

HIV is not transmitted under fully suppressive therapy: The Swiss Statement – eight years later

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The “Swiss HIV Statement”

Eight years ago, on January 30th 2008, the Swiss Federal Commission for AIDS-related Issues (“the Commission”, now the Swiss Federal Commission for Sexual Health) published a statement which – in the field of human immunodeficiency virus (HIV) – rapidly received the name “The Swiss statement” [1]. The statement addressed the infectiousness of an HIV-positive person once the virus was stably suppressed for at least 6 months with antiretroviral therapy (ART). Despite the lack of results from large randomised studies, the Commission felt, based on an expert evaluation of HIV transmission risk under therapy, that the risk of HIV transmission in such a situation was negligible. The publication was primarily aimed at Swiss physicians, informing them that it was about time to discuss new data on infectiousness with patients. Problematic differences in prevention messages were already being observed by the Commission: some physicians openly discussed the very low risk of transmission on ART and reassured patients who said they had condomless sex with their steady partner, whereas others told HIV-positive patients under therapy that all condomless sex – even with their HIV-positive partner – was risky.

At the time it was clear that ART did, in fact, reduce the likelihood of transmission, but the Commission’s estimate on the magnitude of this risk was neither discussed with patients nor communicated widely. The Commission summarised the epidemiological and biological knowledge known at the time and concluded that the risk of transmission in a differing HIV status partnership where the positive partner was on fully suppressive ART can be considered negligible. The focus of the paper was on how to communicate this information with an affected partnership where one partner was HIV positive.

The first reactions to the Swiss statement

Reactions to the Swiss statement came from much farther afield and with much more aggression than was ever anticipated. Although the publication was only in German and French and formulated as information for Swiss physicians

on how to inform their patients and their partners, it was immediately reported on in English [2] and subsequently attracted international media attention [3].

Positive reactions came mainly from patient groups who noted that the statement “favours quality of life and – even more – social integration of people with HIV” [4]. Another reaction highlighted that the statement provided for the first time clear information so that “ART has the potential to relieve people living with HIV of the burden of guilt, anxiety and fear of criminal liability at the prospect of transmitting HIV to others” [5].

However, there were many more initial negative reactions, which came mainly from the medical and public health fields. Interestingly, there were two main types of criticism that apparently contradicted each other: one group claimed that – although the statement was true – it should not be made public, because of the fear of risk compensation and/or behavioural disinhibition which would end up increasing HIV and sexually transmitted infection (STI) transmission risks [6]. Another group argued that the risk of HIV transmission from having sex with a partner with suppressed viral load was not negligible (with a specific focus on anal sex).

Is it ethical to withhold information from patients because of (unwarranted) fears that the epidemic might worsen as a result of informing them? The Commission believed that information about HIV prevention needed to be well-considered and individualised. On one hand, it is important to consider unwanted consequences such as risk compensation and/or behavioural disinhibition. On the other hand, basing HIV prevention messages on false and/or out-of-date information can also have serious consequences for the credibility of those delivering them, harming trust between public health bodies and the public, and clinicians and patients. Before the statement was issued, the Commission tried to find evidence for negative consequences caused by risk compensation and/or behavioural disinhibition. It was clear that behavioural disinhibition was already happening, as demonstrated by surveys of condom use [7] and the rapid increase of syphilis incidence among men having sex with men (MSM) in the previous decade [8]. And in San Francisco, where there were good data on the

epidemiology of HIV and STIs, no parallel increase of HIV incidence was observed despite an increase in STIs [9]. However, critics of the statement rarely considered the vast potential for a number of positive effects of knowing that HIV treatment is also prevention. One such effect was on adherence. Altruistic adherence – taking ART regularly so that my partner will not become infected – is a result of the knowledge of noninfectiousness on fully suppressive ART. It was reported by many patients and was recently proposed as a relevant basis for increased adherence [10]. In fact, both adherence and treatment uptake increased immediately after the publication of the statement in Switzerland in 2008 [11]. Although it cannot be shown that this is a result of the possibility to discuss openly the limited risk during ART, it is at least intuitive that knowledge of the additional information about noninfectiousness on ART would help patients motivate themselves to commence and/or adhere to ART. Notably, in Switzerland the rate of suppressive ART among those diagnosed with HIV was 85% in 2012 [12]. This percentage is one of the highest worldwide [13], suggesting a potential beneficial effect of the Swiss statement on treatment adherence.

Why did the Swiss statement claim “negligible risk of transmission”?

