infections. The proposed explanation is that treatment displays a protective effect against HIV transmission⁹. A similar tableau is observed in the Canadian province of British Columbia, with a rise in other sexually transmitted infections (STI) but no shift in numbers of new HIV infections¹⁰. Although there appears to be more high-risk sex, treatment seems capable of reducing the risk of HIV transmission¹¹.

PRE-CONDITIONS FOR SHIFTING THE DYNAMICS OF THE EPIDEMIC

In the wake of such data, research using various statistical models indicates that to obtain significant impact on the dynamics of the epidemic, the main variables are the percentage of infected persons receiving treatment, how early such treatment is initiated, and correct compliance with treatment. More frequent risky behaviours can, however, counterbalance the positive impact of treatments, and the local characteristics of the epidemic may also impact any policy options under debate.

A model that was developed by the British Columbia Centre for excellence in HIV AIDS¹², based on local epidemiological data, demonstrated that HIV transmission could be reduced only if the percentage of infected persons receiving treatment rose from 50% to 75%¹³. Below the 50% threshold, treatment may indeed slow down the increase in new contaminations

⁴ Quinn TC, Wawer MJ, Sewankambo N, Serwadda D, Li C, Wabwire-Mangen F, Meehan, MO, Lutalo T, Gray RH. Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1. *N Engl J Med*, 2000, 342:921-9. The study concerned 415 serodifferent couples who were observed for 30 months.

⁵ Tovanabutra S, Robison V, Wongtrakul J, Sennum S, Suriyanon V, Kingkeow D, Kawichai S, Tanan P, Duerr A, Nelson KE. Male viral load and heterosexual transmission of HIV-1 subtype E in northern Thailand. *J Acquir Immune Defic Syndr*. 2002 Mar 1;29(3):275-83. Data concerned 493 couples in which the male partner was infected with HIV.

⁶ Castilla J, Del Romero J, Hernando V, Marincovich B, García S, Rodríguez C. Effectiveness of highly active antiretroviral therapy in reducing heterosexual transmission of HIV. *J Acquir Immune Defic Syndr*. 2005 Sep 1;40(1):96-101. 393 serodifferent couples were enrolled in the cohort between 1991 and 2003.

⁷ Fang CT, Hsu HM, Twu SJ, Chen MY, Chang YY. Decreased HIV transmission after a policy of providing free access to highly active antiretroviral therapy in Taiwan. *JID* 2004;190: 879-85.

⁸ Reynolds, S. et al. ART reduced rate of sexual transmission of HIV among HIV-discordant couples in rural Rakai, Uganda. Sixteenth Conference on Retroviruses and Opportunistic Infections, Montreal, abstract 52a, 2009. Sullivan, P. et al. Reduction of HIV transmission risk and high risk sex while prescribed ART: results from discordant couples in Rwanda and Zambia. Sixteenth Conference on Retroviruses and Opportunistic Infections, Montreal, abstract 52bLB, 2009.

⁹ Buchacz K, Kellogg T, McFarland W, Kohn R, Dilley J, Louie B, Kent C, Holmberg S, Klausner, CDC Atlanta, Trends in primary and secondary syphilis and HIV seroincidence among men who have sex with men in San Francisco, 1998-2002, Conference on Retroviruses and Opportunistic Infections, Boston, presentation 88, 2005.

¹⁰ Lima VD, Johnston K, Hogg RS, Levy AR, Harrigan PR, Anema A, Montaner JS. Expanded access to highly active antiretroviral therapy: a potentially powerful strategy to curb the growth of the HIV epidemic. *J Infect Dis.*; 2008 Jul 1;198(1):59-67. p. 65.

¹¹ Porco TC, Martin JN, Page-Shafer KA, Cheng A, Charlebois E, Grant RM, Osmond DH. Decline in HIV infectivity following the introduction of highly active antiretroviral therapy. *AIDS*. 2004 Jan 2;18(1):81-88

¹² The mission of the British Columbia Center for excellence in HIV, created in 1992 by the province's Ministry of Health, includes the development of research protocols and cost-effective public health programmes in the fight against HIV.

¹³ Lima VD, Johnston K, Hogg RS, Levy AR, Harrigan PR, Anema A, Montaner JS. Expanded access to highly active antiretroviral therapy: a potentially powerful strategy to curb the growth of the HIV epidemic. *Op. cit.*

but it does not reverse the trend. Drawing from these results, the public authorities of British Columbia have already embarked on a population-wide prevention policy that is partially based on the idea that in a concentrated epidemic situation treatment may be able to shift the dynamic of the epidemic. This strategy has been deemed to be cost-effective; statistical models indicate that improving the screening and treatment of HIV-positive persons leads to increased cost in the short term, but reduced expenditure for society in the medium and long-term, because of new infections that have not taken place.

If policy regarding the HIV epidemic is to shift to this perspective, that will necessitate improved and earlier screening, as well as earlier onset of care for persons who are tested positive. A number of studies indicate that if transmission is to be reduced, treatment should start before the threshold of 200 CD4¹⁴. Even more radically, a model recently developed under the auspices of WHO explores the conditions under which treatment might conceivably reduce the incidence of the epidemic to the point where it would be eradicated¹⁵. Examining the context of a very active and generalized epidemic such as that in South Africa, the study posits systematic screening of every person over the age of 15, repeated annually. If treatment were systematically offered to every HIV-positive person independently of any clinical or biological consideration, the model predicts that the epidemic would be eradicated by roughly the year 2050.. (The authors do however note that the strategy poses serious ethical, as well as practical, problems).

