

*Caveat: This is not an official English translation of the original French and German Swiss Guidelines on infectiousness of HIV on effective ART circulating the web. But I have tried in the translation to be as true as possible to the original document (In case of doubt, you have to refer to these original French or German documents)*

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## **HIV-positive individuals without additional sexually transmitted diseases (STD) and on effective anti-retroviral therapy are sexually non-infectious**

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The Swiss National AIDS Commission, following a proposal of the special commission of the Federal Office of Public Health on HIV/Aids Clinical and Treatment, after a review of the scientific data and after an extensive discussion, resolves that: An HIV-infected individual without additional STD and on an anti-retroviral therapy (ART) with completely suppressed viremia (in the following: “effective ART”) is sexually non-infectious, i.e. he/her cannot pass on the HI-Virus through *sexual contact* as long as the following conditions are fulfilled:

- The HIV-infected individual complies with the anti-retroviral therapy (ART), the effects of which must be evaluated regularly by the treating physician;
- The viral load (VL) has been non-detectable since at least six months (i.e. viremia is suppressed);
- There are no additional sexually transmitted diseases (STD) present.

### **Introduction**

One of the objectives of the Swiss National AIDS Commission (EKAF) is to publish new insights on the infectiousness of HIV-positive people on optimally effective therapy. The EKAF wants to alleviate fears of people living with or without HIV and thus wants to allow part of the 17'000 people living with HIV in Switzerland to have as much as possible a “normal” sexual life.

### **Scientific data and evidence**

In the following the term “effective ART” is defined as meaning stable HIV-treatment with fully suppressed viral load in blood (viral load below the limits of detection in blood plasma, <40 copies/ml). The treatment is considered “stable” if the viral load on ART has stayed undetectable for at least six months.

The EKAF is fully aware that the medical and biological data available today do not permit to prove on strictly scientific grounds that an HIV-infection on effective ART is *not* possible (as the non-occurrence of an improbable, but still thinkable event is not provable). The situation is comparable to the situation in 1986, when the statement “HIV cannot be transmitted through kissing” was published and communicated. This statement could never be proven. But after 20 years of experience with HIV its high plausibility has been ascertained. With view to the statement “HIV-positive individuals without additional STD and on effective anti-retroviral therapy are sexually non-infectious”, however, scientific data and evidence are much better than what was available in 1986. This is why the EKAF and the other organisations involved are convinced that the actual available information is sufficient to support the above statement.

The following concentrates on the evaluation of the transmission risks under effective ART in the context of unprotected sex.

### **Epidemiological data**

In sero-different couples (one person is HIV-positive, the other HIV-negative) the risk of transmission depends on the viral load of the HIV-infected partner [1] (Figure 1).

In a prospective study of 393 heterosexual sero-different couples, there were no infections among partners of persons on ART during a period of 14 years compared to a rate of transmission of 8.6% among couples without ART [2].

In another prospective study of 92 sero-different couples, where in 41 cases the HIV-positive partner had started therapy, there were 6 infections in partners. All these occurred in partners of untreated patients with a plasma viral load of at least 1'000 copies/ml [3].

Among 62 sero-different couples, which chose to have unprotected sex in order to conceive (male partner was HIV-positive, on ART), not in even one case was there a transmission to the female partner [4].

Transmission of HIV from mother to newborn also depends on the maternal viral load, and can be avoided by taking anti-retroviral therapy [5-8].

In the "San Francisco Men's Health Study", HIV-incidence in gay men during the years between 1994 and 1996 was at 0.12 (infections per couple). ART has been available since 1996. During the years between 1996 and 1999, HIV-incidence in gay men decreased to 0.048, taking into account the fact that not even all HIV-infected men were on therapy [9].

The rate of transmission is massively increased during primo-infection. Studies show that an important proportion of all newly acquired infections is caused by partners which were themselves only recently diagnosed with HIV-infection [10-12].

