

## Scientific Contribution

# Uncertain Risk, Public Health, and Ethics: Considering the Ethical Framework for HIV Prevention Strategy

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**Abstract:** This article outlines and discusses, from an ethical point of view, the direction for the public health authorities concerning their strategies to prevent HIV infection, with a particular focus on a future strategy that takes into account the progress of biomedical prevention. The article clarifies important and considerable issues in relation to decision-making conducted in the context of an uncertain risk.

This paper highlights two issues of particular significance to our ethical framework: 1.) the level of risk and 2.) the distinction between personal moral matters and public health ethics. Based on this framework, the author suggests that the public health authority should seek a biomedical prevention strategy that implements behavioral research in line with the welfare of people vulnerable to infection. The strategy should enable the diversified preference of citizens to the greatest extent possible.

**Keywords:** HIV/AIDS, public health, biomedical prevention, uncertain risk, level of risk, sexual ethics, liberal state, resource allocation

## **1. Modification of HIV prevention strategy: influence of biomedical prevention measures**

This article outlines and discusses, from an ethical point of view, a potential direction for the responsible public health authorities concerning their strategies to prevent human immunodeficiency virus (HIV) infection, with particular focus on a future strategy that takes into account the progress of biomedical prevention

Udo Schüklenk, who has been involved in ethical issues concerning HIV infection for a long time, contributed a short editorial, “Ethics of Public Health Promotion Messaging in the Age of Successful HIV Treatment Regimes,” to *Bioethics* in 2014.<sup>1</sup> Schüklenk presented an important issue about the future of HIV prevention strategy in the context of today’s developments in biomedical prevention. The concern is whether this new approach to biomedical prevention may promote unprotected and unsafe sex.

First, then, we will analyze the background from which this thought process originates, and discuss its applicability to the present reality of HIV infection.

### **1.1. The past and present of HIV infection: the treatment context**

Through the HIV infection mechanism, immunity decreases and, without timely intervention, the affected patient suffers from opportunistic infection —AIDS onset — resulting in eventual death. HIV acts as a parasite to CD4 cells, which control immunological function in the human body, and rapidly multiplies, while destroying the CD4 cells. It

is through this mechanism that immunity decreases, and the number of CD4 cells in blood is the main indicator for measuring the degree of the infection's progression.

Since the U.S. Center for Disease Control and Prevention first reported an unknown immunodeficiency syndrome in 1981, the infection spread globally, and fatalities rapidly increased. However, the disease management modalities for this fatal disease greatly changed after 1996. Through a combination of several antiretroviral (ARV) drugs<sup>2</sup>—Highly Active Antiretroviral Therapy (HAART)—we are able to check the disease progression and prevent AIDS onset, although a cure for the virus is still not yet available. With HAART, an HIV patient can maintain quality of life, even while HIV-positive. HIV infection, then, is considered a chronic disease. However, HAART is *de facto* limited to the developed countries, where access to ARV is available to those who can afford it. This access is not yet available to those needing ARV globally, with some exceptions. It may be said that the main concern in HIV/AIDS strategy at this stage is the accessibility of ARV drugs, rather than the development of a cure.

## **1.2. Modification of the HIV prevention strategy**

In line with the novel developments in managing HIV infection in the recent decades, the prevention strategy has changed as well. Public health policies that aim to prevent HIV transmission often conflict with some sexual desires. Various sexual acts need to be limited to some extent in an effort to prevent the spread of Sexually Transmitted Infections (STI), of which HIV is only one amongst many. The “safer sex” strategy, which involves using a condom at each act of coitus, became part of prevention

strategies of the last decades. Condoms have been the main means of preventing the spread of HIV, as the safer sex strategy avoids the problems associated with “abstinence” and “being faithful,”<sup>3</sup> and also reduces the risk of contracting HIV. Therefore, the primary role of the HIV prevention messaging in health promotion has become an effort to encourage people to modify their behaviors to use a condom during each act of coitus.

In addition to safer sex, the prevention measure known as “ARV-related prevention/ biomedical HIV prevention<sup>4</sup>” has begun to attract attention. This prevention strategy utilizes ARV therapy as a means of preventing HIV infection. ARV therapy is considered an effective means of HIV prevention because it reduces the viral load in the bloodstream (the current goal of treatment is to lower the viral load below measurable limits). ARV therapy has shown to be effective at preventing mother-to-child transmission in 1994,<sup>5</sup> leading developed societies to adopt its use. Several studies have reported the effectiveness of biomedical prevention against sexual transmission.<sup>6</sup> Based on that evidence, the Swiss National AIDS Commission issued a statement (the Swiss Statement) in 2008, which has become controversial. The Swiss Statement affirms that an HIV-infected person on ARV therapy whose viral load has been suppressed below the limits of detection (below 40 copies/ml) for at least six months is not sexually infectious<sup>7</sup>. The basis for this controversial hypothesis becoming actual policy was a randomized controlled trial known as HPTN 052.<sup>8</sup> This study was designed mainly as a means of testing the efficacy of biomedical prevention. In a randomized trial, 1736 serodiscordant (where partners have differing HIV status)

