



TRICK OR TREAT?

**Antiretroviral therapy
as HIV prevention**

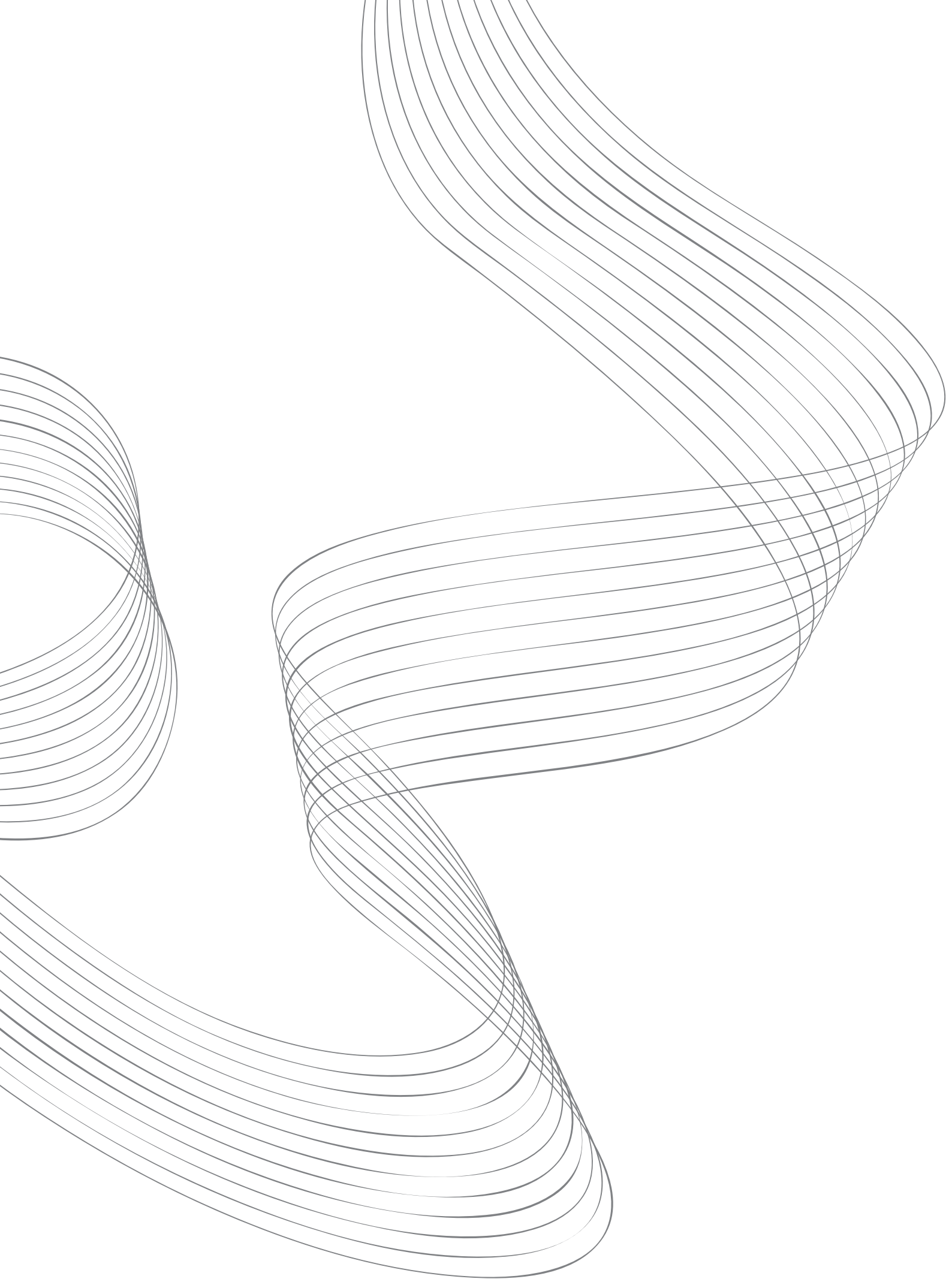
EDITOR | DEAN MURPHY



Foreword

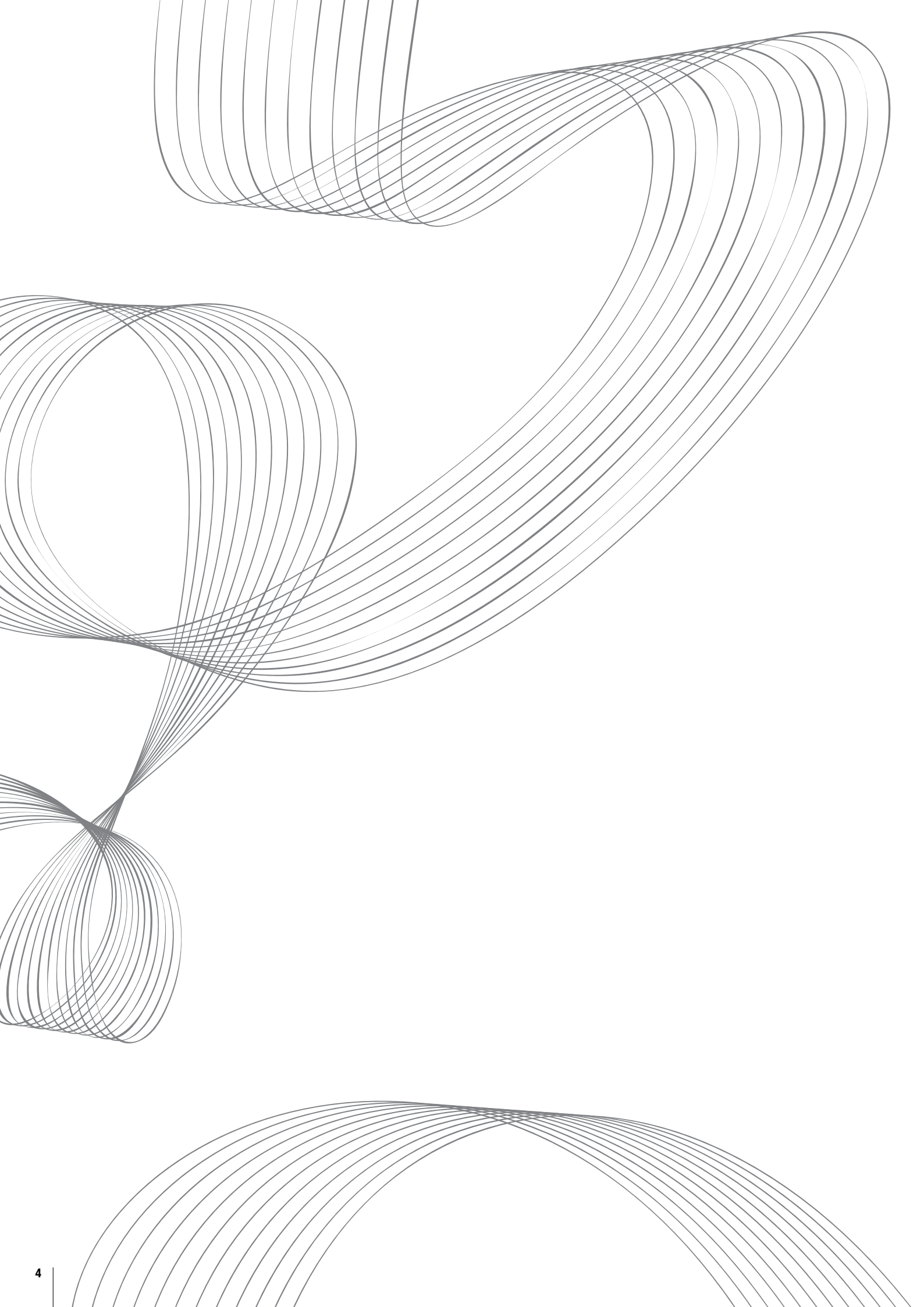
There is increasing interest in the potential of novel biomedical approaches to reshape the landscape of HIV prevention. Proven or potential interventions such as microbicides, pre-exposure prophylaxis, and male circumcision provide opportunities for HIV prevention in diverse settings around the globe. In the foreseeable future, however, no single product will prevent the spread of HIV. There is a need to identify a range of effective, practical, and affordable preventive strategies, and to determine how best to combine them. This monograph focuses on the potential of antiretroviral (ARV) therapy for people living with HIV to reduce or prevent transmission to sexual partners. AFAO invited a group of authors from the Australian HIV sector to consider this issue with a particular focus on recent international discussions as well as its application to the Australian context. Each of these authors makes an important contribution to this debate.





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Introduction

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There has been widespread debate about the role of antiretroviral (ARV) therapy in preventing HIV transmission. This discussion has intensified since the release of the ‘Swiss statement’ [1] (discussed throughout this volume) in January 2008 and the publication of various studies and epidemiological models that examine the potential impact of early and extensive ARV therapy on the HIV epidemic.