Other studies have focused on assessing the importance of compliance with treatment, and the risk that resistances might appear that could adversely affect the effectiveness of the strategy. Most of these fears regarding adverse reactions concern modifications of behaviour.

Since the advent of antiretroviral treatment, some studies have noted a negative effect on individual prevention behaviours. This can take the form of increased exposure to the risk of HIV transmission, and may also include increased transmission of other STIs which facilitate HIV transmission. These elements may decrease the beneficial effects of treatment¹⁶ However, data indicates that this diminished caution mostly involves people who are not infected, or who do not know whether they are infected. Studies suggest that the discovery of infection and initiation of care is a strong factor in adopting prevention behaviours. A meta-analysis of high risk behaviour following the introduction of highly active antiretroviral treatments¹⁷ shows that these behaviours are not more present among people who are infected with HIV and who receive treatment than in people who are infected but do not receive treatment¹⁸. Results of the SMART study¹⁹ offer data on modified behaviour in people undergoing treatment; they indicate that infected persons take *fewer* risks after they have initiated treatment, and these safer practices are maintained over time.

1.1.2 THE FRENCH CONTEXT

Reduction of the transmission rate through treatment is dependent on the specific epidemiological situation, characteristics of transmission within the most affected groups, performance of the local screening system, and conditions of care. Strategy must therefore be tailored to groups and territories²⁰, and these parameters need to be assessed to examine to what extent, and under which conditions, treatment could be beneficial in the French context.

FRANCE : THE CHALLENGES OF A CONCENTRATED EPIDEMIC

The situation in mainland France is that of a concentrated epidemic. Transmissions mostly occur within groups exposed to particularly high risk. This situation is preferable to that of a generalized epidemic, but it does not make the epidemic easy to control. The populations exposed to the highest risk of transmission are highly dissimilar (gays and persons from

¹⁴ Auvert B, Males S, Puren A, Taljaard D, Caraël M, Williams B. Can highly active antiretroviral therapy reduce the spread of HIV? A study in a township of South Africa. *J Acquir Immune Defic Syndr*. 2004 May 1;36(1):613-21. Abbas UL, Anderson RM, Mellors JW. Potential impact of antiretroviral therapy on HIV-1 transmission and AIDS mortality in resource-limited settings. *J Acquir Immune Defic Syndr*. 2006 Apr 15;41(5):632-41.

¹⁵ Velasco-Hernandez JX, Gershengorn HB, Blower SM. Could widespread use of combination antiretroviral therapy eradicate HIV epidemics? *Lancet Infect Dis*. 2002 Aug;2(8):487-93. Granich R M, Gilks C F, Dye C, De Cock K M, Williams BG. Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission : a mathematical model. *The Lancet* 2009 Jan 3 ; Vol. 373 : 48 - 57

¹⁶ Hosseinipour M, Cohen MS, Vernazza PL, Kashuba AD. Can antiretroviral therapy be used to prevent sexual transmission of human immunodeficiency virus type 1? *Clin Infect Dis*. 2002 May 15;34(10):1391-5. Epub 2002 Apr 22.

¹⁷ Jin F, Prestage GP, Ellard J, Kippax SC, Kaldor JM, Grulich AE. How homosexual men believe they became infected with HIV: the role of risk reduction behavior. *J Acquir Immune Defic Syndr* 2007 ; 46 :245-47.

¹⁸ Crepaz N, Hart TA, Marks G. Highly Active Antiretroviral Therapy and Sexual Risk Behavior. A meta-analytic Review. *JAMA* 2004; 292: 224-36.

¹⁹ Burman W, Grund B, Neuhaus J, Douglas J, Friedland G, Telzak E, Colebunders E, Paton N, Fisher M, Rietmeijer C. Episodic Antiretroviral Therapy Increases HIV Transmission Risk Compared With Continuous Therapy: Results of a Randomized Controlled Trial. *J Acquir Immune Defic Syndr* 2008;49:142–150.

²⁰ Wilson D, Halperin DT. "Know your epidemic, know your response": a useful approach, if we get it right. *The Lancet* 2008 Aug 9 ; Vol 372 : 423-426.

sub-Saharan Africa) and social factors determining a person's attitudes toward health, the health system, and the place of sexuality in relation to health are probably also quite different. Moreover, the fact that the epidemic is concentrated in these groups does not mean there is no transmission among non-migrant heterosexuals. Finally French Guyana, and to a lesser extent the other overseas French departments, pose specific challenges since within these territories HIV has become a generalized epidemic. Thus we cannot consider that the situation in France is satisfactory, since the epidemic appears to be, at best, stable but cannot be said to be declining²¹.

As mortality is reduced and life expectancy continues to increase through treatments, the number of infected persons will continue growing. The result will be a progressive increase of prevalence which – if nothing is changed in terms of transmission – will increase the number of contaminations. It is thus vital, even in the situation of a concentrated epidemic, that we achieve improved control of transmission.