couples in eight countries—most were heterosexual and only 38 were male/male couples—were enrolled and divided into two groups, with an early-therapy group starting ARV therapy upon enrollment and a delayed-therapy group waiting until their CD4 count had fallen below 250 cells/mm<sup>3</sup> or they had developed an AIDS-related illness. The study was originally designed to report its findings in 2015, but the protocol was modified to begin ARV treatment for the delayed-therapy group in 2011, when it became obvious that reduction in transmissions of the early-therapy group compared with the delayed-therapy was so great so to render delay unnecessary. The authors found that the efficacy of biomedical prevention was 96% and published the results in the same year.<sup>9</sup> The findings of the study made a great impact on prevention policies around the world and prevention strategy based on biomedical prevention (“treatment as prevention”) shifted into high gear.<sup>10</sup> In 2010, the efficacy of a vaginal ARV-based microbicide gel introduced prior to and after intercourse was shown to be statistically significant via a trial of the Centre for the AIDS Programme of Research in South Africa (CAPRISA) 004 for the first time, though it has seen a succession of failures so far.<sup>11</sup> Now, pre-exposure prophylaxis (PrEP) through oral medications is receiving significant attention. PrEP is a prevention method whereby a non-infected party takes ARV therapy prior to exposure to HIV, preventing infection. PrEP was shown to be effective at the Pre-exposure Prophylaxis Initiative (iPrEx) trial, which was the first randomized, controlled, trial testing the efficacy of PrEP. The findings were published in 2010.<sup>12</sup> Although the efficacy of prevention was only 44%, there was considerable variation among participants in adherence to

study protocol, greatly diminishing the preventative effect, and the authors, analyzing the findings, found that the efficacy of the regimen originally designed would have been at least 92% compared with a placebo. After that, the U.S. Food and Drug Administration (FDA) approved Truvada (an ARV drug) to be used for PrEP.<sup>13</sup>

As seen above, though the efficacy of biomedical measures to prevent HIV infection has not been stable compared with condom use,<sup>14</sup> biomedical prevention has begun to attract attention as a method with high preventive effect. That is to say, without any limitation of sexual behavior such as the use of a condom, it is possible to prevent HIV infection by utilizing ARV. However, one growing concern is that biomedical prevention, and in particular PrEP, in spite of the unstable efficacy, may encourage unprotected sex,<sup>15</sup> and such an inadvertent increase is termed behavioral disinhibition or risk compensation.<sup>16</sup>

The direction of future prevention strategies, and whether biomedical prevention should be adopted as the main strategy despite the possibility that it may promote unprotected and higher-risk sex, is a subject of continual debate. Public health authorities, or other authorities responsible for prevention strategy, are required to make an important choice, one that's impossible to make through comparison of mere numbers and among different values. This choice is whether to adopt as the primary prevention strategy the novel biomedical prevention methods that carry a higher risk of infection but fewer restrictions on sexual activity, or whether to retain as the primary option the existing prevention strategy that carries a lower risk, albeit with more restrictions on sexual activity. Should they opt for less risk or should they, accepting

certain risks, allow the enjoyment of sex with fewer restrictions? If the riskier alternative becomes public policy, are people, particularly those with HIV-positive status, required to exercise more caution and responsibility?

Let's now consider these questions, mentioned above, keeping in mind the following caveat: HIV infection paradigms are totally different depending on whether access to ARV is possible. Therefore, we cannot discuss these questions in the same way where, in one area, individuals can lead a social life with HIV as a chronic disease because access to ARV is guaranteed, and where, in another area, because access to ARV is not guaranteed, HIV-positive individuals are still living with a death sentence. Therefore, the following discussion is limited to developed countries, such as Japan, where access to ARV is socially guaranteed.

## **2. Prevention strategy and sexual ethics: ethics of risk**

Since sexual activity was determined to be the primary means of HIV infection, modification of sexual behavior has been sought as a means of preventing infection. What is referred to as a sexual ethics in the context of the HIV infection is a discussion of sexual behavior in consideration of HIV prevention.

The main issue of sexual ethics has been the "duty to warn."<sup>17</sup> This "duty to warn" refers to an obligation where, if a person is infected with HIV, or suspects that he or she may be infected, he or she has an obligation to disclose that fact. Importantly, this disclosure must occur before sexual activity. The obligation is based on two hypotheses: 1.)

people are likely to avoid unsafe and high-risk sex if they know their sexual partners are potentially infected with HIV, and 2.) people should be aware of all risks before taking acts (this concept is based on informed consent).

Contrary to the above-described notions, the strategy adopted by gay communities and AIDS Service Organization (ASOs) in the U.S.—which are also rooted in gay communities—was the “don’t ask, don’t tell” approach.<sup>18</sup> This approach posited that one did not need to disclose the infection or the possibility of infection to a sexual partner as long as he or she practiced risk reduction by using a condom and that instead of disclosure, a person must use a condom with anyone at all times. This approach was adopted by gay communities as safer sex ethics in order to respect their own solidarity, to avoid disruption due to HIV status, to enjoy sexual activity, maintain a sex-positive culture, and protect homosexuality from social discrimination.<sup>19</sup>

Should the ‘duty to warn’ or ‘don’t ask, don’t tell’ be endorsed? Although the argument between these two claims has not yet been resolved, discussion of the duty to warn is muted and, instead, the message of safer sex ethics has become the mainstream answer of prevention strategy<sup>20</sup>. In the prevention messages delivered in Japan, very little is mentioned about the duty to warn.<sup>21</sup> Many factors underlie safer sex ethics becoming the mainstream, but the critical factor is that safer sex ethics is more in line with the underlying goals of public health than the duty to warn. Not everyone is aware of his or her risk exposure levels or HIV status. Rather, infection is more likely by an individual who is not aware of his or her HIV status. It is, therefore, not reasonable to



place the burden of infection control only or mainly on the HIV-positive individuals. Moreover, such a burden might interfere with public health measures aimed at decreasing the spread of the epidemic by driving the HIV-positive underground, for once people become aware of their HIV-positive status through testing, their responsibility becomes excessively burdensome, and they will consequentially become more likely to avoid making their HIV status known.<sup>22</sup>

These HIV-prevention strategies are not morally mutually exclusive. When we review decisions and choices, these strategies are best understood in historical context. As well, two points of analysis are necessary: first, at the outset, review the relationship between the severity of the risk and the severity of ethical obligations; second, consider the differences of dimension within each claim.