Observational studies on the effect of ARVs on HIV transmission at a population level have been undertaken in different epidemiological contexts. For example, Montaner and colleagues examined data from British Columbia, Canada, which has a predominantly injecting drug use epidemic and concluded that between 1996 and 2009, the number of individuals receiving combination ARVs increased by 547% and the number of annual HIV diagnoses fell by 52% during the same period [2]. Overall, there was a significant correlation between the number of people on ARVs and the number of people newly testing HIV positive per year. Also, for every 100 additional people on ARVs, the number of new HIV cases decreased by a factor of 0.97, or by 3%. Other studies from San Francisco and Denmark have also demonstrated a positive effect of ARV therapy on HIV epidemics. In San Francisco, where the majority of HIV infections are among gay men, community viral load decreased from 2002 to 2008 and was accompanied by decreases in new HIV infections, as measured by both new diagnoses of HIV cases and HIV incidence. The trend in mean community viral load was significantly associated with newly diagnosed HIV cases from 2004 to 2008 ($P = 0.003$) and HIV incidence from 2006 to 2007 ($P < 0.0005$). The total number of newly identified HIV cases decreased from 798 in 2004 to 434 in 2008 [3]. In a retrospective analysis of national data collected from 2000 to 2008 among heterosexuals in Denmark, there was a decrease of risk of sexual transmission from 7.9% in the first six months of ARV therapy, to 1% in the second six months (with overall risk in the first year equal to 5%); to 0.03% after five years on ARV therapy [4].

Other studies however have shown no such effect of ARVs on HIV transmission. A recent analysis of data from a study of gay men in Sydney found that the per-contact probability of HIV transmission has not changed since the introduction of new HIV treatments. For receptive unprotected receptive anal intercourse the per-contact probability of infection was 1.43% [95% confidence interval (CI) 0.48–2.85] if ejaculation occurred inside the rectum, and it was 0.65% (95% CI 0.15–1.53) if there was

withdrawal prior to ejaculation. The estimated transmission rate for insertive UAI in participants who were circumcised was 0.11% (95% CI 0.02–0.24), and it was 0.62% (95% CI 0.07–1.68) in uncircumcised men [5].

Most observation studies of HIV transmission in serodiscordant couples—such as the study from Rakai, Uganda, which is referred to most often in the literature [6]—have not investigated the risk of transmission when viral load is undetectable due to ARV therapy. Studies conducted in the context of ARV therapy have also shown somewhat mixed results. Although findings of studies from Spain [7] and Africa [8, 9] have shown that HIV transmission is significantly reduced among heterosexual couples when the HIV-positive partner is on ARVs, a recent Chinese study has shown a different result with reported seroconversions being evenly distributed among couples in the treated and untreated arms [10]. To date, no studies of transmission have been conducted among men who have sex with men (MSM) where anal sex is the primary transmission route, although funding is currently being sought for a study on HIV transmission between partners in serodiscordant gay relationships in Australia, and another study is currently underway in Europe.

In addition to observational studies, a number of mathematical models on ARVs as prevention have been published. While there is almost universal agreement that ARV therapy reduces HIV transmission, the question remains as to the extent and duration of this effect particularly for different populations, different routes of transmission, and in the context of other factors such as concurrent STIs.

In the mid-1990s when ARV therapy was introduced in Australia, HIV diagnoses began to stabilise and decrease among MSM despite increases in risk practices across this same period. With high HIV testing rates and a ‘hit early, hit hard’ approach to ARV therapy in the late 1990s, Australia provided in many ways a natural experiment in the impact of ARV therapy on transmission.

After declining in the second half of the 1990s, HIV notifications among MSM in Australia and elsewhere began to increase in 2000 [11]. A mathematical model published on the Australian epidemic has shown that the number of HIV notifications could have been significantly higher had it not been for the effectiveness of ARVs in decreasing HIV viral load in treated individuals [12]. However this does not mean that earlier diagnosis and uptake of treatment of people with

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HIV would on its own reverse the increase in HIV notifications. The model suggests that changes in numbers of sexual partners, disclosure of HIV status, HIV testing rates and ARV therapy among MSM since 1999 have had only a modest impact on HIV incidence. The increased HIV notifications seen among MSM in Australia can only be accounted for by a large increase in a ‘transmission-increasing factor’ such as an increase in sexually transmissible infections (STIs). Similarly, looking into the future, although modelling suggests that earlier diagnosis of HIV infection and initiation of ARV therapy would have an impact on the Australian epidemic, projections of HIV notifications to 2015 are most sensitive to changes in assumptions regarding rates of STIs and rates of condom use.

Earlier models based on the predominantly MSM epidemics of HIV in San Francisco and Australia also predicted that increased use of ARVs could reduce the incidence of HIV transmission. However, these prevention gains could be partially offset if increases in risk-taking behaviours or viral resistance develop [13, 14]. Paradoxically, at the level of individuals (or rather, couples) ARV therapy might create the conditions of possibility for HIV transmission to be reduced dramatically, or even eliminated. Experts in Europe have suggested for some time that for heterosexual couples attempting conception, unprotected sexual intercourse—especially if limited to around the time of ovulation—is very low risk even where the male partner is HIV positive, as long as complete suppression of HIV with ARV therapy is achieved [15, 16]. The ‘Swiss statement’ went further by extending this possibility to all (heterosexual) serodiscordant couples if certain conditions were met.

The authors in this volume were invited to consider the issue of ARV therapy as prevention with a particular focus on recent debates and their application to the Australian context, as well as wider implications. Each of these authors makes an important contribution to this question.

One large international study (HPTN 052), which examines the impact of ARV therapy (and viral load at different levels) on HIV transmission, is currently underway. However, as **Andrew Grulich** and **Iryna Zablotska** outline in their chapter, even this study—because it includes very few male serodiscordant couples—will not provide sufficient answers to this question for HIV epidemics such as Australia’s, which are largely located among men who have sex with men (MSM). They go on to outline the case for, and design of, a study that would estimate HIV transmission between serodiscordant male partners, and in particular could demonstrate the impact of ARV therapy and viral load (in blood plasma and semen) on HIV transmission for both insertive and receptive anal sex.

Susan Kippax examines in detail two of the papers cited most often in the current debate on ARV therapy as prevention. She emphasises that debates about the assumptions on which each of the papers is based, have obscured the fact that these papers focus on very different outcome levels. One of these papers looks at ARV therapy in preventing the sexual transmission of HIV within serodiscordant couples, and the other models the roll out of a ‘test and treat’ strategy to lower and potentially eradicate HIV transmission in the population at large. Kippax then goes on to argue the important contribution of social science to the debate, particularly with reference to a population-wide strategy of universal testing and early ARV therapy.

Although the benefits for PLHIV of treatment for HIV infection are well established, the individual clinical benefits of early initiation of ARV therapy (at CD4 <500 rather than CD4<350), and treatment in primary HIV infection, have not been demonstrated in randomised trials, and the field is in a state of equipoise. The evidence on which changed treatment guidelines is based comes from observational studies. However, some jurisdictions have already recommended earlier initiation of ARV therapy. Although primarily based on opinion about the benefits of treatment at higher CD4 counts benefits to individuals living with HIV, the revised US guidelines also note the likely impact of treatment on transmission for people in serodiscordant couples as a consideration in decisions about starting ARV therapy.

This paradox between the unknown individual clinical benefit of treatment at high CD4 counts for PLHIV and the likely public health benefit of reduced HIV incidence is taken up by **Sean Slavin** in particular who asks whether this is a paradox that can be reconciled. There is of course one context in which ARV therapy has been proven beyond doubt to have an impact on the epidemic and that is in the prevention of mother to child transmission (PMCT). Despite this, decisions by HIV-positive pregnant woman about treatment are still complex, as described by **Karalyn McDonald**, who reports on the considerations of these women such as the toxicity of antiretroviral drugs on the unborn child or infant.

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As mentioned above, in January 2008 an intense debate was opened up by the publication of the 'Swiss statement', which declared that PLHIV with suppressed viral load were not infectious to their sexual partners. There has been much subsequent discussion about the accuracy, interpretation and application of this statement, including from authors in this volume. **Martin Holt** and **Evelyn Lee** analyse recent survey data from Sydney and Melbourne and conclude that only a very small number of men in these two cities would fit the criteria set out in the 'Swiss statement'—if it was interpreted as applying to gay men.

Phillip Keen examines responses to the 'Swiss statement', looking particularly at Australia, Germany, France and the United States. He also examines the way in which health promotion campaigns have incorporated the evolving knowledge related to viral load and its impact of HIV transmission over the last decade. In a slightly different way, **Colin Batrouney** examines some of the seeming contradictions inherent in health promotion activities, in particular the complexity in reconciling the contingent factors that comprise post-condom risk reduction strategies with the desire for absolute assurances about the risk of HIV transmission. Drawing on social and behavioural research from Australia and the United States, Keen and Batrouney both also report on the attitudes of gay men towards ARV-based prevention strategies.