Sexually transmitted diseases increase the risk of HIV-transmission (without ART). Mathematical models show that it is mostly syphilis, which has an epidemiologically relevant impact on this effect [13].

After a few days or weeks of discontinuation of therapy, HIV-viral load increases rapidly. There is at least one case report of transmission during such rebound [14].

### **Biological data**

The concentration of HIV RNA in genital secretions during therapy decreases to values below the limits of detection [15-17].

The viral load (free HIV-RNA) in female genital secretions is as a general rule lower than in blood and not detectable under effective ART. An increase in the genital viral load happens generally after, not before an increase in plasma viral load [18].

Cell-associated viral genomes can still be detected in genital secretions even under ART [15, 19-21]. But these are not fully infectious virus. HIV-infected cells in sperm do not contain LTR-circular DNA as a sign of a locally active proliferation of virus [22].

The concentration of HIV RNA in sperm influences the risk of transmission. With no detectable HIV RNA, the risk of transmission declines asymptotically towards zero [23] (Figure 2). These biological data indicate that the risk is greatly diminished during effective ART.

During HIV-primoinfection the viral load increases massively in genital secretions [24], which explains higher rates of transmission during the early phase.

During sexually transmitted diseases (STD; e.g. urethritis, genital ulcer) viral load in genital secretions (but not in the blood) is increased in the subsequent couple of weeks and decreases again after successful STD-treatment [25]. Even on effective ART can sperm viral load slightly increase in the presence of a STD (urethritis). This effect is however very discrete and much smaller than without effective ART [26].

### **Conclusions**

During effective ART, free virus is absent from both blood and genital secretions. All epidemiological and biological data indicate that there is no relevant risk of transmission during an ART, which is completely adhered to.

The risk of HIV-transmission during sex without condom in the context of a completely suppressed viral load is much smaller than 1 : 100'000. Although a residual risk cannot be scientifically excluded, the risk is negligibly small in the opinion of the EKAF and the other organisations involved.

## **Importance and validity of the statement “HIV-positive individuals on effective ART are sexually non-infectious”**

### **Implications for physicians**

This information aims to communicate to physicians the criteria allowing them to establish, whether the statement “the HIV-infected patient is sexually non-infectious” applies. The statement is valid, as long as the following conditions hold true:

- The HIV-infected individual is consistently adhering to the anti-retroviral therapy (ART) and is regularly followed by his/her physician;
- The viral load (VL) during ART is below the limits of detection and has been so for at least the last six months (i.e. viremia is suppressed);
- There are no infections with additional sexually transmitted diseases (STD) present.

The *medical* indication for starting an ART on the basis of actual therapy guidelines possesses still first priority. An earlier starting point of treatment purely based on “preventive considerations” is not recommended for the time being: aside from the additional costs involved, there are doubts, whether HIV-infected individuals can be sufficiently motivated to follow long term therapies as prescribed without medical indications.

Treatments discontinued and poor adherence involves a high risk of the development of resistant virus populations, thus causing harm to public health and worsening individual prognosis. A preventive indication of ART might therefore be applicable only in exceptional circumstances for extremely motivated people living with an HIV-infection. No patient shall be pushed or talked into therapy based on “preventive” considerations alone.

### **Implications for HIV-infected individuals without additional STD and on effective ART**

HIV-infected individuals without additional STD and on effective ART in a stable relationship with an HIV-negative person need to know, that they are not putting their stable partner at risk, as long as they are taking the ART consistently and as prescribed, are regularly followed by their physicians and do not have other additional STD. The decision of whether a sero-different, stable couple wishes to stop protection in their sexual relations has to be taken by the HIV-negative partner – after ample information and counselling.

### **Importance for HIV-infected individuals without stable partnerships**

HIV-infected individuals on effective ART shall know that they – as long as they are taking the ART consistently and as prescribed, are regularly followed by their physician and do not have other additional sexually transmitted diseases (STD) – do not transmit the virus sexually.