### **2.1. Levels of risk and ethics**

Sexual ethics, where duty to warn and safer sex ethics were developed as an axis, incorporates a discussion of how we should respond to uncertain risks. Therefore, it seems that development of sexual ethics is closely related to the level of risk of HIV infection. In this context, “risk” has two meanings: risk of simple infection and risk of death resulting from an infection.

In 1994, David L. Chambers noted that the duty to warn was discussed in the context of the pros and cons of sexual intercourse between homosexual male partners.<sup>23</sup> The discussion focused on the conflict between the claim by health authorities that anal sex should be avoided because of heightened risk of infection and the claim by gay

communities that they are entitled to retain their own culture and thought processes with regard to sexual matters. Moreover, the discussion within this particular context incorporated a duty to warn against anal sex, even if a condom is used in intercourse because of heightened possibility of accidents, such as damage to the condom.<sup>24</sup> Gay communities, however, maintained that the duty to warn was obviated by using a condom as a measure of risk reduction. Although several prevention strategies still insist on abstinence,<sup>25</sup> it is very rare to find a suggestion to desist from anal sex in any prevention messages, at least in Japan, and it is also unusual to find a duty to warn in prevention messages in connection with condom use. Regardless, at that time, the duty to warn was demanded when one breached a prohibition against anal sex due to the risk posed by anal sex, even with condom. It follows, then, that with higher risks of transmission, ethical responsibility progressively increases.

As evidenced above, some arguments suggest that the increasing duty and responsibility depends on the level of risk. For instance, according to Bennett et al., “the level of risk of transmission must be allowed to influence the strength of any moral obligation to forewarn others of HIV infection.”<sup>26</sup> Further, according to Chalmers, who built upon the discussion of Bennett et al., we should distinguish the level of severity of duty and responsibility between moral obligations and legal obligations in the context of whether reasonable precautions, including condom use, are implemented.<sup>27</sup>

However, why is the duty to warn not presently emphasized as much as before, in particular where anal sex with condoms is concerned? The

level of risk of transmission in such an instance has certainly not changed in the two decades since Chambers wrote his 1994 paper. It seems that this change might be related to the change in the risk to quality of life due to infection. In 1996, Bayer, who has long been active in the discussion of the ethical aspects of HIV infection, strongly emphasizes the necessity of sexual ethics related to the duty to warn, in creating prevention strategies; as well, the basis of his insistence is the lethality of HIV infection.<sup>28</sup> Even now, HIV infection can still be lethal. But, it is only lifespan-inhibiting in individuals that do not receive ARV therapy. Since 1996, the nature of HIV infection had significantly changed in character. Since the remarkable efficacy of HAART was first reported at the XI International AIDS Conference held in Vancouver<sup>29</sup> in 1996, we have been able to control HIV infection without developing AIDS as long as we have access to ARV drugs, and mortality due to HIV/AIDS in developed countries has decreased dramatically. Today, it is to be said that HIV infection is one of the chronic diseases and the life expectancy of HIV-positive patients is not so different from those who are not infected.<sup>30</sup> Moreover, advances in medicine have greatly reduced the burden of medication, enabling treatment with a once-daily tablet.

This means that the risk to life due to infection changed significantly, from 1996 to the present in developed countries, though the risk reduction depends on whether the access to HIV treatment is accessible. Chambers' description of the process of intense debate about the duty to warn occurred in 1994 and, at that time, HIV infection was definitely lethal. It appears that the impact of the supporters of duty to warn had progressively weakened since 1996. For instance, although Bayer seems

to have strongly criticized the safer sex ethics as “asocial individualism”<sup>31</sup> in 1989, he showed an understanding of the safer sex ethics to some extent in 1996.<sup>32</sup>

Based on the above, it can be said that sexual ethics concerning HIV prevention has changed in severity because of reductions in the risk of infection and the risk to life.

## **2.2. Ethics and public health**

Bennett’s paper in 2000 and Chalmers’ in 2002 are both concerned with the distinction between moral and legal concepts and arguments: the pros and cons of criminalization concerning infection to others. The research also reflects that the duty to warn had come to be discussed not in the context of prevention strategy, but in the context of criminalization. It appears that, at some point in recent history, the duty to warn has come to be discussed in a different context than prevention.