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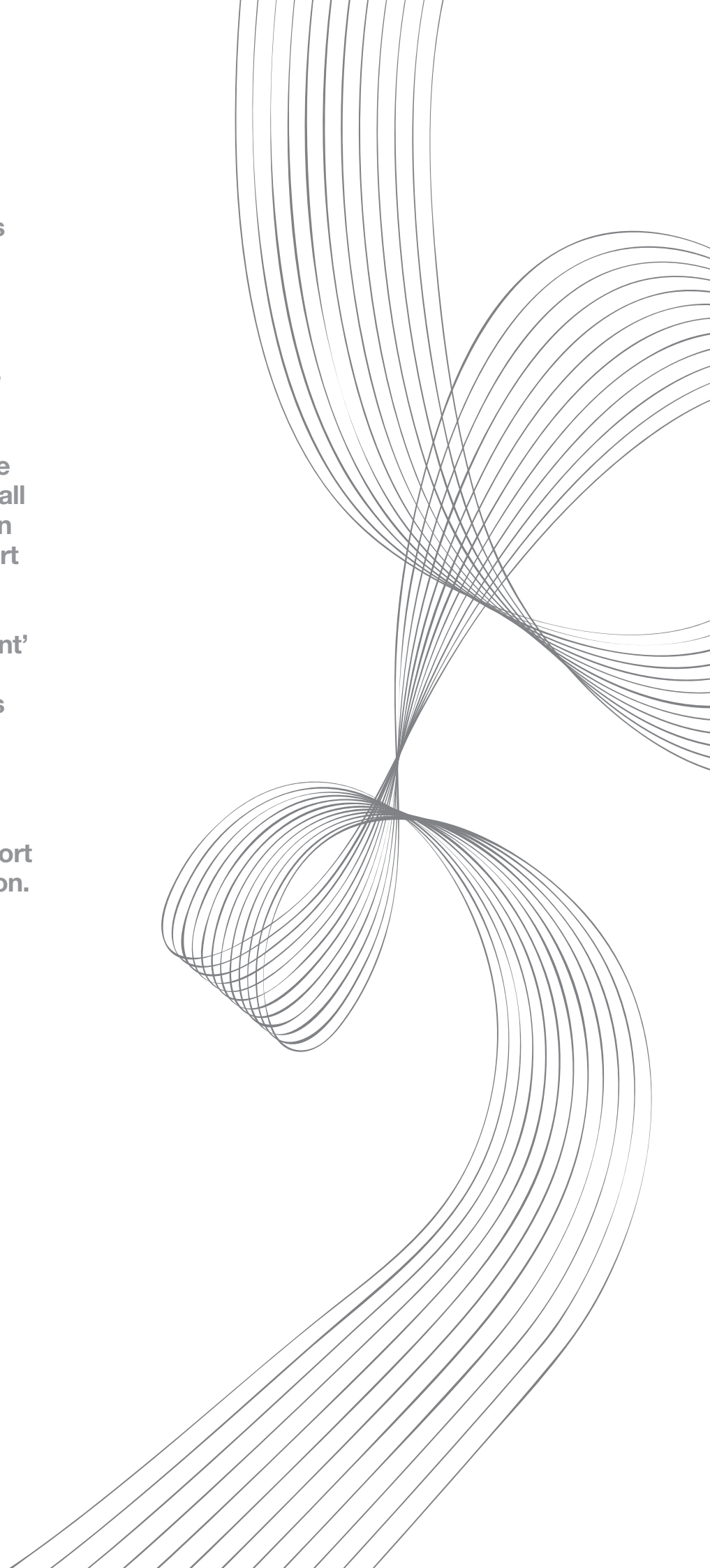
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Abstract

Reviewing Gay Community Periodic Survey data from Melbourne and Sydney, this article qualitatively assesses the proportion of gay men: 1) in serodiscordant relationships; 2) where the HIV-positive partner has an undetectable viral load; and 3) where the partners report unprotected anal intercourse with each other. Only 1% of all gay men or 2% of gay men in relationships appear to report all three criteria. Although it needs to be confirmed whether the 'Swiss Statement' applies to gay men in serodiscordant relationships practising unprotected anal intercourse or not, our analysis suggests that if it does there are relatively few gay men to target with support or harm reduction information.



How many gay men meet the conditions of the Swiss Statement? Indicators from the Melbourne and Sydney Gay Community Periodic Surveys

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Introduction

The Swiss Consensus Statement [1] (or the 'Swiss Statement'), which contends that HIV-positive people are sexually uninfected if they have a sustained undetectable viral load and no other sexually transmissible infections, has caused a considerable amount of controversy [2]. It was swiftly noted that the statement was primarily based on clinical and other data from heterosexual couples where one partner was HIV positive. However, it was unclear whether the assertions of the Swiss team would apply to gay couples in serodiscordant relationships, if the HIV-positive partner otherwise met the conditions set out in the consensus statement. At this point, in the absence of relevant clinical or epidemiological data, it remains unknown whether the 'Swiss Statement' holds for men in serodiscordant couples who practice unprotected anal intercourse with each other when the HIV-positive partner has an undetectable viral load.

A previous analysis of Australian cohort data showed that the majority of gay men in serodiscordant relationships do not practise unprotected anal intercourse, but when they do, the HIV-positive partner is significantly more likely to have an undetectable viral load [3]. A more recent analysis of Australian cohort and cross-sectional survey data found that HIV-negative gay men in serodiscordant relationships are more likely to report unprotected anal intercourse with their HIV-positive partner when the positive partner's viral load is undetectable [4]. However, HIV-positive men in serodiscordant relationships are just as likely to report unprotected anal intercourse with their negative partner if their viral load is detectable or undetectable. The authors concluded that viral load indicators are probably understood differently by HIV-negative and HIV-positive men in serodiscordant relationships. HIV-negative men appear to be more willing than HIV-positive men to rely on viral load as an indicator of infectiousness.

In the analysis presented here, we do not seek to contest or extend the analyses described above. Instead, we seek to assess qualitatively the proportion of Australian gay men to whom the 'Swiss Statement' would be relevant, if it was applied to male serodiscordant couples who practise unprotected anal intercourse. Specifically, we consider how many men report being in a serodiscordant relationship where the HIV-positive partner has an undetectable viral load and unprotected anal intercourse occurs. We examined data from the 2009 Melbourne and Sydney Gay Community Periodic Surveys to assess how common these characteristics were [5, 6]. The following descriptive analyses report data already published in the 2009 Melbourne and Sydney Gay Community Periodic Survey reports, supplemented by previously unpublished breakdowns of practices in serodiscordant relationships.

Serodiscordant relationships

Serodiscordant relationships (where one partner is HIV positive and the other HIV negative) are not very common among gay men in Melbourne and Sydney. One reason for this is that there are not that many HIV-positive men in the overall population of gay men. In 2009, only 6% of gay men in Melbourne and 8% of gay men in Sydney reported being HIV-positive. Over half (58%) of all gay men in Melbourne and 60% of men in Sydney report having a regular sex partner (a boyfriend, partner or fuck buddy) [5, 6]. In Melbourne, 8% of men who had a regular sex partner in 2009 reported being in a serodiscordant relationship, while 11% of men with a regular partner in Sydney reported being in a serodiscordant relationship. The proportions of men in serodiscordant relationships have been stable in Melbourne and Sydney for the last few years. Overall, around one in ten men who are in a regular relationship say they are in a serodiscordant relationship in Melbourne and Sydney. If we include all men, regardless of relationship status (i.e. including single men) about 6% of all gay men in Melbourne and Sydney report being in a serodiscordant relationship.

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Viral load of HIV-positive men

In Melbourne, just over two-thirds of HIV-positive men say they are receiving antiretroviral (ARV) therapy, while over three-quarters of HIV-positive men in Sydney report being on ARV therapy [5, 6]. In Melbourne and Sydney, the proportions of HIV-positive men receiving ARV therapy who say that their viral load is 'undetectable' have increased in the last few years. In 2009, 93% of HIV-positive men in Melbourne receiving ARV therapy and 87% of HIV-positive men in Sydney receiving ARV therapy reported an undetectable viral load.

Unprotected anal intercourse within serodiscordant relationships

Gay men in serodiscordant relationships are much less likely to have unprotected anal intercourse (UAI) with their regular partner, compared with men in concordant relationships (where both partners are either HIV negative or HIV positive). Trying to assess the role of viral load is complicated, given the small numbers of men in serodiscordant relationships who report UAI. For example, in the 2009 Gay Community Periodic Surveys, there were only 32 men in Melbourne and 39 men in Sydney who reported UAI within a serodiscordant relationship [5, 6]. These small numbers equate to 40% of men in Melbourne in a serodiscordant relationship and 30% of men in Sydney in a serodiscordant relationship reporting some UAI with their regular partner in 2009, although we should be cautious about relying on these figures. Relying on the reported viral load of the positive partner in these relationships should be treated with even more caution. However, despite these small numbers, of the total men in Melbourne and Sydney who report UAI with a serodiscordant regular partner, the HIV-positive partner is reported as having an undetectable viral load as a result of ARV therapy in around a half to two-thirds of cases. (The range in these figures stems from the fact that HIV-negative men appear much less knowledgeable about their HIV-positive partner's viral load than HIV-positive men describing their own test results.)

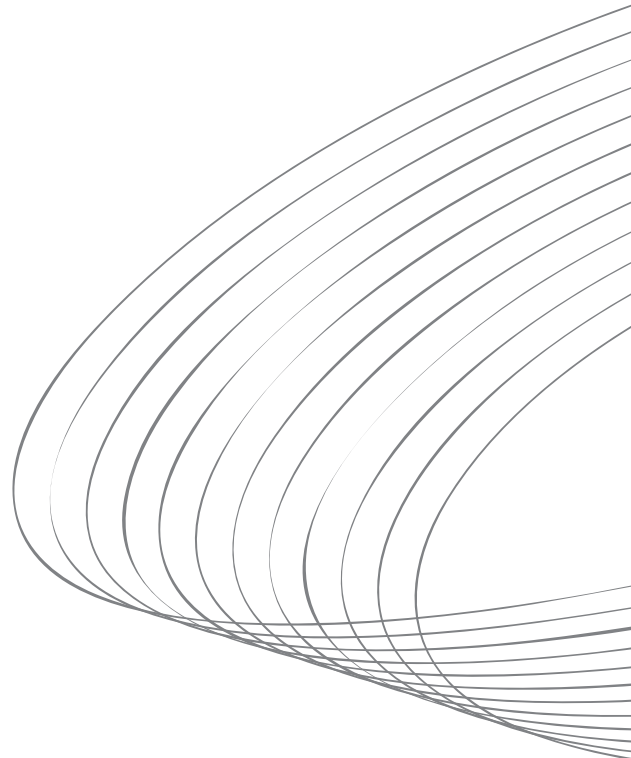
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Summary and implications