### **Importance for HIV prevention**

The statement “HIV-infected individuals without additional STD and on effective ART are sexually non-infectious” does not change current prevention strategies in Switzerland. Outside stable relationships, the obligation to protect oneself must be followed at all times: no HIV-negative individual in a sexual encounter shall refrain from protecting oneself. If individuals trust statements by sexual partners such as “ I am HIV-negative” or “I am on effective ART” too easily, they run a HIV-risk as they would not be able to verify whether their partner really is negative or on effective ART. The responsibility for one’s own health cannot be delegated to other persons in those specific situations.

In a stable, sero-different partnership (one partner HIV-positive, one partner HIV-negative) the decision, whether or not a couple wishes to stop protection, has to be taken by the HIV-negative partner, because it is him/her that has to bear the consequences of an HIV-

infection in the end, in the event that an HIV-transmission should occur contrary to all expectation.

### **Importance for the legal system**

Courts will have to take into account in criminal HIV transmission cases the fact that “HIV-infected individuals without additional STD and on effective ART are sexually non-infectious”. Unprotected sex between an HIV-infected individual without additional STD and on effective ART and an HIV-negative individual does not comply with the criteria for an attempt at propagation of a dangerous disease according to section 231 of the Swiss penal code, nor for an attempt to endanger grievous bodily harm according to section 122, 123 or 125 of the Swiss penal code.

### **Counselling by physicians of HIV-patients on ART**

Patients on ART will be informed by their treating physicians about the topic of “non-infectiousness on effective ART” and its conditions on the next occasion and patients will get an appropriate counselling according to their current partnership situation.

### **Contents of the counselling by physicians**

In the counselling of a stable, sero-different couple (both of them are present) the conditions of non-infectiousness have to be talked about with all due detail:

- The individual with an HIV-infection takes an anti-retroviral therapy (ART) consistently and as prescribed and has its effect evaluated regularly by the treating physician (based on valid standards of treatment);
- The viral load (VL) under ART has been below the limits of detection for at least six months (i.e. viremia is suppressed);
- There are no other additional sexually transmitted diseases (STD) present.

Couples shall understand through the counselling that adherence (therapy compliance) will become a common theme in their relationship when they decide not to use protection. Furthermore, and mostly due to the importance of additional STDs, the couple must understand that rules must be defined for sexual contacts outside of the stable relationship.

Heterosexual couples must additionally consider the issues of conception or contraception if protection with condoms is stopped. Topics should include

- Eventual interactions between hormonal contraceptives and ART, which could reduce the effectiveness of contraceptives;
- Potential teratogenic effects of substances; which means in practice: avoiding efavirenz when trying to conceive.

On the other side, insemination via sperm washing is no longer indicated on effective ART if it is done only to exclude transmission of HIV.

The counselling situation is setting a stage for answering questions of sero-different couples. Counselling should also be used in strengthening the HIV-negative individual (not the HIV-positive individual!) in taking the decision, whether he/she wants to stop using condoms, and in allowing the couple to reach common agreements about issues of adherence, sexual contacts with partners outside stable relationships (because of the risk of STD) and eventual conception. At future clinical controls relating to ART, the patient is to be asked about the status of these agreements.

HIV-infected individuals without additional STD and on effective ART, who are not living in a stable partnership, are being informed by their treating physician about their “non-infectiousness under effective ART”. This information can have a liberating effect as many studies show that the sexual life of HIV-infected individuals are diminished because of fears of infecting others. In the best interests of people living with HIV physicians will continue to recommend Safer Sex to those people having anonymous or occasional sex encounters to minimise risk of additional STDs. Dependent on the amount of such types of sexual contacts regular controls and tests of additional STDs should be performed. Affected persons should be sensitised to symptoms of STD.