In a paper published in 2002, Ainslie insisted that the duty to warn was a discussion in a different realm from safer sex ethics.<sup>33</sup> Ainslie asserted that both differ in that duty to warn is a discussion of morality while safer sex ethics is a discussion of public health. Because the duty to warn allows for unsafe sex—provided that is consensual—it does not make sense to consider it as an apparatus of public health any longer.<sup>34</sup> At the same time, Ainslie criticized the deception of solidarity that gay communities incorporated in their discussion of safer sex ethics. According to Ainslie, if their communities truly intended to pursue solidarity, they should have directed their solidarity efforts towards clarifying HIV status and respecting each other’s autonomy.<sup>35</sup> Certainly,

the “don’t ask, don’t tell” approach has disseminated throughout the gay communities, and it has become uncommon to take legal action in instances of infection. However, this does not mean that the duty to warn is no longer a moral duty, but rather that individuals in gay communities are more prone to forgive those who fail to disclose HIV infection. It follows, then, that if the duty to warn is a moral duty and safer sex ethics is an apparatus of public health, both are somewhat independent issues, yet each is necessary.

Moreover, the distinction between the two claims has political significance. For Ainslie, to respect the duty to warn as a moral duty and to regard the autonomy as a fundamental value is a moral matter each individual should pursue, and those who fail to follow the duty to warn should not be pursued through legal action. This is so because “a liberal state should not require its citizens to subscribe to a particular set of substantive values.”<sup>36</sup> If we intend to continue to value the liberal state as an ideal, we should clarify the distinction between such moral duty as the duty to warn as an individual pursuit and public health strategy as the responsibility of the state. Therefore, the public health authorities should not incorporate the duty to warn into their messaging because not only does it not provide any benefit to public health, but it also risks driving the HIV-positive underground.

In the context of the political values of the liberal state, it seems suggestive to refer to safer sex ethics as “ethics”. Ainslie points out that public health organizations such as ASOs accept bare and empirical facts reflecting the reality of individuals’ acts, while “philosophers whose concern is what we ought to do can downplay these empirical facts about

our sexual decision-making.”<sup>37</sup> Without judging the possibility that people would not live up to consent-based morality and creating a distance from morals based on “a particular set of substantive values,” the public health focus on pursuing the mission of suppression of infection rates is never value-neutral. Therefore, public health does incorporate general ethics to some extent.<sup>38</sup>

This is an attitude common to theorists such as Bayer, who insist on the significance of the duty to warn. Bayer posits that systematic behavioral research on individuals’ actual, rather than hypothetical behavior, is essential to discussing the ethical aspects of HIV prevention strategy, respecting the moral values of trust and candor propping up the duty to warn.<sup>39</sup> Bayer’s attitude, which is subject to verification by behavioral research in tandem with a discussion of ethics, seems to be similar to Ainslie’s attitude of distinguishing between moral values and public health<sup>40</sup>.

### **3. On the direction of prevention strategy in the future**

In reviewing the discussion of sexual ethics so far, this article identifies two main concerns and suggests a new direction of prevention strategy based on the relationship between varying levels of risk and ethics as well as the clear distinction between moral matters and public health. Let’s now consider the direction of HIV prevention strategy and public health messaging, taking into account the modern progress of biomedical prevention measures.<sup>41</sup>

Let’s first distinguish between moral matters and public health. As

Ainslie suggests, if we intend to retain the notion of the liberal state—though the definition of the liberal state is up for as debate, as is the consideration whether Japan is a liberal state—, we should respect this distinction. Further, based on the distinction, public health administrations should not deliver any strategies and messages that go beyond the so-called reasonable risk reduction, such as the duty to warn, because such obligations are personal moral matters for each individual.

Schüklenk insists that campaigns insisting on safer sex while suppressing unprotected sex—which is, in fact, not “unprotected” because of use of biomedical prevention—despite strong evidence favoring biomedical prevention such as PrEP, are ethically deeply problematic, even if they incorporate the intent of prevention of other STIs. Insisting that “there is a reason why most people do not use condoms consistently,” Schüklenk affirms unprotected sex as a reasonable choice for each individual who willingly undertakes some risk in preventing infection by ARV techniques.<sup>42</sup>

F. Venter et al. posits that PrEP does not raise ethical problems in sexual matters, if it encourages and enables risk-taking behavior, and that such an argument is an example of inappropriate moralizing about sex.<sup>43</sup> For instance, malaria prophylaxis and safer mountain climbing equipment are both more likely to result in increased risk-taking behavior—in part potentially burdening the public with medical expenses—, but development of such would not be held up as an ethical issue. Compared to them, moralizing about sexual activity would be inappropriate since doing so only encourages high-risk sexual behavior and creates new ethical problems; therefore prescriptions on sexual

activity should not be a matter of public health.

Following F. Venter et al., one of the main ethical issues that public health authorities should consider regarding biomedical prevention is resource allocation, which incorporates issues related to social security and the availability of medicine<sup>44</sup>. Beyond PrEP, then, a biomedical prevention strategy such as treatment as prevention is cognizant of the secondary prevention effects of treatment for HIV-positives. In developed countries such as Japan, if there is no particular difficulty within the social security system supporting the continued treatment of HIV-positives persons, no new discussion concerning resource allocation would be created. Moreover, there are some reports that biomedical prevention strategies could be cost-effective. Although starting ARV therapy at early stages could temporarily increase the burden of medical expenses, several simulated analyses suggest that we could expect long-term cost benefits because of the decrease in the population of HIV-positive individuals resulting from the efficacy of biomedical prevention measures.<sup>45</sup> Therefore, we should consider introducing biomedical prevention measures based on whether they are reasonable enough as measures of risk reduction and whether they call for more severe ethical considerations compared with the use of a condom.