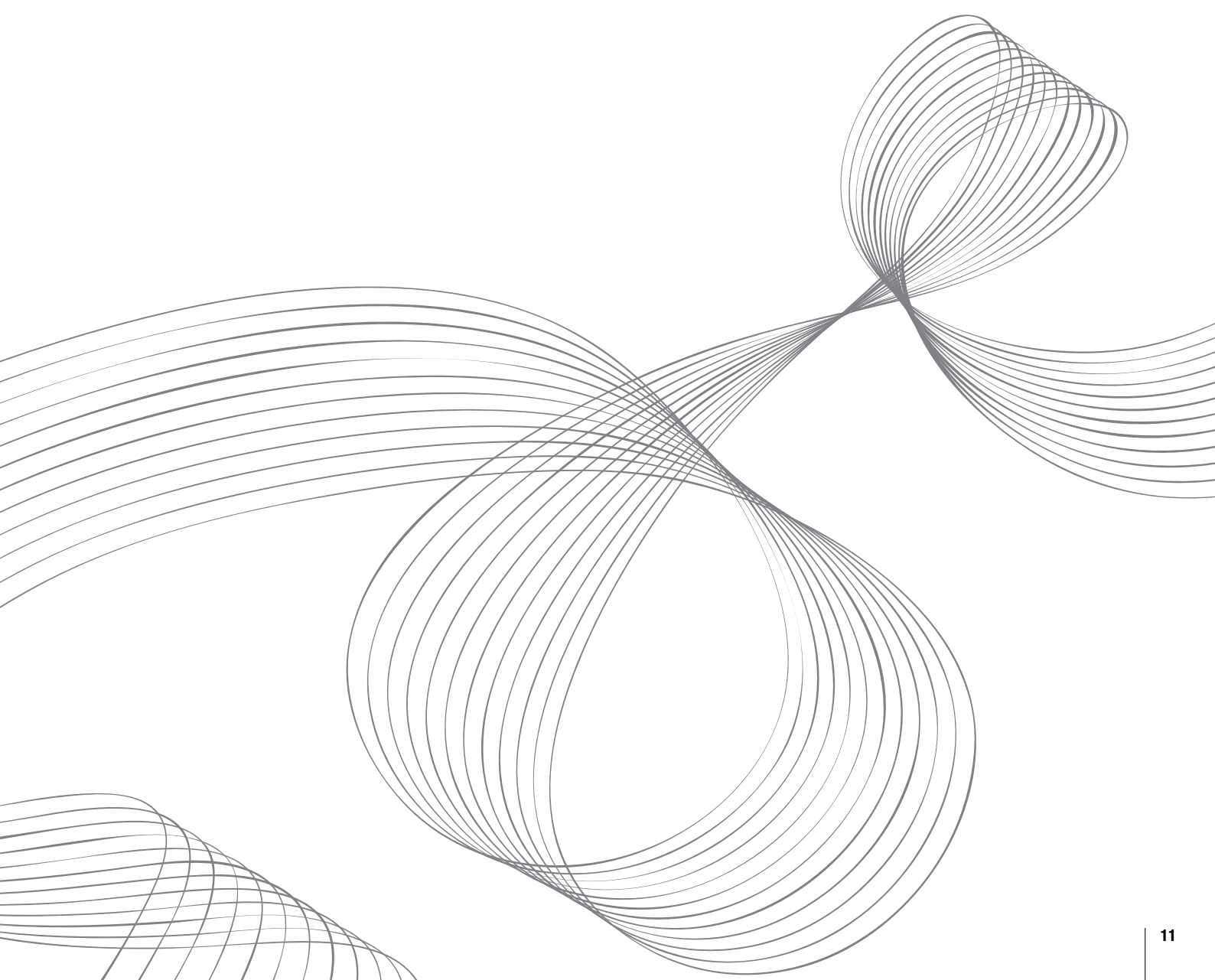
Overall, a relatively small number of gay men in Melbourne and Sydney are in serodiscordant relationships (~6%). Around 30–40% of men in serodiscordant relationships report any UAI, and in these cases the positive partner is reported to have an undetectable viral load about 60% of the time. The proportions of men in Melbourne and Sydney who report UAI within a serodiscordant relationship where the HIV-positive partner has an undetectable viral load are very small indeed—roughly 1% of all gay men, or 2% of men in regular relationships. This means that there are very few gay men in Melbourne and Sydney who currently meet the conditions stipulated in the 'Swiss Statement', if it were found to apply to men practising anal intercourse (and before we take into account the other conditions, such as a lack of concurrent infections).

Clearly, more work needs to be done to ascertain whether the 'Swiss Statement' holds for men in serodiscordant relationships practising anal intercourse with each other. However, given current data, it appears that there are relatively few gay men in serodiscordant relationships who report using viral load test results to inform decisions about unprotected anal intercourse with each other. Given that there appear to be few gay men currently reporting practices similar to those described in the 'Swiss Statement', this suggests that: a) the publication of the 'Swiss Statement' does not seem to have drastically affected what men in serodiscordant relationships consider safe sex; and b) if organisations wish to provide advice, support or harm reduction information to men in serodiscordant relationships around the 'Swiss Statement' or the use of viral load indicators, there are relatively few men to target.



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Abstract

Since the late 1990s, HIV incidence in homosexual men has been increasing in most developed countries including Australia. In the last two years, a scientific and public health policy debate on the potential role of antiretroviral (ARV) therapy as a measure to greatly reduce sexual transmission of HIV among homosexual men has been stimulated by two new reports:

1) mathematical modelling conducted by World Health Organisation and showing that universal voluntary HIV testing with immediate ARV therapy of all those diagnosed (a so-called 'test and treat' strategy) could substantially reduce severe generalised heterosexual HIV epidemics; and
2) a consensus statement released by the Swiss National AIDS Commission (the 'Swiss Statement') which asserted that HIV-positive people on effective ARV therapy with undetectable blood plasma viral load (BPVL) for six months or more who were free of other sexually transmissible infections (STIs) could not transmit HIV through sexual contact. Both reports are based on evidence from

heterosexual populations. However, the pressure is building to use ARV therapy as a prevention method among homosexual men, despite major knowledge gaps about the effect of ARV therapy on HIV transmission in this population group. The most reliable evidence can be obtained from prospective studies of serodiscordant relationships. Internationally, a clinical trial currently being conducted (HPTN 052) and due to report in 2013 will provide important data for heterosexual but not homosexual couples. In Australia, there has been a substantial body of research in serodiscordant male homosexual couples, and a current grant submission proposes a study of HIV transmission on serodiscordant homosexual couples. This study aims to quantify the strength of the association between BPVL and HIV transmission risk in male homosexual couples. If funding is obtained, the study can start as early as 2011 and the first evidence to address the issue can be available in 2015.

Antiretroviral therapy as HIV prevention: research evidence

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Introduction

Since the late 1990s, HIV incidence in homosexual men has been increasing in most developed countries including Australia [1]. It has recently become apparent that homosexual men are also greatly over-represented in HIV epidemics in most developing countries [2]. In Australia, around 70% of new diagnoses of HIV occur in homosexual men, and the annual number of new HIV diagnoses increased by almost 40% in the decade to 2008 [3]. HIV prevention services are in search of more efficient and more successful measures to halt the HIV epidemic in homosexual men.

In the last two years, a scientific and public health policy debate has been raging about whether widespread use of antiretroviral (ARV) therapy, through decreasing blood plasma and semen viral load, may decrease HIV transmission. This debate has been widely reported in the lay press [4, 5], and has been the subject of information and education campaigns designed by Australia's HIV community organisations [6]. Research evidence about the effectiveness of ARV therapy as related to prevention of HIV transmission among homosexual men is scarce and is insufficient to inform this debate and provide recommendations.

History of the debate

The issue of the potential use of ARV therapy as an HIV prevention approach has been debated for some time. About a decade ago, studies in untreated HIV-infected African heterosexuals demonstrated that there was a strong relationship between blood plasma viral load (BPVL) and risk of onwards HIV transmission to the regular sexual partner [7]. This population-based cohort study in Uganda showed that the probability of transmission per vaginal coital act was minimal when BPVL in the HIV-positive partners appeared to be below levels that were detectable, and it increased in the presence of genital ulcerations [8].

The use of ARV therapy to prevent the transmission of HIV-1 was suggested as early as 2002 [9]. The goal of effective ARV therapy in people with HIV is to reduce levels of BPVL to undetectable levels [10]. Thus it was hypothesised that ARV therapy, although prescribed to prevent progression to AIDS, may also have an important role in reducing onward sexual transmission of HIV [11]. Ten years later, this remains largely

unproven. Certainly, in mother-to-child HIV transmission, randomised controlled trials have demonstrated that the use of ARV therapy by the mother greatly reduces the risk of transmission of HIV to the newborn baby. As a consequence, HIV transmission from mother to child is now very uncommon in settings where ARV therapy is widely available [12]. The data on the association of ARV therapy with sexual transmission of HIV are much less conclusive.