SCREENING AS A CRUCIAL ISSUE

Delay in screening remains one of the main roadblocks that must be overcome. Of a total estimated 113,000 – 140,000 persons living with HIV in France at the end of 2007, it is generally estimated that 36,000 do not know they are infected, i.e. a proportion close to one-third. About 7,000 persons discover that they are seropositive every year, and more than one-third of them do so only after their infection has reached an advanced stage, identified by CD4 levels below 200 or an outright diagnosis of AIDS. The resulting delay in care constitutes a dramatic waste of therapeutic opportunities for these persons. It also facilitates the spread of the epidemic, whose growth is probably in large part due to transmission caused by persons unaware of their infection²². Improvements to screening, an issue that has already been emphasized by the National AIDS Council in the past²³, is the first requisite for any strategy that aims to reduce the epidemic through the effect of treatment.

Following the diagnosis of infection, medical care and access to treatment appear on the whole to be satisfactory in mainland France. Difficulties do remain in access to care and biomedical follow-up among specific populations of migrants who do not benefit from universal health coverage, because they are illegal immigrants or in other administrative difficulty. However, apart from this group of people, the French welfare system offers infected persons unrestricted access to the full range of ARV treatments currently available, and this leads to very good therapeutic results: the rate of viral suppression is 85% among persons under treatment. This being said, in terms of the impact of treatment on the dynamics of the epidemic, the most significant factor is the number of successfully treated persons with respect to the total infected population, and this is currently estimated at 46%²⁴. It thus remains below the threshold of at least 50% effectively treated persons which, according to the studies conducted in British Columbia, is crucial to achieving the goal of decreasing total contaminations in a concentrated epidemic situation²⁵. Given that medical care is well-organized once infection has been diagnosed, it is once again screening that will be crucial to achieving progress in France in the rate of persons receiving effective treatment. The situation in French Guyana, and to a lesser extent in the other overseas departments of France, is much less favourable, since there are significant difficulties in accessing health care as well as shortcomings in the screening process²⁶.

²¹ L'infection à VIH-sida en France. Bulletin Épidémiologique Hebdomadaire, n°45-46, 1 Dec 2008.

²² It is observed that more risk is taken by people unaware of their status [Marks G, Crepaz N, Senterfitt JW, Janssen RS, Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States. Implications for HIV prevention programs, *J Acquir Defic Syndr*, 2005 Aug 1;39(4):446-53.]. Moreover, the risk of transmission is higher during the first months of the infection [Wawer MJ, Gray RH, Sewankambo NK, Serwadda D, Li X, Laeyendecker O, Kiwanuka N, Kigozi G, Kiddugavu M, Lutalo T, Nalugoda F, Wabwire-Mangen F, Meehan MP, Quinn TC. Rates of HIV-1 transmission per coital act, by stage of HIV-1 infection, in Rakai, Uganda, *J Infect Dis*. 2005 May 1;191(9):1403-9.] and the primo-infection [Brenner BG, Roger M, Routy JP, Moisi D, Ntemgwa M, Matte C, Baril JG, Thomas R, Rouleau D, Bruneau J, Leblanc R, Legault M, Tremblay C, Charest H, Wainberg MA; Quebec Primary HIV Infection Study Group, High rates of forward transmission events after acute/early HIV-1 infection, *J Infect Dis*. 2007 Apr 1;195(7):951-9.].

²³ Conseil national du sida. Rapport suivi de recommandations sur l'évolution du dispositif de dépistage de l'infection par le VIH en France., 16 November 2006.

²⁴ CNS Hearing. This calculation, proposed by D. Costagliola (Inserm), takes into account both the estimated number of infected persons unaware of their serological status and the number of infected persons who have been screened but not yet treated (essentially because their states of immunity gave no reason to initiate treatments considering current recommendations in that matter).

²⁵ Lima VD, Johnston K, Hogg RS, Levy AR, Harrigan PR, Anema A, Montaner JS. Expanded access to highly active antiretroviral therapy: a potentially powerful strategy to curb the growth of the HIV epidemic. *J Infect Dis*.; 2008 Jul 1;198(1):59-67.

²⁶ National AIDS Council. Statements followed by Recommendations on the Policy Employed to Fight the Epidemic of HIV Infection in French Guyana, 21 Feb 2008. Avis suivi de recommandations sur la lutte contre l'épidémie d'infection à VIH aux Antilles, 26 June 2008.

I.2 TREATMENT CANNOT GUARANTEE ZERO RISK OF TRANSMISSION

There is general consensus that treatment can enable a reduction in the risk of transmission population-wide, but there is heated dispute regarding its impact on reducing risk to each individual. The prevention of HIV transmission has to date been based on promoting individual behaviours that prevent virus transmission in situations of potential risk. Prevention through treatment proceeds from a different logical process: it seeks to render people infected with the virus non-contaminating, regardless of their behaviour in situations at risk of transmission. In terms of individual prevention, treatment is not just another tool to be added to an already large range of behavioural tools. It shifts the paradigm on which we have constructed prevention efforts to date. Because we cannot exclude the existence of residual transmission risks to individuals, we should not conceive of treatment in terms of opposition to other, behavioural tools of prevention, but as a complement to them.

RESIDUAL RISK CANNOT BE EXCLUDED

The quantification of risk is a matter of dispute at the individual level, because most studies look at relatively small groups of people and rarely include established homosexual couples. Available data show that the risk of transmission is weak when the infected partner in heterosexual intercourse is receiving treatment. However, they cannot establish that the risk is zero. Moreover, some researchers consider that this residual risk is greater for men who have sexual intercourse with other men²⁷. In January 2008, a set of recommendations for doctors issued by the Swiss Federal Commission for problems linked to AIDS, which was published in the Swiss medical bulletin (*Bulletin des Médecins Suisse*), created controversy because it assumed that the residual risk of transmission was negligible, and stated that treatment protected individuals from contamination -- that an HIV infected person who strictly complied with a highly active antiretroviral multi-therapy treatment plan, who presented undetectable viral load for more than six months, and who had no other sexually transmitted infection, could not transmit HIV during heterosexual intercourse. In response to the desire for procreation formulated by many serodifferent couples, the report concluded that if the infected partner in such a stable heterosexual couple fulfilled these conditions, then together with the seronegative partner, he or she could agree to refrain from using condoms during sexual intercourse.