One of the most frequent misconceptions about the statement relates to the method used to estimate the risk of transmission during ART. The lack of data from randomised studies led some experts to claim that the statement was based on absolutely no data. Although the statement was based on a clear analysis of all the available data, it began with another example of limited knowledge. In the mid-Eighties, the public was told that HIV cannot be transmitted by kissing or via nonsexual household contact, despite limited prospective data to support this. In fact, only one study has properly evaluated the question, based on 100 household contacts [14]. The reason why we were confident enough at the time to claim there was no risk by kissing or living with an HIV-positive partner was simply because we did not observe such cases. If this were treated as rigorously as the issue of sexual transmission on ART, one would have to use the 95% confidence level to express the upper margin of risk. The zero cases among household contacts would have to be expressed with a 95% confidence interval of 0–30%. Interestingly, no additional studies have ever been performed to demonstrate the risk of kissing, despite the upper 95% confidence limit (30% transmission rate) from this small single study. We all agree that the overall observation of nondocumented cases is the strongest argument to make us believe kissing is safe.

However, the same “evidence” of nonobservation was also available in 2008 for the case of HIV transmission from a person with fully suppressed viral load on ART. There was absolutely no indication – neither from individual case reports nor from the few observational studies – that a single person with a suppressed viral load had transmitted the virus. In fact, if transmission would have occurred at a rate above 1:100 000 sex acts, we would have expected at least one published event at that time. This estimate was based on the frequency of reported condomless sex among

couples of different HIV status (25% in anonymous questionnaires) and the large number of patients on therapy (>400 000 in Europe and the US for the past 5 years) and an average frequency of three sex acts per month in those with a steady partner (approximately 30% of the population) and on a reporting likelihood of only 1%. The fact that no such case was reported worldwide was probably the strongest argument the Commission had.

Importantly, the Commission also summarised the evidence from published or presented prospective studies, but only a few prospective studies evaluating the transmission risk under ART were available at the time. While these studies summarised less than 200 years of observation on ART, they did clearly demonstrate no transmission in this setting. However, with the limited number of partnerships, the upper 95% confidence interval of zero transmission was only in the range of 1 per 100 patient years. But all the evidence from these studies was much less persuasive than the mere fact that no single case of transmission in the described setting had ever been observed and documented.

At the time the Swiss statement was published it was known that the landmark HPTN 052 study, which aimed to address the effect of ART on the risk of transmission in a randomised controlled fashion, was underway. However, based on the original study plan results were not expected until 2016. For the reasons described below, the Commission decided not to wait with its statement until the HPTN 052 results were available. From the HPTN 052 protocol it was also known that the study would be terminated early if a certain difference in transmission rates was found, which would render the continuation of the two arms unethical. As a result, the HPTN 052 study was powered to conclude (in the case of no observed transmission during suppressive ART) that the 95% confidence interval for the risk of transmission would be smaller than 0.3 in 100 partner-years (less than 1 in 300 partner-years). Thus, it was clear already in 2008 that in the best case of zero transmissions the HPTN 052 study would only be capable of proving an upper 95% confidence level for transmission (1 in 300 partner-years) that was much less than the Commission anticipated from the “no documented case”.

Some signals of urgency to issue the Swiss statement

But why didn't the Commission just wait for the results of the randomised controlled trial? It was faced with a number of circumstances that it considered so important that its members felt it was impossible, perhaps even unethical, to wait for the results from HPTN 052. Three issues were of greatest concern:

First and most importantly, in Switzerland there were numerous cases of unjust criminal convictions of individuals on suppressive ART who had sex without condoms with an HIV-negative partner. Some of these convictions took place even where the HIV-negative partner was aware of their partner's HIV-positive status and had consented to not using condoms. These prosecutions, for perceived “HIV exposure”, took place under Article §231 of the Swiss Criminal Code (spreading of dangerous diseases), with prison sentences ranging between 18 months and 4 years, plus a

fine of up to CHF 80 000 – much harsher than for other (non-HIV-related) “crimes” charged under this statute [15]. Consequently, the legal experts in the Commission voted for a clear statement in order to stop these unjust prosecutions.

Secondly, the Commission had observed a growing number of couples of different HIV status (serodiscordant couples) who wanted to conceive a child, but were unable to achieve their goal with condomless sex, owing to the overemphasised fear of transmission. In 1996, in St. Gallen we started to collaborate with European centres offering reproductive assistance to HIV-serodiscordant couples. As in other places worldwide, intrauterine insemination with processed semen was offered to HIV-negative partners of HIV-positive men. With on-going counselling in this population we started to realise in the early 2000s that first, all male partners were under fully suppressive ART, and second, the perceived risk (by the partners) was orders of magnitude higher than our own estimates. Based on their excessively high perception of the risk, these couples selected an intervention that was associated with significant cost and effort and had a significantly lower success rate than natural conception. When we started in 2003 to inform these couples about the known low risk of transmission (1/100 partner-years, or lower), all partners (with the exception of a single couple) opted to select natural conception (with additional safeguards like timed intercourse and pre-exposure prophylaxis) as their preferred mode of conception [16].