Interest in the potential role of ARV therapy as a measure to greatly reduce sexual transmission of HIV at the population level was stimulated in 2008–09 by two new reports. First, authors from a World Health Organisation research group reported results of a mathematical model showing that universal voluntary HIV testing with immediate ARV therapy of all those diagnosed (a so-called 'test and treat' strategy) could substantially reduce severe generalised heterosexual HIV epidemics [13]. Second, a consensus statement released by the Swiss National AIDS Commission (the 'Swiss Statement') asserted that HIV-positive people on effective ARV therapy with undetectable BPVL for six months or more and who were free of other sexually transmissible infections (STIs) could not transmit HIV through sexual contact [14]. These reports—and the role of ARV therapy in HIV prevention more broadly—have been extensively challenged on multiple grounds, and there is substantial concern that they may over-state the case for ARV therapy as HIV prevention. UNAIDS and national public health authorities, including in Australia, released responses emphasising that condoms were the only proven method of prevention of sexual transmission of HIV [15].

Research gaps

The ensuing scientific debate has highlighted key knowledge gaps in definitively determining the role of ARV therapy in prevention of sexual transmission of HIV [10].

1. Does SPVL always reflect BPVL?

The biological effect of ARV therapy in the prevention of sexual transmission of HIV is proposed to occur through its effect on reducing HIV in genital secretions. Although it is usually stated that there is a strong correlation between blood plasma viral load (BPVL) and seminal plasma viral load (SPVL)

“The data on the association of ARV therapy with sexual transmission of HIV are much less conclusive...”

“Successful ARV therapy does rapidly and substantially reduce HIV levels in semen, but there have been very few longitudinal studies, especially of the longevity of this relationship...”

[16, 17], in a recent meta-analysis of 19 cross-sectional studies the correlation co-efficient was rather weak and was only 0.45 [18]. Successful ARV therapy does rapidly and substantially reduce HIV levels in semen, but there have been very few longitudinal studies, especially of the longevity of this relationship [19]. Recently, detectable SPVL has been estimated to occur in 5% of men who have had undetectable BPVL for six months or more who do not have an active STI. [20]. SPVL was detectable despite undetectable BPVL at one or more time points in 48% of 25 men in another cohort [21].

There are at least three possible reasons for the discordance between BPVL and SPVL. First, antiretroviral agents vary in their ability to penetrate the male genital tract [19]. Some, such as tenofovir and lamivudine, penetrate semen at high concentrations, whereas others, such as efavirenz [21] and most protease inhibitors, penetrate poorly and are present in semen at lower levels than in blood [22]. Low drug levels in the genital tract can lead to the emergence of HIV in the semen despite undetectable BPVL, and transmission of drug-resistant strains of HIV [23]. Second, STIs associated with urethritis, whether symptomatic or asymptomatic, lead to large increases in levels of SPVL without causing substantial changes in BPVL [18]. Third, non-adherence to ARV medication has also been shown to be associated with poorer correlation of BPVL with SPVL [18].

2. How strong is the relationship between BPVL and risk of HIV transmission?

The use of ARV therapy to prevent sexual transmission of HIV assumes that there is a very strong association between reducing BPVL and reducing sexual transmission. For example, the WHO model assumed a 100-fold reduction in infectiousness associated with ARV therapy [13], and others have assumed a two to ten fold reduction [15]. In fact, there is very limited longitudinal evidence about the rate of heterosexual transmission from individuals with undetectable BPVL due to ARV therapy.

The highest quality studies of viral load and the risk of sexual transmission of HIV are in HIV serodiscordant couples, because of the certainty of the transmission direction which can be confirmed with phylogenetic analysis of HIV [7] (pages 24–27). However, a recent meta-analysis reported only two studies, with fewer than 300 person years of follow up, which followed heterosexual individuals on ARV therapy with undetectable BPVL and their HIV negative sexual partners. Although no transmissions were recorded, the confidence intervals for HIV infection rate were broad and included a substantial rate of transmission from individuals with undetectable BPVL [15].

In heterosexuals, the question of whether ARV therapy will reduce sexual transmission of HIV is being addressed directly by an ongoing randomised controlled trial of early versus standard ARV therapy of individuals in serodiscordant couples. The primary outcome in this study is the rate of HIV infection in the initially HIV-negative partners [28]. It is anticipated that the results of this trial may be available as early as 2013 and may stimulate recommendations for the use of ARV therapy for prevention purposes. In contrast to heterosexuals, there have been no prospective studies of BPVL and HIV transmission in homosexual male couples. The ongoing randomised controlled trial is recruiting the great majority of its participants from developing countries with high HIV prevalence, and has enrolled almost no homosexual couples. Given the order of magnitude higher transmission risk associated with anal as compared to vaginal intercourse [29], it is quite plausible that the relationship between undetectable BPVL and HIV transmission is substantially less strong in homosexual men, the population which accounts for more than 70% of newly acquired HIV infection in Australia [3].

Research demands and constraints

In Australia, as in most of the developed world, HIV transmission has recently increased markedly in homosexual men despite the fact that an increasingly large majority of HIV positive men are receiving ARV therapy [3] (pages 30–31). There is a growing demand for effective and efficient means to downturn the course of the epidemic. The pressure is mounting to employ ARV therapy as a prevention method, despite the fact that evidence about the effect of ARV therapy on HIV transmission among homosexual men is scarce.

Research conducted by the National Centre in HIV Epidemiology and Clinical Research (NCHECR) and published in 2010 has demonstrated that the per-contact probability of HIV transmission through anal intercourse in gay men in Sydney has not decreased since the early 1990s, when almost no people with HIV were receiving effective ARV therapy [32]. This is suggestive—although by no means conclusive—evidence that ARV therapy is substantially less than 100% effective in preventing HIV transmission in homosexual men. This study was a large cohort of homosexual males, but it did not enrol serodiscordant couples.

“... there is very limited longitudinal evidence about the rate of heterosexual transmission from individuals with undetectable BPVL due to ARV therapy.”

“It is anticipated that the results of this trial may be available as early as 2013 and may stimulate recommendations for the use of ARV therapy for prevention purposes.”

The most conclusive evidence would be obtained from a prospective study of serodiscordant male homosexual couples, but conducting transmission studies in such couples is challenging for several reasons. First, a high proportion of relationships in homosexual men are non-monogamous, and assigning infection as being from the regular partner is difficult. This may be resolved by the use of a detailed sexual behaviour history combined with phylogenetic methods. Phylogenetic analysis is used to establish the relationship between viruses from two different sources and the probability that they have a recent common origin. It is a useful tool to trace a suspected HIV transmission between two individuals [33–35].

Second, conducting such studies is also challenging from legal and ethical perspective in view of the current legal framework in the Australian states. It is possible that an HIV transmission occurring within a serodiscordant couples study may be classed as an offence under public health and/or criminal legislation. In addition, it is theoretically possible that a complaint could be made and brought to the justice system irrespective of whether or not transmission actually occurred.

This issue demands careful consideration by researchers and community partners in such studies. The risk could be ameliorated by at least two approaches. First, if the consent process for entry into the study includes acknowledgment by the HIV-negative partner that he is aware of the HIV-positive status of his partner, and that he is aware of the means by which HIV is transmitted, it would be clear that the exposure to HIV occurred with the informed consent of the HIV-negative partner. Second, if sexual risk behaviours are reported only by the HIV-negative partner, and not by the HIV-positive partner, there would be no data that could possibly be construed as an ‘admission’ by the HIV-positive partner of knowingly exposing a person to HIV. Of course, it would be preferable if public health and criminal laws relating to consenting sexual practices leading to HIV transmission were repealed, but the existence of such laws should not be allowed to impede the conduct of important research which may lead to the implementation of effective public health interventions provided the welfare of study participants can be maintained.

NCHECR: Background work and research plans

In Australia, substantial research on HIV transmission among homosexual men, conducted by the National Centre in HIV Epidemiology and Clinical Research (NCHECR) and the National Centre in HIV Social Research (NCHSR), provides important background for studies with serodiscordant male couples. Analyses of data from the Australian national behavioural surveillance (Gay Community Periodic Surveys) indicate that about 10% of gay community-attached men in steady relationships consistently report having serodiscordant partners [36]; about 50% of these men report unprotected anal intercourse (UAI) in their relationship, and this has increased significantly over time (p trend < 0.01) [37]. The Health in Men (HIM, 2001–2007) and Positive Health (PH, 2000–2007) cohorts in Sydney [38] also reported that a significant proportion of HIV-negative (45%) and HIV-positive (32%) men in serodiscordant partnerships engaged in UAI in their relationship, but serodiscordant partners may differ in their understanding of BPVL when negotiating condom use and safer sex practices [39]. While the characteristics and the average rate of break-ups in serodiscordant and seroconcordant relationships did not differ (30% and 26% per year, $p=0.416$), HIV incidence was higher in the former (2.20 per 100 PY, 95% CI 0.96–4.30; HR=3.12, 95% CI 1.38–7.05), and this was despite the fact that the majority of HIV-positive partners were reportedly on ARV therapy and had undetectable BPVL. Incidence was highest in men whose serodiscordant relationship was of less than one year (6.10 per 100 py, 95% CI 2.01–13.66), in men under 35 years (4.69 per 100 py, 95% CI 1.53–10.57), and in those reporting UAI in the relationship (5.01 per 100 PY, 95% CI 2.18–9.61) [39].

In addition to the above, the following pilot work has been conducted by researchers from the NCHECR:

- a series of community consultations with the main community partners, including AIDS Councils and People Living with HIV/AIDS organisations in NSW and Victoria.
- a survey of clinical practices in Sydney and Melbourne to determine their willingness and capacity to take part in the study.
- legal consultations with the HIV/AIDS Legal Centre, to seek advice on how to secure confidentiality and protection for the participants.

“The most conclusive evidence would be obtained from a prospective study of serodiscordant male homosexual couples”

“Incidence was highest in men whose serodiscordant relationship was of less than one year.”