In a press release, the French National AIDS Council called for caution regarding this type of extrapolation of treatment's impact on transmission to the level of the individual²⁸. In its recommendations published in July 2008, the French expert group also expressed reservations concerning the extent to which treatment protects the individual²⁹.

Because of uncertainties regarding the correlation between the risk of sexual transmission and the level of viral load measured in the blood, there may be residual risks of transmission. A correlation has been established between a decline in plasma viral load following treatment and seminal viral load³⁰. These data have been clarified^{31,32} and qualified, in a study that noted the presence of latent HIV in the seminal cells of men who showed undetectable viral load³³, and research demonstrating leaps in viral load following STIs³⁴. Thus the fact of undetectable viral load at a specific time does not mean that it will be absent at all times, and undetectable viral load in plasma does not necessarily eliminate all risk of viral presence in sperm.

²⁷ Wilson DP, Law MG, Grulich AE, Cooper DA, Kaldor JM. Relation between HIV viral load and infectiousness: a model-based analysis. *Lancet*. 2008 Jul 26;372(9635):314-20. The transmission risk during unprotected intercourse in the case of undetectable viral load, based on 100 sexual episodes, is 0.22% per annum for women-to-men transmissions, 0.43% for men-to-women transmissions and 4.3% for men-to-men transmissions.

²⁸ National AIDS Council. Press release, 30 January 2008.

²⁹ Yeni P [dir.], *Recommandations du groupe d'experts, rapport 2008*, op. cit., p. 78 : *Suivi de l'adulte infecté*, page 28: "Interpretation of this data is difficult, and appropriateness for the individual will only be established at the end of the trial currently underway. Some models of collective benefits show the epidemic coming to end. Therefore, early screening is crucial, and the offer of treatment is highly relevant. To date, the only well-tested prevention method is the condom."

³⁰ Vernazza PL, Gilliam BL, Flepp M, Dyer JR, Frank AC, Fiscus SA, Cohen MS, Eron JJ. Effect of antiviral treatment on the shedding of HIV-1 in semen. *AIDS*. 1997 Aug;11(10):1249-54.

³¹ Vernazza PL, Troiani L, Flepp MJ, Cone RW, Schock J, Roth F, Boggian K, Cohen MS, Fiscus SA, Eron JJ. Potent antiretroviral treatment of HIV-infection results in suppression of the seminal shedding of HIV. *The Swiss HIV Cohort Study*. *AIDS*. 2000 Jan 28;14(2):117-21.

³² Cu-Uvin S, Caliendo AM, Reinert S, Chang A, Juliano-Remollino C, Flanigan TP, Mayer KH, Carpenter CC. Effect of highly active antiretroviral therapy on cervicovaginal HIV-1 RNA. *AIDS*. 2000 Mar 10;14(4):415-21.

³³ Nunnari G, Otero M, Dornadula G, Vanella M, Zhang H, Frank I, Pomerantz RJ. Residual HIV-1 disease in seminal cells of HIV-1-infected men on suppressive HAART: latency without on-going cellular infections. *AIDS*. 2002 Jan 4;16(1):39-45.

³⁴ Sadiq ST, Taylor S, Kaye S, Bennett J, Johnstone R, Byrne P, Copas AJ, Drake SM, Pillay D, Weller I. The effects of antiretroviral therapy on HIV-1 RNA loads in seminal plasma in HIV-positive patients with and without urethritis. *AIDS*. 2002 Jan 25;16(2):219-25.

Other studies have shown a correlation between plasma viral load and viral load measured in the genital tracts of women, while they also note the continued presence of the virus in certain cases -- a fact which may indicate specific reservoirs³⁵. The difficulty of measuring and obtaining samples in the female genital tracts and secretions means there can to date be no definite answers concerning the risk of transmission. Plasma viral load remains the best predictive criterion for measuring viral load in fluids³⁶, but we still need better understanding of the relationship between the presence of the virus in the genital tract and the type of treatment that is being used³⁷, and we also need better understanding of its correlation with risk of transmission³⁸. There is a study underway regarding the importance of treatment in reducing the risk of sexual transmission of HIV-infection, and its results are expected in 2012. This multinational study involves 1750 serodifferent couples and will evaluate the degree to which treatment helps avoid the transmission of HIV infection³⁹. However, although it may clearly establish that treatment is effective in reducing infection in population-wide terms, the study can only suggest the precise degree to which it reduces infection of every individual. It may deliver data, but its confidence interval will not enable us to state decisively that the risk is zero. There may be particular criteria for exposure and decisive levels of viral load in the plasma below which transmission risk is zero, but this study will not be able to determine precisely what they are.

INFORMATION THAT DOES NOT PRESENT AN EITHER / OR OPPOSITION BETWEEN TREATMENT AND CONVENTIONAL PREVENTIVE TOOLS

The existence of a risk of contamination that is small but may be above zero demands first and foremost that people undergoing treatment, as well as their partners, should be fully informed. This is all the more important since the attitudes of both the partners regarding treatment as a possible method of prevention is unlike that with traditional means of prevention.