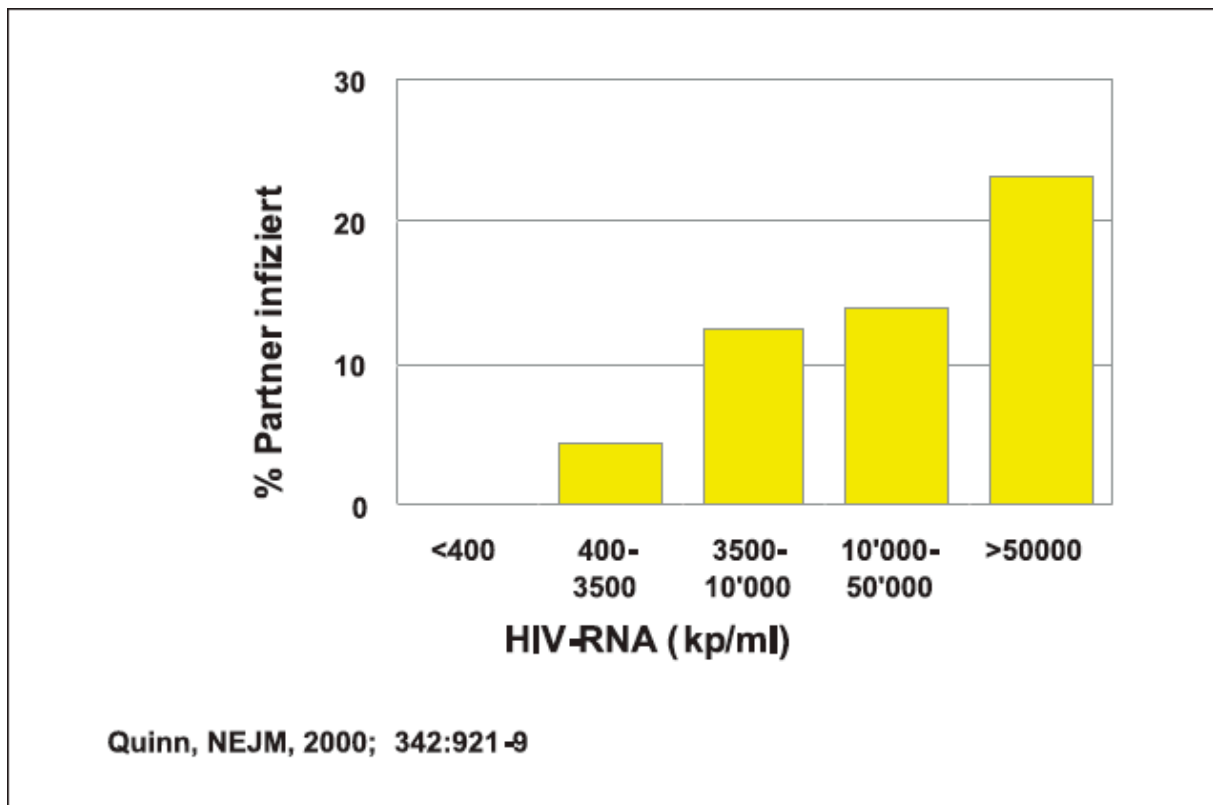
Physicians have brochures\* and websites\*\* at their disposal, and they can get support from counselling venues of regional Aids-organisations\*\*\*. The EKAF encourages physicians to actively take up and engage with these resources.