“The study is also designed to investigate the relationship between semen viral load and HIV transmission risk and the reasons why viral load in semen may be detectable despite being undetectable in blood plasma.”

NCHECR has gained substantial interest and strong support from the gay and HIV community organisations, health services and legal experts to address the issue whether ARV therapy can prevent HIV transmission among homosexual men. A group of the NCHECR researchers in collaboration with clinicians (St. Vincent Hospital in Sydney and Melbourne Sexual Health Centre) and community partners (Positive Life NSW) are currently preparing for a prospective quantitative study of serodiscordant male homosexual relationships to address this issue.

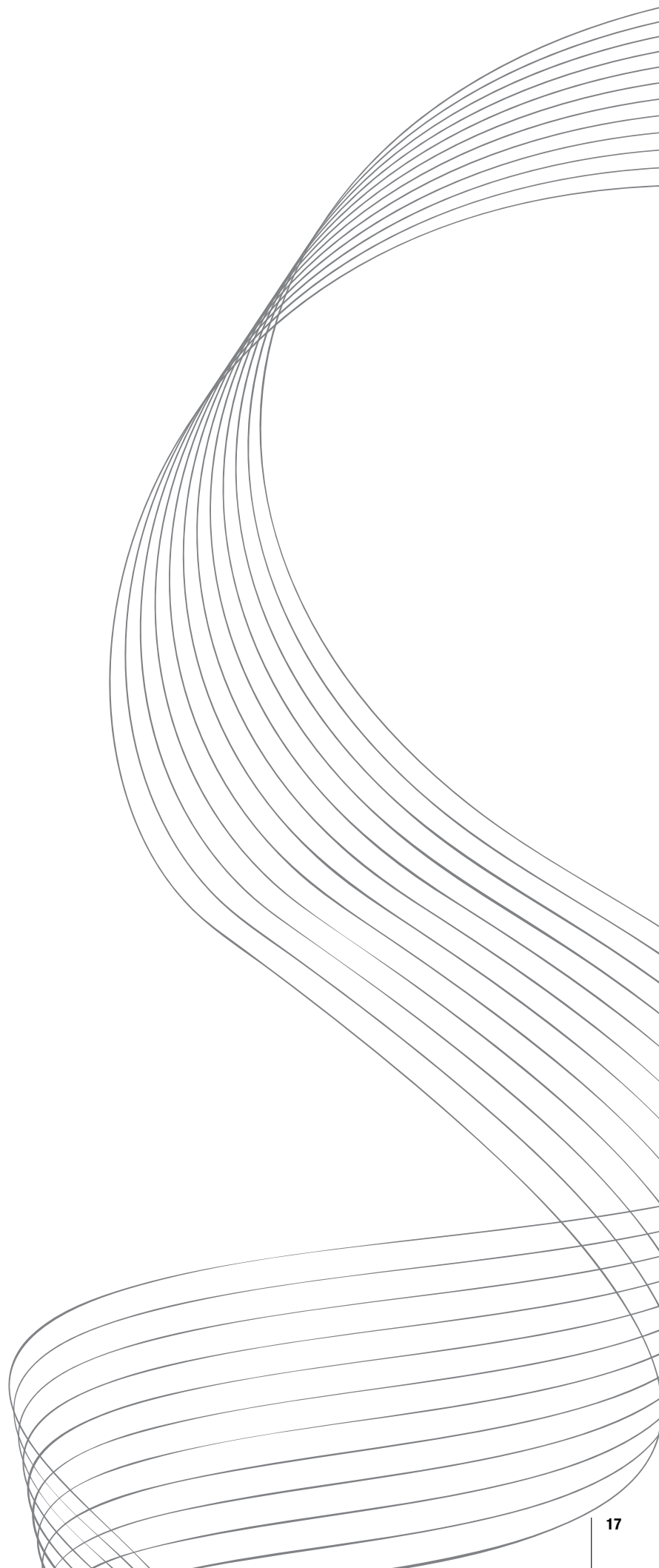
The proposed study intends to collect evidence about the use of viral load by homosexual men in negotiating sexual practices. It will estimate the efficacy of ARV therapy, with and without undetectable BPVL, in preventing transmission of HIV and explore factors which may influence the effect of ARV therapy and undetectable BPVL on HIV transmission (including the type of ARV combination, adherence to ARV therapy, and the presence of concurrent STIs). The study is also designed to investigate the relationship between semen viral load and HIV transmission risk and the reasons why viral load in semen may be detectable despite being undetectable in blood plasma. This is of key importance in controlling HIV epidemics in developed countries, and is also required for the development of guidelines for how ARV therapy may help prevent HIV transmission among homosexual men.

Depending on the result of submitted funding applications, the study can start as early as 2011 and the first evidence about the role of ARV therapy in HIV prevention among homosexual men could be available in 2015. Upon completion of the study, its results will allow the development of practical recommendations for HIV prevention agencies and policy makers on the applicability of the 'Swiss Statement' and 'test and treat' strategies with regard to HIV transmission in male homosexual couples.

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Abstract

The use of HIV treatments for prevention purposes gives rise to a number of paradoxes. Public health focuses on the health of populations and while mathematical models suggest universal testing and treatment may eradicate HIV, such a program at this stage is highly impractical. Furthermore, universal treatment implies involuntary treatment in some cases and this breaches the human rights of individual PLHIV (people living with HIV). Notwithstanding this, a reduction in infectiousness in individual PLHIV should be welcomed as this will alleviate much current anxiety associated with serodiscordant relationships.

Treatment as prevention: a paradox we can live with?

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Introduction

The fact that HIV treatments influence infectiousness and therefore act to prevent secondary infection has produced a worldwide debate that has opened some old fissures between public health and human rights. Within the debate are complex ethical questions involving and affecting people living with HIV (PLHIV), physicians, public health workers and researchers. This article attempts to tease out some of these questions and consider their consequences for PLHIV.

Ever since combination antiretroviral (ARV) therapy and viral load testing became widely available in the mid 1990s, clinicians and PLHIV have postulated that a lower viral load implies lower infectivity. This is a reasonable conclusion to draw, and from the late 1990s behavioural monitoring of gay men's sexual practices in Australia began to note an increase in the rate of unprotected sex between both regular and casual partners [1]. Further investigation revealed that, for some HIV-positive gay men, viral load was a factor in decisions not to use condoms [2]. In other words, these men were interpreting an undetectable viral load as indicating they were less likely to pass on the virus to sexual partners.

The Swiss statement

The meaning of these changes in sexual practice has been widely debated, with much disquiet expressed about the safety of the approach. Discussions about the relative risks associated with unprotected sex have sought to include a wide range of potential mitigating factors, such as concomitant STIs (sexually transmissible infections), the sexual position of the HIV-positive person (insertive or receptive) and whether plasma viral load matches that found in semen or vaginal fluids. Recently, epidemiologists, excited by the prospect that HIV treatments may have an impact on HIV incidence, began modelling the effects of different levels of treatment access and adherence. There is disagreement about the degree of the effect but there is consensus that widespread HIV treatment uptake would act to slow the epidemic to some extent. Debate reached a crescendo in 2008 following the publication of a consensus statement by the Swiss Federal AIDS Commission, which

concluded that an undetectable viral load meant the virus could not be transmitted in the context of heterosexual sex [3]. Reactions to the statement included concern that this message would lead to the erosion of a safe sex culture based on condoms and trepidation about the applicability of the theory to homosexual sex.

When approaching this debate, it is important to distinguish between the effects of treatment at a population and an individual level. This is a subtle point on which a great deal hinges because it implies the question of whether what is good for populations is good for all individuals counted within them and whether what is good for individuals may create difficulties for a population overall. These are quite different emphases with different effects. Populations should not simply be considered aggregates of individuals.

Mathematical models

In the context of this discussion, epidemiologists have modelled population effects measured as HIV incidence and prevalence depending on whether a hypothetical proportion of people with HIV take treatments. As a result, they argue a spectrum of positions, from caution about the effectiveness and cost of universal treatment to unbridled enthusiasm that through universal testing and treatment HIV may one day be eradicated [4, 5]. This notion has been enthusiastically taken up by some media whose hyperbole stretches the limits of credibility in overlooking the various practical limitations of such a concept [6]. Physicians and mainstream public health leaders tend to be more cautious, while also acknowledging the potential of the idea.

Although the media have played a role in overstimulating the issue, the modellers must take some responsibility for the effects of the knowledge they generate if it is to have any more significance than an intellectual game. The reality is that mathematical models are taken up by journalists and discussed more widely and the question, 'Why don't we test and treat everyone?' starts to be discussed. Rather than retreating to a position that disavows the importance of mathematical models, this is the practical question worth considering.

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"When approaching this debate, it is important to distinguish between the effects of treatment at a population and an individual level."

Population vs. individual benefits

Given the current limitations of antiretroviral therapy, universal testing and treatment is a pipe dream. Even the simplest drug combinations require daily dosing and better than 95% adherence: anything below this level risks producing drug resistant strains of the virus that may be further transmitted. Where adherence is likely to be a problem, it is usually better to delay treatment than risk this outcome. The decision to start treatment is almost always a weighty one, which should not be rushed if the best possible long-term outcome is to be achieved. Some of the common barriers to adherence include alcohol and drug use, cognitive deficiencies, and a raft of social factors such as homelessness and stigma. A public health approach that aims for the eradication of the virus in a population necessarily puts the public health goal ahead of the individual's clinical needs and ignores the complexity of many of these barriers and their basis in systems of degradation like class and race. The only way to achieve the level of coverage required would be to use some amount of coercion in some populations, further exacerbating the degradation.