To date, the means available for avoiding transmission of the virus have been, in technical terms, the same for both uninfected persons and for virus carriers. Prevention of primary transmission (becoming contaminated) and secondary transmission (transmitting infection) were both based on either behaviours of continence – no penetration, no risk of transmission – or the systematic use of condoms: protected intercourse, every time⁴⁰. In addition, other behavioural strategies, such as reducing the number of sexual partners, also contribute to reducing primary and secondary transmission risks. Within such a model, each individual is equally and fully invested with the responsibility of ensuring there is no transmission, whether by self-protection or to protect the other⁴¹, and is responsible for this during each sexual act.

Conversely, treatment is medicalised, non-behavioural and dissociated from the sexual act, and it means that virus carriers are not highly contaminating. Both partners no longer equally share control over this method of prevention, since it depends entirely on the infected partner, who, if no other method of protection is used, is entirely responsible for reducing risk for sexual partners. As an individual tool of prevention, treatment redefines the issue of responsibility in the fight against AIDS. It vests seropositives who use it with a special, unreciprocated responsibility to protect partners, and it is situated outside the context of sexual intercourse, particularly in terms of proper compliance with treatment, which is a precondition for its efficacy.

The promotion of the possibility of reducing the risk of transmission through treatment must therefore be accompanied with a clear message of caution. Treatment is a tool that cannot replace use of the condom, which remains, if it is correctly used, a trustworthy method by which everyone can protect themselves from HIV infection, regardless of

³⁵ Kovacs A, Wasserman SS, Burns D, Wright DJ, Cohn J, Landay A, Weber K, Cohen M, Levine A, Minkoff H, Miotti P, Palefsky J, Young M, Reichelderfer P; DATRI Study Group; WIHS Study Group. Determinants of HIV-1 shedding in the genital tract of women. *Lancet*. 2001 Nov 10;358(9293):1593-601.

³⁶ Cu-Uvin S, Snyder B, Harwell JI, Hogan J, Chibwesa C, Hanley D, Ingersoll J, Kurpewski J, Mayer KH, Caliendo AM. Association between paired plasma and cervicovaginal lavage fluid HIV-1 RNA levels during 36 months. *J Acquir Immune Defic Syndr*. 2006 Aug 15;42(5):584-7.

³⁷ Neely MN, Benning L, Xu J, Strickler HD, Greenblatt RM, Minkoff H, Young M, Bremer J, Levine AM, Kovacs A. Cervical shedding of HIV-1 RNA among women with low levels of viremia while receiving highly active antiretroviral therapy. *J Acquir Immune Defic Syndr*. 2007 Jan 1;44(1):38-42.

³⁸ Kalichman SC, Di Berto G, Eaton L. Human immunodeficiency virus viral load in blood plasma and semen: review and implications of empirical findings. *Sex Transm Dis*. 2008 Jan;35(1):55-60.

³⁹ The roughly six-year HTPN 052 study is being conducted in countries including Brazil, India, Thailand, Zimbabwe, Malawi and South Africa. www.hptn.org/research_studies/hptn052.asp.

⁴⁰ Abstinence cannot be a goal; the failure of policies to control the spread of the epidemic through sexual abstinence has been amply demonstrated. Nevertheless, abstinence does exist, and its impact on the dynamics of the epidemic is not negligible: according to the VESPA study conducted in France in 2003, the population of persons affected by HIV, compared to the general population of relevant age, is characterized by a significant proportion reporting that they had no sexual intercourse in the last 12 months (22%). The absence of sexual activity is more frequent with women (29%) than men (19%). *Enquête Vespa – premiers résultats, ANRS-Actualités en santé publique*, Nov 2004.

⁴¹ This is the meaning of the “shared responsibility” that is often used to qualify this preventive model.

knowledge of the serological status of their partners. Seronegative people, or people who are not aware of their personal serological status but who wish to protect themselves, have no reason to abandon the protection which condoms offer, both because the treatment their partners receive does not necessarily mean an absolute guarantee of protection, and because they may not know with certitude that the partner is compliant with treatment or has undetectable viral load. Caution also suggests that even if they are receiving effective treatment, seropositive persons who are concerned to protect their partners should maintain maximal protection, using condoms in addition to the very reassuring supplemental security that treatment provides. Treatment should be thought of as a tool that gives regular condom users a significant additional margin of security. Additionally, condoms remain the only possible method of protection from other STIs