This experience demonstrated the fact that HIV-positive individuals (and their partners) might in fact decide differently following a comprehensive counselling offering all the facts about transmission risk known at the time. Had we not issued the statement, we would have been withholding information that ended up making a major difference in the lives of our patients. Unfortunately, elsewhere in the world such public discussion of these lower-than-perceived transmission risks were not taking place; some authorities (and clinicians) worldwide are still not providing this information, despite an ethical obligation to do so.

The third argument that motivated the group to publish the Swiss statement and to promote shared decision making (rather than place responsibility for HIV prevention solely on the person living with HIV) was the imbalanced consideration of different risks in the public debate. We have mentioned the striking difference between perceptions of the risk of transmitting HIV by kissing as opposed to condomless sex under ART, when the available data to support the statements are compared. More striking is the difference in the communication of sexual transmission risk for hepatitis C virus (HCV) infection to steady heterosexual partners. We know that sexual transmission of HCV is rare [17] but heterosexual transmission has clearly been reported [18]. Nevertheless, the US Centers for Disease Control (CDC) states in its recommendation: “HCV-positive persons with one long-term steady sex partner do not need to change their sexual practices” [19].

Eight years later – no surprising evidence

Now, eight years later, very little has changed in our estimates of HIV transmission risk. Importantly, the most convincing evidence – the fact of no documented transmission under ART – still remains the most stringent argument supporting the Swiss statement. In fact, another eight year period of no such documented case presentation markedly increases the strength of the initial argument, at least doubling the evidence.

More importantly, the Swiss statement was provocative and fuelled the scientific search for such cases, as proposed in an editorial [20]. However, despite the publication of the Frankfurt case [21], which was observed years prior to the Swiss statement, no other case has been presented since. Notably, the Frankfurt case involved a couple with documented transmission, but transmission during the time before or shortly after treatment initiation in the index case could not be ruled out, as discussed in the aforementioned editorial.

As mentioned above, the HPTN 052 study [22] saw only cases of transmission during ART that occurred shortly (days) after the initiation of therapy. If only transmissions after the first six months of ART are considered (as stipulated in the Swiss statement) the efficacy would have been 100% with a transmission risk of zero. In this case, the observation time would have to be shortened by this six-month period, which also affects the upper 95% estimate of the transmission risk for a “zero-event”. This modification of the risk assessment results in an upper 95% confidence limit of “zero-risk” of 0.3/100 partner-years. This upper level of the confidence limit is 3–4 times less than the available evidence from studies available to the Commission in 2008. In addition, the prospective, on-going PARTNER study, which specifically recruited serodiscordant couples that have condomless sex, including 40% MSM couples, has supported the evidence of zero transmissions with an additional 894 partner-years of follow-up [23], further increasing our confidence that the true risk is close to if not zero.

Nevertheless, some authors still use upper confidence limits to extrapolate the 10-year risks based on these confidence levels and conclude implausibly high cumulative risk estimates. Using this strategy, Lasry et al. postulated incredibly high cumulative transmission risks for some types of exposures [24], such as a 2% risk after 10 years of exposure in a serodiscordant heterosexual partnership, a risk that should already have resulted in multiple transmission cases observed in the Swiss HIV Cohort Study, which has not yet occurred. The best interpretation of such mathematical exercises is to conclude that our upper confidence limits are much too high to reflect real life.

Several groups have accepted the information from the HPTN 052 and PARTNER studies to give sufficient confidence that condomless sex is safe in heterosexual couples but continue to question the safety of ART to prevent sexual transmission among men who have sex with men (MSM). However, the nonobservation argument that was used in the Swiss statement and has only become stronger after another eight years of observation, also applies to

MSM, perhaps even more so, since MSM still remain the most HIV-affected group globally and therefore contribute substantially to the result of “nonobservation”. In addition, a two-year interim analysis from the MSM-only Opposite Attracts study has, as expected, observed no transmissions [25].

Was the feared increase in HIV infections due to a disinhibitory effect of the Swiss statement satisfied? From the Swiss HIV cohort study we know that condomless sex has become much more prevalent after its publication [26]. Despite this increase in condomless sex, we have observed a constant decrease in new HIV infections in Switzerland since 2008 (Bulletin 18.5.15).