While the international debate about universal test and treat programs continues unabated at the highest levels of the international AIDS research and public health sectors, many community-based HIV educators and policy workers in Australia remain nonchalant about the possibility of such a program in this country. However, there are two issues that should give pause for thought. First, people in Australia are regularly treated involuntarily in certain circumstances, notably the mentally ill on community treatment orders using slow release subcutaneous 'depo' drug injections or directly observed therapy. In such circumstances involuntary treatment is heavily regulated by statute and clinical guidelines, both of which place the health and safety of the patient at the centre of any decision to treat. A further example is the use of Depo Provera to control the fertility of people with an intellectual disability. This too is justified through a focus on the wellbeing of the patient and any potential child. To justify treatment in these circumstances using an argument for population health would invite a comparison with eugenics or totalitarian regimes of the past. Nonetheless these examples are precedents for involuntary treatment and, in relation to HIV, they should be countered with both an ethical and a practical argument. The latter because the prospect of a depo formulation of at least three HIV drugs is currently remote and programs of directly observed treatment are resource intensive outside of certain very specific populations.

Second, coercion doesn't always need to be explicit. It may only be necessary to change treatment guidelines and for doctors to implement them. A recent suggestion in Australia proposes treating individuals at the time of seroconversion, regardless of whether it is clinically indicated. It is argued that viral load is often extremely elevated at this point and there is a high risk of secondary infection. One argument says that the potential benefit to the community from a kind of chemical containment strategy would be significant and would reduce HIV incidence. The ethical problem remains whether the treatment recommendation is made in the interests of the patient. Given that scientific opinion about the desirability of early treatment has varied considerably over the years, this cannot be decided categorically. Any departure from this principle could only be countenanced if there were full disclosure about the reasons for offering treatment (i.e. a public health benefit) and informed consent was gained. Meanwhile, education and counselling should not be dismissed. Would it not be simpler, more cost effective and more ethical to inform individuals who are seroconverting of the risks of onward transmission and allow them to decide to limit that possibility by using condoms or abstaining from sex?

Human rights

For PLHIV the possibility of involuntary treatment, or treatment undertaken for reasons other than patient welfare, raises questions about human rights. At various times the epidemic has given rise to tensions between the individual rights of PLHIV and some of the more authoritarian tendencies of public health, which, for instance, might have initially preferred involuntary measures such as isolation of PLHIV from the rest of the community. In countries such as Australia a respect for individual rights has always trumped such possibilities. Likewise, medical ethics support the notion that individual patient welfare should be the first priority of any treatment decision and this makes it unlikely that physicians will warm to the idea of alternate aims. Bioethics and human rights are increasingly converging in such documents as the UNESCO Universal Declaration on Bioethics and Human Rights [7]. When the distinction between individual rights and population benefit is less clear, PLHIV have often endured subtle (or not so subtle) messages that place them in a position of primary responsibility for prevention. An example in the United States was the campaign in the early 2000s 'HIV stops with me', which was underpinned by the position of the Centers for Disease Control and Prevention on positive prevention that emphasises disclosure and personal responsibility [8]. Using treatment to affect the spread of HIV would likely involve this dimension. Recent discussions among PLHIV facilitated by the Global Network of People Living with HIV/AIDS (GNP+) and UNAIDS have suggested a move away from positive prevention

“A public health approach that aims for the eradication of the virus in a population necessarily puts the public health goal ahead of the individual's clinical needs”

“PLHIV have often endured subtle (or not so subtle) messages that place them in a position of primary responsibility for prevention.”

The 'Swiss Statement' thus confirmed what many PLHIV had long suspected and the effect of this was heartening, not least because it has opened up the possibility of serodiscordant relationships, where previously many regarded this as too risky.

with its implications of personal responsibility towards a rights-based approach that puts prevention into a broader framework of health and human rights [9]. At a population level, the use of universal testing and treatment for prevention is a bad idea because it is impractical and unethical. It is impractical because such a large-scale program is unlikely to achieve the uptake or adherence required and would therefore risk producing and spreading drug resistant strains of the virus. It is also impractical because health systems, even in developed countries, do not have the resources to test and treat millions of people. Any attempt to do so would likely compromise the quality of care that PLHIV currently receive. It is unethical because using treatment as prevention places population goals ahead of individual patient welfare.

Paradox

Notwithstanding these many reservations about treatment as prevention, a deeply paradoxical picture emerges when the focus is individual people living with HIV and their sexual partners. As outlined initially, Australian behavioural surveillance indicates that HIV-positive gay men have been acting for many years on the supposition that effective treatments reduce infectivity [2]. While there is certainly a debate about the relative risks of this approach, it is worth noting that, for many PLHIV, feeling less infectious equates with reduced anxiety about transmitting the virus to sexual partners. We know from surveys of PLHIV that sexuality is a significant site of anxiety with a quarter of the gay men, 43% of the women and 61% of the heterosexual men in a recent study declaring they did not currently have sex [10]. Anything that acts to support sexuality, an important element of wellbeing, should be encouraged. The 'Swiss Statement' thus confirmed what many PLHIV had long suspected and the effect of this was heartening, not least because it has opened up the possibility of serodiscordant relationships, where previously many regarded this as too risky. For some PLHIV the link between undetectable viral load and infectiousness may lead to more unprotected sex. However, for others, it is likely to be regarded as an additional supporting element in a personal prevention strategy that continues to include condom use. In thinking about these two possibilities, biomedical prevention and condoms, it is important to remain focused on the goal of preventing transmission. It is overly simplistic to equate safe sex with protected sex (i.e. sex with a condom) and not see that other prevention strategies are available. With this in mind, it is difficult not to detect a moralising tone in some of the more insistent and alarmist calls for gay men to always use condoms. Such calls have been heard in opposition to negotiated safety and strategic positioning and have raised fears about epidemics of other STIs and overstated the real risk of HIV infection to justify their stances. In all

likelihood the efficacy of condoms is probably higher than the treatment as prevention approach, although this remains to be tested among gay men. However, in pursuit of the ideal standard of universal condom use let us not reject out of hand other strategies that may not be as good, but neither are they bad.

Notwithstanding the benefits for individual PLHIV and serodiscordant couples from treatment as prevention, it is worth remembering that for a proportion of people on treatments (10–20%) an undetectable viral load is unattainable [11]. We must be careful not to stigmatise this group when making the link between viral load, infectivity and sexuality and we must be careful not to deny them the possibility of sexual relationships.

Treatment is now recommended to commence at an earlier disease stage and more effective and tolerable treatments have greatly improved the prognosis for people with HIV. In making the decision to treat, based on the best clinical advice, PLHIV are experiencing enhanced wellbeing that manifests in various ways, including an increased confidence that they will not pass on the virus to their sexual partners. We need further research to explore the relative risk associated with an undetectable viral load and sex without condoms among gay men, but the possibility that effective treatment can have a preventative effect is encouraging.

To further complicate the picture there is not a simple binary between populations and individuals, there are also social, cultural and institutional factors to consider. Arguably, one of the benefits to arise from our response to HIV has been the collective process through which communities have practised prevention. This has included challenges to homophobia, heterosexism and practices and institutions that oppress women. Some writers see in biomedical prevention technologies an undermining of communities' capacities to redefine sexual practice in socially progressive ways. They see biomedical prevention as individualising because it is delivered in the private space of the clinic from a physician to a 'patient', implying a top down power dynamic [12]. In an Australian context this view seems overly pessimistic since treatments also exist as social objects that are often made meaningful through interactions that PLHIV have with community organisations, through treatment officers and publications such as *Positive Living*. People with HIV also engage actively with each other and their doctors, learning how to integrate treatments into their daily lives and manage side effects. In this sense treatments are a tool of empowerment. Furthermore, the fact that gay men have apparently been devising risk reduction strategies that incorporate HIV treatments is a signal that these drugs are understood through social processes.

"In making the decision to treat, based on the best clinical advice, PLHIV are experiencing enhanced wellbeing that manifests in various ways, including an increased confidence that they will not pass on the virus to their sexual partners."