Reviewing results of trials and research on biomedical prevention, reported one after another, it is difficult to decide which is more reasonable, biomedical prevention measures or condoms. Research suggests the efficacy of biomedical prevention, especially treatment as prevention, in addition to the evidence of HPTN052.<sup>46</sup> What has been noted among these studies was the PARTNER study, which is carried out



concurrently in many countries of the EU.<sup>47</sup> HPTN052 established the efficacy of ARV therapy as a prevention measure in heterosexual couples, but the study featured too few homosexual couples (male-male couples) to establish efficacy. So, the PARTNER study was designed to remedy this gap in knowledge. The authors recruited 1,110 serodiscordant couples in the EU—nearly 40 % of whom were gay male couples—and, on the condition that the HIV-positive partner had to be on ARV therapy with the most recent viral load below 200copies/ml and the couples had been engaging in unprotected sex at least on occasion, the study aims to clarify whether infection will appear in the uninfected partner, and, if so, how. As of March 2014, after two years of PARTNER study, the study authors reported no transmitted cases.<sup>48</sup> Although this study is still ongoing, it could establish more significant efficacy of biomedical prevention because the findings are based on behaviors more in line with the reality than HPTN052 and because it incorporates MSM—a common acronym in HIV epidemiology referring to “men who have sex with men”—couples.

Based on evidence as substantive as above, many states have now changed their prevention policies. The FDA approved PrEP and Japan modified its medication guidelines. For example, the current *modus operandi* of the medical establishment is to recommend artificial reproductive technology as risk reduction measures for discordant couples seeking pregnancy. However, in the U.S., because of the cost of artificial reproductive technology, some medical experts have begun to recommend pregnancy via unprotected sex while utilizing biomedical prevention measures as a more cost-effective option.<sup>49</sup> The joint expert advisory between the British HIV Association and the U.K. Department of Health

considers biomedical prevention measures in vaginal sex “as effective as consistent condom use” and “extremely low risk” in anal sex, though there is no established evidence<sup>50</sup> of the risk reduction in anal sex. In Canada, to argue against criminalization of HIV infection in light of development of prevention measures and medication, an experts group published a paper, targeted to the legal profession, which analyzed the infection rates by sexual behaviors and prevention measures, including biomedical measures. The paper argues that, even without condom use, the risk of infection has become negligible through biomedical prevention.<sup>51</sup>

As evidenced above, determining which is more effective, risk reduction through condom use, or risk reduction through biomedical prevention measures, is becoming more difficult. Therefore, just because one endorses risk reduction via biomedical prevention, one does not necessarily have any convincing rationale for furthering ethical duty and responsibility as compared with risk reduction through condom use which is a technique always subject to the possibility of accidents.

Of course, risk reduction using a condom is still a valid and significant prevention technique. The message of risk reduction with a condom should continue to be delivered as one of the important prevention measures. However, just because biomedical prevention measures could encourage unprotected sex neglecting the condom use, it should not be accepted that the state responsible for public health—if it is a liberal state—refrain from advancing and delivering biomedical prevention. Also, there is no rationale to demand further action and responsibility from HIV-positive individuals than adherence of medication and control of viral load. Instead, the liberal state should

actively pursue biomedical prevention measures as a technique enabling widened preference of sexual behavior of individuals.

However, because the efficacy of biomedical prevention measures depends on the adherence of medication for both treatment as prevention and PrEP, we have to demonstrate its efficacy through future behavioral research. Although the preventive efficacy of medication itself, such as that indicated by HPTN052, is also available in Japan, individuals' behavior is very likely to differ by region and culture. The public health authority of Japan (if Japan is a liberal state) should seek improvements to biomedical prevention strategy through implementing behavioral research in line with the welfare of people vulnerable to infection—such as MSM, drug users, and sex workers—as well as HIV positive individuals in order to enable the diversified preference of citizens as much expression as possible, consistent with the results of sound and fair research on cost-effectiveness.

Because HIV is an infectious disease, it is natural for a nation taking public health responsibly to make efforts at preventing the spread of the disease. However, HIV infection is related to sexual activities, which are a fundamental part of life, and the HIV-positive person must be able to enjoy a quality of life despite infection. Aggressively pursuing a minimum risk of infection greatly limits the quality of life of everyone, particularly people testing HIV-positive, and can bring a society nothing but certain exclusion or isolation of affected groups. That is why the state, if it is a liberal state, before imposing legal and lifestyle handicaps on HIV-positive persons, should transparently perform a risk evaluation based on scientific evidence and prepare an effective preventive strategy.

Therefore, biomedical prevention should be promoted more positively because it is not only an effective prevention measure, but also because biomedical prevention minimizes the limitations on the quality of life of HIV-positive persons. If there is such a firm public health foundation, the moral activities of individuals associated with disclosure can be performed more safely because the risk of a more discriminatory response is reduced.

#### **4. Some ideas for additional consideration**

Although the basic direction of HIV prevention strategy in the future is clear, there are several other issues that need consideration.

##### **4.1. Risk of healthism/nanny state**

Giving too much importance to public health can cause an ambivalence on the part of the liberal state. As a result of managing the safety and health of citizen, the state can compromise the diversity of citizens' lifestyles because of a tendency to intervene into all aspects of life. On this point, there is some discussion of the notions of "healthism" or "nanny state."<sup>52</sup> There are at least three issues at stake here: 1.) methods of determining the risk levels, 2.) distinguishing between personal moral matters and public health as a state responsibility, and 3.) ensuring transparency in order to enable citizens to monitor the progress of the aforementioned issues as they are evaluated by public health authorities.