The Swiss statement tried to identify a situation with highest confidence for the statement of “no-risk” based on the available evidence. Therefore it was noted that a negative effect of interfering STIs could not be ruled out. However, more recent evidence suggests that this additional safety measure is less important. The randomised 052 and the prospective PARTNER study did not see such an effect [22, 23]. Kelly et al. also documented stable HIV viral load suppression in the rectum in the presence of bacterial STIs [27].

Despite increasing evidence, no global acceptance

In summary, in the past eight years one randomised and two on-going observational trials continue to support the “no-risk” hypothesis of the Swiss statement, while the basis for the statement – the absence of observed cases – has further increased over time. Since this was a hot topic since its publication, one might expect an even higher degree of scrutiny amongst physicians to investigate and publish suspected cases compared with the years before 2008. Therefore, a further lack of documented cases should be even more convincing than it was in 2008.

But still some authorities such as the CDC remain reluctant to consider condomless sex with a partner under fully suppressive ART to be safe enough to recommend that clinicians openly discuss this option with their patients. In fact, the CDC even proposed that HIV-negative individuals with HIV-positive steady partners should not only use condoms but should also be offered pre-exposure prophylaxis (PrEP) as an additional safeguard. The recommendation comes without a calculation of the number and cost to prevent a single case of HIV infection [28].

No more HIV exposure prosecutions in Switzerland

There were three key issues that motivated the publication of the Swiss statement in 2008, rather than waiting for the evidence from HPTN 052: criminalisation, conception, and the conviction that it was ethical to engage patients in shared decision making. The positive effects of the statement have exceeded the Commission's expectations, both in terms of geography and impact.

Until 2008, Switzerland was one of the countries with the highest numbers of convictions for perceived or potential HIV exposure. The effect of the statement was so convin-

cing that Geneva's Deputy Public Prosecutor, Yves Bertossa, called for a revisit of an HIV exposure prosecution after reading about the Swiss statement [29]. The Geneva Court of Justice subsequently quashed the conviction and there have been no further reports of prosecutions for HIV exposure since the ruling.

Furthermore, the Swiss statement has influenced other expert groups to produce statements that have impacted criminal law policy in some jurisdictions, including Canada [30], England, Wales and Scotland [31] and Sweden [32]. Despite this, the number of jurisdictions that recognise the prevention benefit of treatment in a criminal law context is still frustratingly low [33]. We hope that other experts in HIV science, public health and law around the world will live up to their professional and ethical responsibilities to assist those in the criminal justice system to understand and interpret current medical and scientific evidence regarding HIV and take similar action [34].

No need for artificial insemination in Switzerland

The second positive development in Switzerland after the statement was the “normalisation” of conception in Swiss HIV-serodiscordant couples. Swiss patients and their partners learned rapidly that there was no relevant risk of transmission under optimal treatment, thus the need for artificial reproductive technology to conceive a child was no longer an issue for fertile couples. As a consequence, reproductive assistance has not further been used in Switzerland after the statement which was well supported by Swiss physicians and experts in HIV prevention in Switzerland. Numerous affected couples have now conceived naturally in Switzerland. In contrast, in neighbouring countries where an official declaration on transmission risk is still lacking, reproductive centres still offer insemination with processed semen, sometimes at high cost, meaning that the reproductive rights of people living with HIV are sometimes not achieved.

Empowerment of clinicians and people living with HIV

The Swiss statement has also empowered clinicians and other healthcare workers around the world to talk honestly and openly with their patients about the prevention benefit of ART. In 2013, consolidated HIV treatment and prevention guidelines from the World Health Organization (WHO) [35] recognised for the first time the additional HIV prevention effect of ART. Subsequently, the International AIDS Society produced guidance influenced by the pragmatism and honesty of the Swiss statement to help healthcare workers counsel their patients with better understanding and greater clarity on the treatment and prevention benefits of ART [36].

Perhaps the most important legacy of the Swiss statement has been the empowerment of people living with HIV. In 2009, at an international technical consultation on “positive prevention” convened by the Global Network of People Living with HIV/AIDS (GNP+) and UNAIDS, a new rights-based programme was conceived: “Positive Health,

Dignity and Prevention (PHDP)". Before this, many "positive prevention" programmes had placed an undue burden of responsibility for HIV transmission on HIV-positive people. PHDP shifts the focus of preventing HIV transmission to a shared responsibility of all individuals irrespective of HIV status [37]. Central to this are evidence-informed, human-rights-based policies and programmes that support individuals living with HIV to make choices that address their needs and allow them to live healthy lives free from stigma and discrimination, such as those implemented in Switzerland following the Swiss statement [38]. These positive benefits should never be underestimated as we strive to end the dual epidemics of HIV and HIV-related stigma.

Funding / potential competing interests: No financial support and no other potential conflict of interest relevant to this article was reported.

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