\* “HIV-positive – what next? For people who have recently discovered that they are HIV-positive”, available from Aids-Hilfe Schweiz, Konradstrasse 20, 8005 Zürich, Tel. 0041 44 447 11 11, Download: <http://www.aids.ch/shop/produkte/infomaterial/pdf/1048-04.pdf> (see also the clearing house of Aids Action Europe on [www.aidsactioneurope.org](http://www.aidsactioneurope.org) under Aids-Hilfe Schweiz)

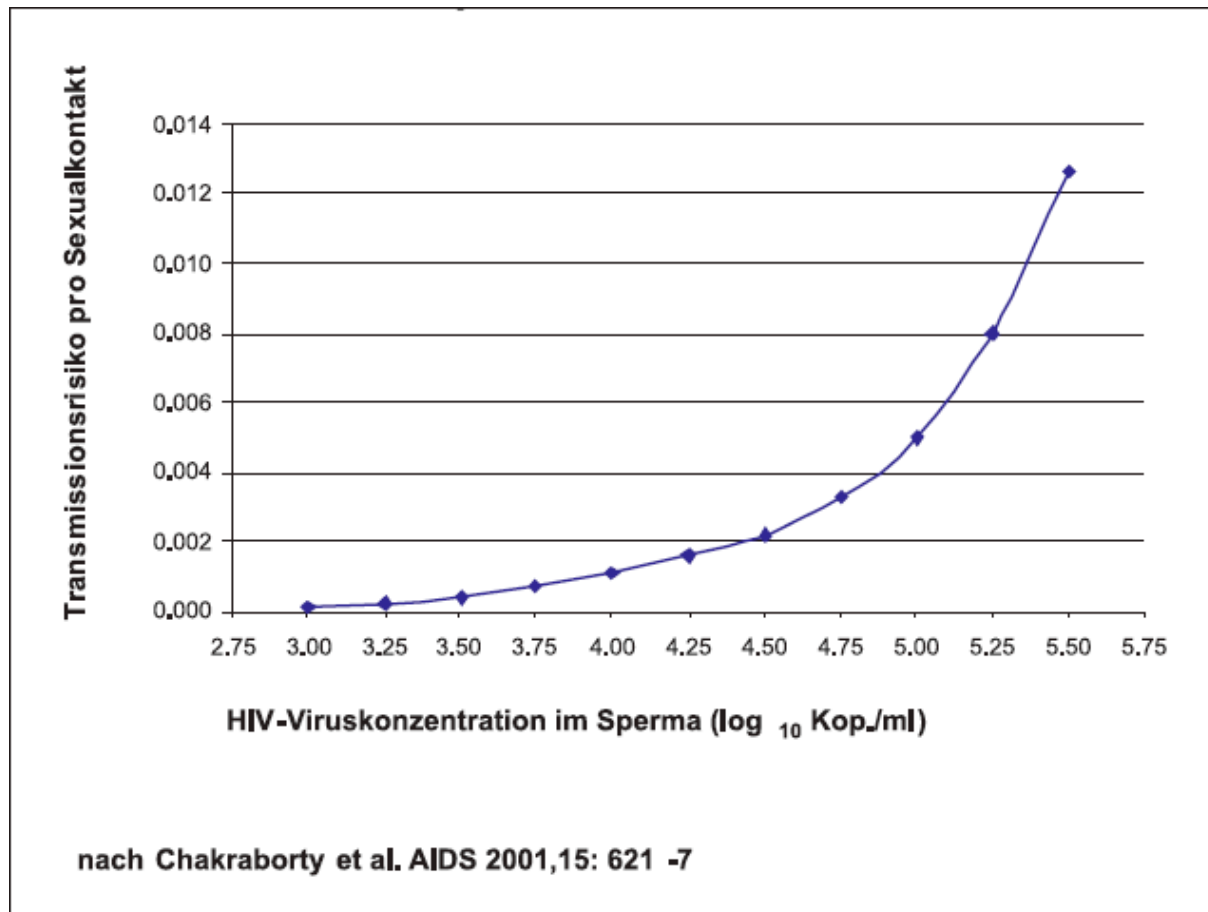
\*\* [www.aids.ch](http://www.aids.ch)

\*\*\* [www.aids.ch/e/index.php](http://www.aids.ch/e/index.php)

**Figure 1**  
**Viral Load and risk of transmission**



**Figure 2**  
**HIV-RNA in sperm and risk of transmission**



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