It is possible that this framework is also available to matters of

other health promotion strategies that the state might employ. However, we need to distinguish, in the level of risk context, between health promotion activities and matters of precautionary principles. This is so because the standard of precautionary principles in health promotion is so strict that it can cause too much interference in daily life. This point requires extensive analysis and should be considered in a separate article.

#### **4.2. Weakening the approach to the social dimensions of HIV**

S. Kippax et al, who had been an important advocate of preventative activities in Australia, expressed some concern about the direction of biomedical prevention strategies.<sup>53</sup> The concern is that biomedical prevention can weaken the approach to the social dimensions of HIV. Intervention in social situations of vulnerable groups and improvement of such situations by promoting condom use has been considered essential. This also means that public health activities have aimed to reduce the social stigma of vulnerable groups, such as MSM, drug users, and sex workers, with HIV prevention activities as the driving force.<sup>54</sup> However, the main target of biomedical prevention strategy is how people, both HIV-positive and PrEP users, can maintain their access to healthcare facilities, or, in a more limited scope, how they can adhere to a health regime. Of course, in order to maintain access to healthcare and adherence to a health regime, intervention is needed, if not a complete transformation of social situations of key populations vulnerable to HIV infection. However, in terms of depth and content, this intervention can be expected to differ from the intervention into sexual behavior rooted in lifestyle, value, culture, and religion. Kippax et al. expressed concerns

that weakening interventions into social situations of key populations can be expected. Public health authorities should be careful not to overlook necessary approaches to the social dimension of key populations within the limited range of public health matters.

#### **4.3. Violence of resource allocation**

As F. Venter et al. pointed above, one important ethical issue of biomedical prevention strategies is resource allocation in the context of distributing ARV drugs. This issue can cause a significant conflict among recipients, given the variety of values and interests. Recently, it was reported that a local assemblyman in the Hyogo prefecture of Japan noted his doubt about the necessity of government initiatives targeting gay males, who voluntarily engage in high risk sexual activities, in consideration of more important issues such as screening for cancer.<sup>55</sup> Mindful of the discriminative aspect of this statement, we should be committed to being aware that this statement is based on the framework of resource allocation. We need to be committed to the development of a positive argument about resource allocation in connection with the idea of distributive justice.<sup>56</sup>

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## Notes

<sup>1</sup> U. Schüklenk. Ethics of Public Health Promotion Messaging in the Age of Successful HIV Treatment Regimes. *Bioethics* 2014; 28: ii-iii.

<sup>2</sup> In the paper, the author refers to “ARV” and “ARV drugs” interchangeably.

<sup>3</sup> The ABC approach, including abstinence, faithfulness, and condom use, is still recommended as an important HIV prevention strategy, incorporated as the ABC approach of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), which was launched by President George W. Bush in 2003, and is the U.S. Government initiative to relieving the suffering of those affected by HIV/AIDS on the global scale. Available at: <http://www.pepfar.gov/reports/guidance/75837.htm> [Accessed 29 June 2014].

<sup>4</sup> In the paper, the author refers to “biomedical prevention” as “ARV-related prevention/ biomedical HIV prevention”.

<sup>5</sup> E. M. Connor et al. Reduction of Maternal-infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. *N Engl J Med* 1994; 331(18): 1173-80.

<sup>6</sup> M. S. Cohen et al. The Ethical Odyssey in Testing HIV Treatment as Prevention. *Clin Trials* 2012; 9(3): 343-4.

<sup>7</sup> P. Vernazza et al. Les personnes séropositives nesouffrant d’aucune autre MST et suivant un traitement antiretroviral efficace ne transmettent pas le VIH par voie sexuelle. *Bull Med Suisse* 2008; 89: 165-9; M. S. Cohen. HIV Treatment as Prevention and “The Swiss Statement: in for a Dime, in for a Dollar?” *Clin Infect Dis* 2010; 51(11): 1323-4.

<sup>8</sup> M. S. Cohen et al. HIV Treatment as Prevention and HPTN052. *Curr Opin HIV AIDS* 2012; 7: 99-105.

<sup>9</sup> M. S. Cohen et al. Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *N Engl J Med* 2011; 365(6): 493-505.

<sup>10</sup> J. Cohen. Breakthrough of the Year. HIV Treatment as Prevention. *Science* 2011; 334(6063):1628.

<sup>11</sup> Q. Abdool Karim et al. Effectiveness and Safety of Tenofovir Gel, an Antiretroviral Microbicide, for Prevention of HIV Infection in Women. *Science* 2010; 329(5996): 1168-1174.

<sup>12</sup> R. M. Grant et al. Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. *N Engl J Med* 2010; 363(27): 2587-99.

<sup>13</sup> FDA News & Events. “FDA Approves First Drug for Reducing the Risk of Sexually Acquired HIV Infection,” 16 July 2012. Available at:

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm312210.htm> [Accessed 29 June 2014].

<sup>14</sup> However, the correct and consistent use of a condom can completely prevent HIV infection in principle. Incorrect and inconsistent use, or accidents such as condom failure, are not so rare that the reported efficacy has considerable variation. See NAM Aidsmap, “Challenges in Determining Condom Efficacy. Available at: <http://www.aidsmap.com/Challenges-in-determining-condom-efficacy/page/1324950/> [Accessed 29 June 2014].