PART II A PARADIGM SHIFT: EVOLVING TOWARDS A NEW APPROACH TO FIGHTING THE EPIDEMIC IN FRANCE

II.1 AUTHORITIES HAVE A NEW RESPONSIBILITY TO REAFFIRM RESPECT FOR INDIVIDUAL RIGHTS

Assimilating the impact of treatment on the risk of HIV transmission into policies for fighting the epidemic will modify those policies significantly. Unlike traditional models for fighting infectious diseases such as tuberculosis, the fight against AIDS has not, historically, taken this factor into account. Because of the absence of treatment methods in the early years of the epidemic, its particularly stigmatizing character, and the important role played in responding to the epidemic by infected persons, essentially from the gay community, the fight against AIDS has been based in every aspect on respect for the autonomy, the rights, and the active implication of individuals. Screening policy is constructed on the strict respect of its voluntary nature and the possibility for individuals to maintain anonymity. In the absence of a vaccine-type tool and treatment that could make infected persons non-contaminating, control of the epidemic has been founded solely on modification of behaviour, involving calls for individual responsibility regarding practises that ensure that all individuals neither transmit nor become infected. Among behavioural strategies developed by medical authorities and community activists, efforts have been focused on promoting condom use during all acts of vaginal and anal penetration.⁴² Additional actions have gradually been launched against structural roadblocks to prevention, targeting discrimination and stigmatisation, issues of gender, and social and cultural barriers. More recently, there has been emphasis on screening in terms of the individual benefits arising from early access to treatment, and in terms of the possibility for a stable couple where both partners are seronegative to consider abandoning use of condoms⁴³. Apart from this specific context, knowing one's serologic status is not a central element in the conception of prevention that has prevailed to date, since regardless of serological status both partners participated in this preventive approach.

To construct a strategy to fight the epidemic by maximal use of the effect of treatment on risk of transmission, we need to take a new look at several aspects of this model. It sets out a new set of challenges to health authorities in terms of screening, access to care, communication and, finally, research.

A PUBLIC ISSUE OF PRIMARY IMPORTANCE

Screening and treatment are no longer only up to individuals, but become important questions for the larger community. This may involve calls for rethinking individual autonomy. From the point of view of public health, increasing the numbers of persons screened and treated becomes an important goal that gives government health authorities unprecedented responsibility in controlling the epidemic. The new challenge may give rise to well-founded concern that public policies regarding screening and guides to medical practice could adopt more coercive approaches. If wide-scale screening and treatment of infected persons will decrease the epidemic, it could be tempting to envisage systematic and compulsory screening of the population and more or less coercive requirements for treatment of persons identified as HIV positive.

Government and health authorities do need to put in place effective policies to reinforce screening, but they should be careful not to yield to this kind of reasoning. Improving the efficacy of screening does not invalidate any of the reasons behind rejecting compulsory screening to date. Maintaining free and informed consent to screening remains a matter of respect for fundamental individual rights and is also, from the point of view of public health, a necessity: experience has amply demonstrated the superiority of approaches based on voluntary adherence and the inefficacy of those based on

⁴² In addition to condoms, other behavioural strategies have been promoted in various countries or regions of the world, either for political or ideological reasons or to respond to a specific epidemiological context: advocating sexual abstinence, trust, fewer sexual partners, or postponing first sexual intercourse. The first two strategies have demonstrated their lack of efficacy in terms of controlling the epidemic; the two latter solutions may have had some impact on the macro level but reduce the risk of transmission to the individual by only a small amount; they do not constitute reliable means of individual protection.

⁴³ This protocol for ceasing use of condoms is often termed "negotiated security," and requires both partners to respect a necessary waiting period, because of delay in seroconversion, before they jointly take the test, and to make a reciprocal commitment either to protect themselves in the case of sexual intercourse outside of the couple, or not to have sex with other partners.

coercion⁴⁴. However, in order for screening to improve and widen its net, the policy of supplying screening does need to be rethought, and it should notably be more systematically proposed⁴⁵. Both in terms of screening and access to care, setting up policies that integrate treatment as prevention will mean that public authorities will have to anticipate increased demands for material, financial and human resources arising from a very significant rise in the number of persons screened and treated, compared to the current situation.

Communication regarding the need to seek screening and treatment will also need to be rethought, since it will now play a central role in discourse about prevention. Communication has to date been implicitly based on the drawbacks of treatment (its difficulty and adverse reactions), in order to convince the general uninfected population to protect themselves. It may now consider focusing on the benefit of treating infected persons, thus contributing to helping the wider public understand how important it is to know one's serological status, and to "normalising" use of the screening procedure as an ordinary part of health care follow-up. Although the condom should certainly continue to be promoted, this should be articulated within a wider concept of individual prevention, including clear and full information of the protective effect of treatment as well as its limits.

Finally, strategies to control the epidemic that draw on the effect of treatments will also necessitate increased support for research. This efficacy of this type of strategy will be increased if treatments available in the near future can be made more effective, not just in terms of viral suppression but also in improved tolerance and ease of compliance. Thus we need more research into adverse reactions; the long-term effects of the infection and of treatments; the development of more convenient pharmaceutical formulations; therapeutic education; and, more generally, improving the quality of life of persons undergoing treatment.

II.2 A NEW PREVENTION PACT: REINFORCING INDIVIDUAL FREEDOM

TREATMENT MUST HAVE ITS PLACE IN INDIVIDUAL PREVENTION

To claim that treatment and condom use should not be considered opposed to one another but framed as complementary partners means that use of the one should not exclude the other, and that maximal security seems to be guaranteed by the combined use of both. It also means that in an imperfect scenario, use of one of these two methods will always appear preferable to no protection at all. Treatment may constitute a valuable instrument to prevent a large number of contaminations of people who, in the real world and for multiple reasons, do not (or do not always, or do not adequately) use condoms.

The efficacy of the condom in preventing HIV transmission, though near-perfect in theory, is dependent on the conditions of its use. Studies of cohorts of condom-users have demonstrated transmission even in the most rigorous user groups claiming completely systematic condom use for all acts of penetration. In real life, the systematic and correct use of condoms reduces HIV transmission risk by (depending on studies) 90% to 95% compared to the absence of protection⁴⁶. Condoms thus sharply reduce the rate, but they do not deliver zero risk, particularly when their use is less than systematic.