<sup>15</sup> U. Schüklenk, op. cit., ii-iii; F. Venter et al. Exposure Ethics: Does HIV Pre-exposure Prophylaxis Raise Ethical Problems for the Health Care Provider and Policy Maker? *Bioethics* 2014; 28(6): 269-74.

<sup>16</sup> L. A. Eaton et al. Risk Compensation in HIV Prevention: Implications for Vaccines, Microbicides, and Other Biomedical HIV Prevention Technologies. *Cur HIV/AIDS Rep* 2007; 4(4): 165.

<sup>17</sup> C. A. Erin & J. Harris, Aids: Ethics, Justice, and Social Policy. *J Appl Philos* 1993; 10(2): 165-74. ; David. L. Chambers, Gay Men, AIDS, and the Code of the Condom. *Harv C. R. –C. L. L. Rev* 1994; 29(2): 353-85. ; R. Bayer. AIDS Prevention – Sexual ethics and responsibility. *N Engl J Med* 1996; 334(23): 1540-42. ; M. D. Stein et al. Sexual Ethics. Disclosure of HIV-Positive Status to Partners. *Arch Intern Med* 1998; 158(3): 253-7.; D.C. Ainslie, Questioning Bioethics: AIDS, Sexual Ethics, and the Duty to Warn. *Hastings Cent Rep* 1999; 29(5): 26-35. ; R. Bennett et al., Ignorance is Bliss? HIV and Moral Duties and Legal Duties to Forewarn. *J Med Ethics* 2000; 26(1): 9-15. ; D. C. Ainslie, AIDS and Sex: Is Warning a Moral Obligation?. *Health Care Anal* 2002; 10(1): 49-66.; J. Chalmers. The Criminalization of HIV Transmission. *Sex Trans Infect* 2002; 78: 448-51. ; C. S. Bryan. HIV/AIDS and Bioethics: Historical Perspective, Personal Retrospective. *Health Care Anal* 2002; 10(1): 5-18.

<sup>18</sup> D. Ainslie 2002, op.cit., 50.

<sup>19</sup> However, consistent strategy has not been expanded from the beginning, and there were some claims that, even while encouraging the use of a condom, HIV-positives should disclose their infection (D. Ainslie 1999, op.cit., 27) .

<sup>20</sup> Even some developed countries still criminalize non-disclosure. However, as will be discussed later, insofar as prevention strategies within the public health context are concerned, this tendency is recognizable. See, e.g., WHO, Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations. July 2014.

<sup>21</sup> Even in a brochure on safer sex that targets HIV-positives, it is



- advocated for a slightly different purpose, such as reducing their psychological burden rather than for prevention. See, e.g., National Hospital Organization Osaka National Hospital AIDS Medical Center, Nichijouseikatsu to Sex Life. Available at: <http://www.onh.go.jp/khac/knowledge/sexlife.html> [Accessed 29 June 2014].; Bureau of Social Welfare and Public Health, Tokyo Metropolitan Government. *TANPOPO*. 2014: 18. Available at : <http://www.fukushihoken.metro.tokyo.jp/iryu/koho/kansen.files/tanpopo.pdf> [Accessed 29 June 2014]
- <sup>22</sup> D. Ainslie 2002, op.cit., 63.
- <sup>23</sup> D. L. Chambers, op.cit., 354.
- <sup>24</sup> C. A. Erin & J. Harris, op.cit., 167 ; R. Bayer, op.cit., 1541.
- <sup>25</sup> See the discussion of the ABC approach of PEPFAR, op. cit. note 2.
- <sup>26</sup> R. Bennett et al., op.cit., 12.
- <sup>27</sup> J. Chalmers, op.cit., 450.
- <sup>28</sup> R. Bayer, op.cit., 1540.
- <sup>29</sup> L. Kallings & C. McClure. *20 Years of the International AIDS Society. HIV Professionals Working Together to Fight AIDS*. International AIDS Society: Switzerland; 2008: 28.
- <sup>30</sup> A. I. van Sighem et al. Life Expectancy of Recently Diagnosed Asymptomatic HIV-infected Patients Approaches that of Uninfected Individuals. *AIDS* 2010; 24(10): 1527-35.
- <sup>31</sup> D. Ainslie 1999, op.cit., 28.
- <sup>32</sup> R. Bayer, op.cit., 1540-42.
- <sup>33</sup> D. Ainslie 2002, op.cit., 55-57.
- <sup>34</sup> D. Ainslie 2002, op.cit., 55.
- <sup>35</sup> D. Ainslie 2002, op.cit.,61.
- <sup>36</sup> D. Ainslie 2002, op.cit.,63.
- <sup>37</sup> D. Ainslie 2002, op.cit.,57.
- <sup>38</sup> This attitude required of public health authorities of liberal states seems to share a certain essence with a distinction made by J. M. Mann between medicine, dominated by ethics as individual matters, and public health, in which the concept of human rights is valid as a social construct [J. M. Mann. *Medicine and Public Health, Ethics and Human Rights. Hastings Center Rep* 1997; 27(3): 6-13].
- <sup>39</sup> R. Bayer, op.cit., 1542.
- <sup>40</sup> The argument between safer sex ethics and duty to warn is historically based on events in the gay community. The discussion of safer sex ethics for public health will hold up in heterosexual circles as well. For instance, many current modalities of prevention messaging in Japan do not distinguish sexuality. However, duty to warn as moral duty might be

treated differently between heterosexual and homosexual relationships because each has a different culture and style of relationships. Other considerations will be necessary when considering the difference of duty to warn between heterosexual and homosexual relationships.