The limitations of condoms as a method for prevention are well known: non-systematic use, incorrect use, and condom rupture. Risk-taking continues to be an issue, for reasons that differ according to groups or situations: the existence of risk or risky behaviours may be denied; serodifferent couples may have unprotected intercourse; and risk may be recurrently or systematically taken in circumstances when serological status has not been discussed or the use of condoms has not been negotiated, for reasons linked to gender relationships within society, or community or personal constraints. Risk-taking may occur as part of processes that are different for men, women, gays and migrants. Despite their desire to protect themselves or to protect others, some people experience sexual difficulties when using condoms, or they may feel weary of maintaining lifelong protective behaviour. Risk perception and management are subjective, and

⁴⁴ Conseil national du sida, Opinion and report on obligatory or systematic HIV screening, 18 Dec 1991 ; Guidelines on HIV/AIDS infection risks following sexual assault, 12 Dec 2002 ; HIV testing during pregnancy and the perinatal prevention of mother-to-child transmission, 14 March 2002.

⁴⁵ National AIDS Council. Report followed by recommendations on developments in HIV infection screening programmes in France, 16 Nov 2006.

⁴⁶ Pinkerton S D, Abramson P R, *Effectiveness of condoms in preventing HIV transmission*. Soc. Sci. Med. Vol, 44, No. 9, pp. 1303-1312, 1997 ; Weller SC, Davis-Beaty K, *Condom effectiveness in reducing heterosexual HIV transmission*. Cochrane Database of Systematic Reviews 2002, Issue 1. Art. No.: CD003255. DOI: 10.1002/14651858.CD003255.

rely less on abstract general statements than on a balance of perceived level of risk and expected benefits in a given situation. The practise of fellatio without condom use, for example, reveals acceptance of a small but significant risk of contamination.

In terms of the individual, "zero risk" does not distinguish between use of treatment and use of the condom. However, these methods differ in terms of their conditions of use and modalities of action. Treatment may constitute an answer in certain situations where condom protection fails, and for that reason it should play a part in a broader vision of prevention.

A NEW PERCEPTION OF INFECTION AND TREATMENT FOR PERSONS LIVING WITH HIV

Knowledge that treatment, provided it is properly observed, strongly reduces the risk of HIV transmission will change infected persons' perception of their infection. Many people living with HIV are above all anxious not to transmit the virus to their partners, whether within an established couple or during occasional encounters. This fear leads a significant percentage of them to abstain from sexual intercourse once they discover that they are infected⁴⁷.

Knowledge that treatment reduces their risk of transmission reassures such people and allows them to enjoy their sexuality in a more serene and less conflicted manner. It can offer great relief to people who know they are infected but feel unable to reveal their status to their partner or to suggest condom use, and it can provide a welcome element of security for women and men who, for various reasons, encounter exceptional situations where prevention is not practiced. Forgetting a condom, or even ruptures and slips, appear less dramatic and easier to cope with in the knowledge that risk is reduced.

The risk-reductive effect of treatment constitutes an additional motivation for its usage, distinct from therapeutic indications per se. This should be discussed as part of the decision to initiate treatment. It becomes possible to consider starting treatment earlier, at a stage in which its therapeutic benefit is not clear, purely for its preventive effect. As with the issue of screening modalities, respect for personal autonomy is at stake here. For the same reasons -- fundamental individual rights and the need for patients' voluntary adherence to all aspects of their care -- it may be necessary to reaffirm the importance of individual freedom of choice in this respect.

Recommendations from the 2008 French expert report specify that although there are insufficient medical arguments for recommending antiretroviral treatment to asymptomatic patients with more than 500CD4, "*it appears however acceptable to respond to a patient's request to initiate treatment despite a CD4 lymphocyte level above 500/mm3, particularly in respect of reducing the risk of sexual transmission of HIV*".⁴⁸

It is possible and even probable that recommendations regarding optimal initiation of treatment will continue to evolve towards even earlier onset of treatment, both because studies may establish the therapeutic benefit of initiating treatments at higher CD4 levels⁴⁹ and because pharmacological progress is also leading to treatments that are more effective, better tolerated and easier to take. However, the initiation of treatment that will be life-long, despite its probability of leading to significant adverse effects, is not and never will be a minor decision, particularly since proper and durable compliance is crucial.

In this regard, the effect of treatment on transmission risk usefully combines concern for non-transmission to others and concern for self, and may therefore possibly improve compliance with treatment. However, if evidence continues to build regarding the benefits of early onset of treatment both from the medical point of view (individual benefit) and from the perspective of public health (collective benefit), physicians will need to place increased emphasis on informing patients about the constraints and limitations of treatment as a prevention tool, as well as about its benefits, to ensure that they are ready to commit to treatment and desire to do so. The preventive effect of treatment is not an invitation to its prescription across the board, but reinforces the need for voluntary adherence of patients, and demands an in-depth dialogue between doctor and patient on such topics as sexuality and prevention.