<sup>41</sup> Some have discussed, for a period of time, an ethical issue of “semi-forcing” medication to HIV-positives with the aim of prevention, rather than for therapeutic purposes. See, e.g., U. Schüklenk. AIDS – New Ethical Challenges. *Bioethics* 2008; 22(8): ii., H W. Jaffe & T Hope. Treating for the Common Good: A Proposed Ethical Framework. *Public Health Ethics* 2010; 3(3): 193-8. However, this author suspects that the discussion of this issue has not been an active one. It seems to depend on that, because CIPRA [P. Severe et al. Early versus Standard Antiretroviral Therapy for HIV-infected Adults in Haiti. *N Engl J Med* 2010; 363(3): 257-65] and START (Available at: <http://www.thestartstudy.org/> [Accessed 29 June 2014]) , still ongoing, have presented evidence about the benefits of early medication for HIV-positives in a positive light, and subsequently, the framework of research ethics that H W. Jaffe & T. Hope applied to this issue, which considers subjects as a kind of sacrifice, has lost its ability to convince.

<sup>42</sup> U. Schüklenk, op.cit., ii-iii.

<sup>43</sup> F. Venter et al, op.cit., 271-2.

<sup>44</sup> It is notable that some are concerned that inappropriate ARV intake may contribute to community drug resistance. However, Venter argues that we cope with drug resistance in medicine on a regular basis, and therefore, this issue falls flat as an ethical argument as well.

<sup>45</sup> R. M. Granich et al. Universal Voluntary HIV Testing with Immediate Antiretroviral Therapy as a Strategy for Elimination of HIV Transmission: a Mathematical Model. *Lancet* 2009; 373(9657): 48-57. ; R. P. Walensky et al. Cost-Effectiveness of HIV Treatment as prevention in Serodiscordant Couples. *N Engl J Med* 2013; 369(18): 1715-25.

<sup>46</sup> See, e.g., F. Tanser et al. High Coverage of ART Associated with Decline in Risk of HIV Acquisition in Rural KwaZulu-Natal, South Africa. *Science* 2013; 339(6122): 966-71.

<sup>47</sup> See the following associated Internet sites: PARTNER study website (Available at: [www.partnerstudy.eu](http://www.partnerstudy.eu) [Accessed 29 June 2014]); NAM Aidsmap. “The PARTNER Study.”(Available at: <http://www.aidsmap.com/The-PARTNER-study/page/2407924/> [Accessed 29 June 2014]).

<sup>48</sup> NAM Aidsmap. “No-one with an Undetectable Viral Load, Gay or Heterosexual, Transmits HIV in First Two Years of PARTNER Study.”

Available at: <http://www.aidsmap.com/page/2832748/> [Accessed 29 June 2014].

<sup>49</sup> The Washington Post. As Mixed-status HIV Couples Weigh Risks, More Elect to Conceive the Old-fashioned Way. 24 April 2014. Available at:

[http://m.washingtonpost.com/national/health-science/as-mixed-status-hiv-couples-weigh-risks-more-choose-to-conceive-the-old-fashioned-way/2014/04/24/8c8b11a4-b9d4-11e3-96ae-f2c36d2b1245\\_story.html](http://m.washingtonpost.com/national/health-science/as-mixed-status-hiv-couples-weigh-risks-more-choose-to-conceive-the-old-fashioned-way/2014/04/24/8c8b11a4-b9d4-11e3-96ae-f2c36d2b1245_story.html) [Accessed 29 June 2014].

<sup>50</sup> S. Fidler et al. Position Statement on the Use of Antiretroviral Therapy to Reduce HIV Transmission, January 2013: The British HIV Association (BHIVA) and the Expert Advisory Group on AIDS (EAGA). *HIV Med* 2013; 14(5): 259-262.

<sup>51</sup> M. Loutfy et al. Canadian Consensus Statement on HIV and its Transmission in the Context of Criminal Law. *Can J Infect Dis Med Microbiol* 2014; 25(3): 135-40.

<sup>52</sup> T. Okita. Essay on Political, Philosophical Analysis Concerning Framework of HIV Prevention Activities. *METAPHYSICA* 2010; 41: 1-12.; M. Minkler. Personal Responsibility for Health. *Promoting Health Behavior*. Georgetown University Press 2000: 3-16.; Nuffield Council on Bioethics. *Public Health: Ethical Issues*. London; 2007: v, 92, 134-5, 146-7.

<sup>53</sup> S. Kippax et al. Beyond the Distinction between Biomedical and Social Dimensions of HIV Prevention through the Lens of Social Public Health. *Am J Public Health* 2012; 102(5): 789-799.

<sup>54</sup> Y. Higashi. Vulnerability to HIV Infection and Sexual Health/Rights. *Syakai Mondai Kenkyuu* 2008; 57(2): 34.

<sup>55</sup> The Asahi Newspaper. "Douseiaisyu heno HIV keihatsu, Hitsuyouka," Hyougo Knegi ga Hatsugen. 17 April 2014.

<sup>56</sup> We should refer to John Rawls' argument about the notion of "pure procedural justice" in comparison with the notions of perfect and imperfect procedural justice (John Rawls. *A Theory of Justice, Revised Edition*, Harvard University Press, 1999, 73-78.)