NEW PERCEPTIONS OF PREVENTION FOR THE GENERAL POPULATION

The effect of treatment on transmission risk redefines the motivations for screening and, if necessary, treatment. A new form of responsibility arises, and it should become central to the philosophy underlying HIV prevention: the responsibility for all sexually active persons to know their serological status through periodic screening, and to seek treatment if

⁴⁷ Cf. *supra*, note 40

⁴⁸ Yeni P [dir.], *Recommandations du groupe d'experts, rapport 2008, op. cit.*, p. 34-35

⁴⁹ *Recommandations du groupe d'experts, rapport 2008, op. cit.* recommends that treatment should be offered to asymptomatic patients when levels reach between 350 and 500 CD4/ml, but suggest that in the future the benefits of initiating treatment at even higher CD4 levels may be established. Recent data on the mortality of patients compared to CD4 levels at onset of treatment consolidate this hypothesis. [Kitahata M *et al.*, *Effect of Early versus Deferred Antiretroviral Therapy for HIV on Survival*, N Engl J Med 2009;360.]

infection is diagnosed. The discourse regarding prevention needs to be modified to emphasize the benefits of treatment, in terms of both direct therapeutic benefit and its preventive effect. Screening needs to be perceived as an ordinary part of regular, periodical follow-up care. Knowledge of one's serological status should be seen both as a benefit for self – since, as with many pathologies, therapeutic success depends on early onset of care – and as an indispensable means opening access to all available prevention tools. Thus reformulated, screening and the promotion of treatment in case of diagnosis of infection constitute an opportunity for re-implicating the general population in the struggle to prevent AIDS.

Inclusion of treatment within the palette of tools for preventing transmission is likely to produce changes in social perceptions of the disease. Part of the stigmatisation and discrimination aimed at persons living with HIV arises from the public's fear of seropositive persons as vectors for contamination. Such fears of disease and of seropositive persons do not only result from the risk of transmission; they stem in large part from images associated with how contamination operates -- images of sexuality, homosexuality and drug addiction -- which continue to be projected on infected persons. Inasmuch as the infection "is vectored by the body fluids around which, in a deep and archaic manner, we construct our thoughts about life, identity, parenthood, filiation and matrimony"⁵⁰, the impact of treatment on the risk of transmission may not necessarily have significant impact on these social perceptions of the disease. Nevertheless, in the long term, the public spread of information regarding reduced risk of transmission in people receiving treatment may contribute to a more general perception that infected persons are not a danger when they know and accept their serological status and receive treatment. Restoring the dignity of persons living with HIV – the perspective of less dramatic personal attitudes towards their own disease and its transmission, and the perspective of a less highly fraught approach to their disease on the part of society – should help restore prudent behavior. It may be possible to envisage the development of a social climate that will make it easier to discuss one's serological status with one's sexual partner, and make it easier to adopt proper prevention behaviour, including condom use.

This new prevention model is based on improving knowledge, so as to help individuals to better protect themselves and others. By this is meant knowledge of self -- i.e. serological status, and relationships to risk, to sexuality, and to partner or partners -- and knowledge about methods of protection and their limits. It implies a discourse on prevention that is more complex, but which will be easier to 'hear' and understand if it highlights its faith in the exercise of individuals' free choice and intelligence, giving them additionally both the means and the knowledge to do so.

⁵⁰ CNS Five Year Report, 1989-1994, p.7.

RECOMMENDATIONS

As a consequence of the present statement, the National AIDS Council recommends:

1. PUBLIC AUTHORITIES

- Regarding health policy:
 - o Should strengthen screening systems and improve continuity from screening to care, in order to increase the number of screened and treated persons;
 - o Should anticipate additional needs and burdens for the health-care system arising from a significant predictable increase in the numbers of HIV patients.
- Regarding research policy:
 - o Should support the development of studies regarding the impact of treatments in preventing sexual transmission of HIV; improved tolerance of treatments; conditions favourable to proper compliance with treatment; and improved quality of life.
- Regarding communications :
 - o Should promote the benefits of screening and treatment to the general public:
 - concerning the benefit of early access to treatment for infected persons and thus the importance for all to know their serological status,
 - concerning the real improvement of treatments currently in use,
 - concerning regular screening as an ordinary act of follow-up care for all sexually active persons,
 - concerning reduced risk of transmission offered by treatment, while also indicating that residual risks may exist.
 - o Should redefine messages on prevention so that they articulate the complementary nature of the different prevention tools:
 - highlighting the need to know one's serological status so as to benefit, if necessary, from treatment,
 - continuing to promote of condom use, which maximizes protection in all cases,
 - encouraging infected persons to consider the question of risk taking and emphasizing the impact of treatment in such situations, while also providing information on the existence of a residual risk that can be further minimized by use of condoms.

2. HEALTH-CARE PROFESSIONALS

- o Should mobilize professional training and information techniques to enable health-care professionals to fully grasp these new treatment issues;
- o Should, especially if they are physicians, raise issues of sexuality with persons they provide care to, informing them of the risks and of the potential preventive effect of treatment, -
- o Should, if they encounter people who are infected by HIV, who experience difficulties in implementing prevention, but who do not require treatment according to current recommendations, raise with these patients the possibility of initiating treatment in order to reduce transmission risks. In all cases, prescribing treatment for its preventive effect should respond to the patient's clearly expressed request.

3. ASSOCIATIONS

- o Associations involved in the fight against AIDS should begin considering how to engage this aspect of treatment and assimilate it into their specific realities and those of their members;

- Associations which may not be aimed specifically at fighting AIDS but which group persons or groups who are specifically concerned by the epidemic, either for the protection of their rights or within the context of social, cultural, recreational or community action (migrant, gay, woman's associations, etc.) should join in efforts to spread messages of prevention urging people to take part in screening. The assistance of social and associative movements that are well acquainted with the groups who are the most exposed to transmission will be vital to reducing late screening.

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