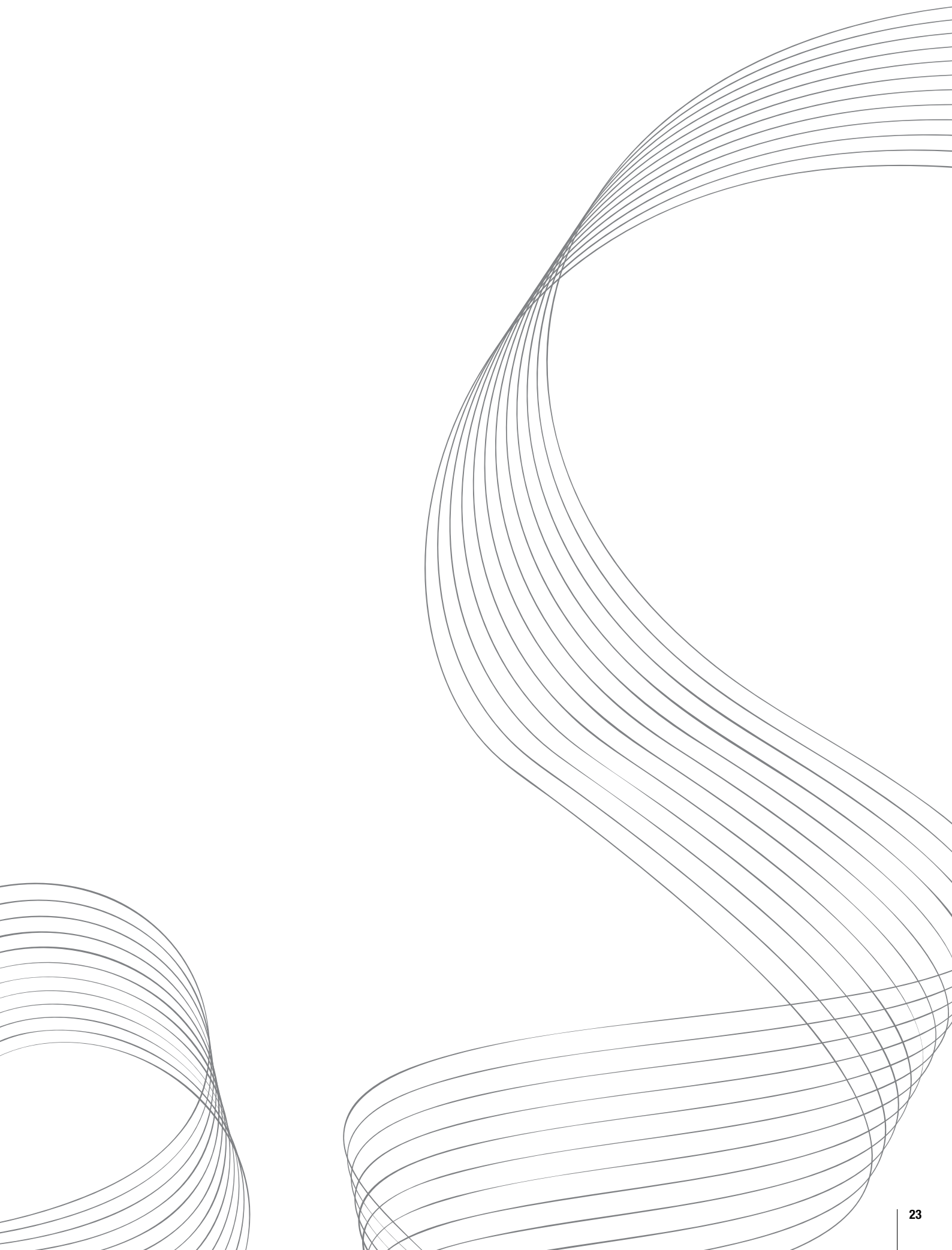
“A public health in which human rights are respected is one where both the individual and common good can be pursued as complementary goals”

Conclusion

The preventative effects of treatments should not be distrusted or feared. People with HIV in Australia have taken up treatments widely as an important tool for health and wellbeing. If optimal treatment has a subsidiary benefit that helps people have better sexual relationships, then this should be supported. The community sector has always had an active, cooperative and critical relationship with drug therapies and the medical establishment. This has led to productive partnerships in the past and there is no reason to think this won't continue. We need to remain vigilant about the more extreme tendencies in public health that hark back to outdated measures such as mandatory testing, treatment and containment. Modern public health has always sought to include respect for human rights and we must continue to insist that the two are inseparable [13]. A public health in which human rights are respected is one where both the individual and common good can be pursued as complementary goals and the abstract notion of 'populations' is replaced by 'communities' seeking to empower their members.

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Abstract

Social science has an important role in investigating the unintended consequences of the ‘test and treat’ strategy—particularly its impact on the ways individuals and communities understand risk and risk reduction. This paper distinguishes between the strategies of using antiretroviral (ARV) therapy in preventing the sexual transmission of HIV within serodiscordant couples (Swiss Consensus Statement), and of using ARV therapy to lower and potentially eradicate HIV transmission in the population at large (‘test and treat’). Social science research has documented that a minority of serodiscordant couples—both gay and heterosexual—have made use of biomedical knowledge relating to ‘undetectable’ viral load.

Given this, people living with HIV and their sexual partners should be fully informed about the special conditions outlined in the Swiss Consensus Statement so that they can make decisions about the risk of HIV transmission within their relationships. While there are few social research findings to date with regard to the impact of this same biomedical knowledge on community sexual practice, concerns have been expressed about the impact of testing on those who repeatedly test HIV negative and the likelihood of behavioural disinhibition among those who receive ARV therapy after testing HIV positive. These and other social and political factors may well undermine the potential effectiveness of the test and treat strategy.

Treatment as prevention: a social science voice

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Introduction

In 2009 Granich et al. published a paper claiming that prevention is possible with universal testing followed by immediate antiretroviral (ARV) therapy for all those diagnosed as HIV positive [1]. The claim is that the strategy—now known as ‘test and treat’—has the potential to eradicate HIV transmission. It has received support from a range of influential players including the World Health Organisation (WHO), the Centers for Disease Control and Prevention (CDC) and researchers such as Anthony Fauci, the director of the United States’ National Institute of Allergy and Infectious Diseases (NIAID). They have endorsed the strategy as a way of dramatically reducing HIV if not completely eradicating it. Some institutions have already begun to act in accord with the recommendations of the strategy. For example, in April 2010 some public health doctors in San Francisco began to offer ARV therapy to all patients who test HIV positive [2], and in the same month South Africa began a massive HIV testing program with the ambitious target of persuading 15 million people to test in the next 14 months [3]. The ‘test and treat’ strategy of Granich et al. has also caused considerable debate and some concern and this paper takes up and discusses the arguments—both pro and con.

Another paper by Vernazza et al. in 2008 [4], which was published before the Granich paper, claims that people living with HIV (PLHIV) are unlikely to transmit HIV to their sexual partners if they are on ARV therapy and their viral load is undetectable at the time of the sexual activity. The Vernazza paper has an individual focus and concerns the likelihood of sexual transmission of HIV within serodiscordant couples: this paper was released as the Swiss Consensus Statement (or the ‘Swiss Statement’). The second paper by Granich et al., which to a large extent has eclipsed the earlier publication, focuses on HIV prevention within populations. While both these documents have provoked a great deal of debate, much of this has confused the two very different aims of the papers: the use of ARV therapy in preventing the sexual transmission of HIV within serodiscordant couples, and the roll out of a test and treat strategy to lower and potentially eradicate HIV transmission in the population at large.

As Garnett and Gazzard note, it is important to differentiate between the role of treatment as prevention within serodiscordant couples and the preventive effects of treatment in the population [5]. My main focus is on the contribution of social science to the debate, particularly with reference to the Granich paper. However I first comment on the Swiss Consensus Statement.

Individual focus: protection of serodiscordant couples

In the ‘Swiss Statement’, Vernazza et al., via an inductive argument based on evidence from earlier studies, claim that in the case of full virological suppression, the relative risk of HIV transmission by sexual contact in the absence of condom use is less than 1 in a 100,000 [4]. They argue that HIV transmission is unlikely within serodiscordant couples if the following conditions are met: the viral load of the HIV-positive partner has been under the limit of detection for at least six months; the HIV-positive partner is on ARV therapy and the medication has been taken consistently; and the sexual partners have no mucosal defects, e.g. as a consequence of sexually transmissible infections.

The Swiss Statement addresses treating physicians about counselling their HIV-positive heterosexual patients who are in serodiscordant relationships. The authors are at pains to point out that with the exception of monogamous couples on fully suppressive ARV regimens, the standard measures of protection—such as condom use—must be followed at all times. They make it clear that any decision to commence treatment must be made according to treatment guidelines and that ARV therapy should not be started for the sole purpose of preventing transmission [4]. The Swiss statement also addresses legal arguments related to intentional HIV infection.

The publication of the Swiss statement met with a number of different responses. UNAIDS and WHO released a cautious statement [6], as did the CDC, the French Ministry of Health, and the Public Health Agency of Canada—all reinforcing the importance of safer sex in preventing HIV. A much more wary statement was released by the Canadian AIDS Treatment Information Exchange (CATIE) arguing that the Swiss findings are not robust as they are based on observational studies

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“...it is important to differentiate between the role of treatment as prevention within serodiscordant couples and the preventive effects of treatment in the population.”

[7]. A more positive statement was made by the British HIV Association affirming that effective HIV treatment significantly reduces the risk of HIV transmission. Later the same year, a team of Australian researchers claimed that ‘although the individual risk of HIV transmission per act is fairly small, the rate of transmission over a large number of acts might be substantial and could be further exacerbated by viral rebounds’ [8] (p. 317).

Since that set of responses, a review of cohort studies of serodiscordant couples [9] and a very recent study [10] have strengthened the claims made by Vernazza et al. The study by Donnell et al. of 3,400 HIV serodiscordant heterosexual couples from seven African countries shows that ARV use by the infected person was accompanied by a ‘92% reduction in risk of HIV-1 transmission to their partner’ [10] (p. 2096). A total of 349 participants initiated ARV therapy during the study, thus allowing the investigators to compare HIV transmission before and after starting treatment. This provides valuable empirical evidence for the prevention benefit of ARV therapy—at least for heterosexual serodiscordant couples. Although these findings are observational, they indicate that under the conditions set out by Vernazza et al., HIV transmission can be dramatically reduced if not eradicated within serodiscordant couples.

Social voice

What has social science to add? Social research has demonstrated that people are influenced by biomedical research findings and indeed many people interpret and act on such research findings before their clinicians or health promotion experts have recommended that they do so. The findings with regard to ‘undetectable’ viral load are no exception.

Australian social research has shown how gay men, using the findings of biomedical research, have fashioned harm reduction strategies for themselves. These strategies have included: use of one’s own and one’s sexual partners’ serostatus—negotiated safety [11–13], positive-positive sex [14] and, more generally, serosorting [15, 16] and strategic positioning [17]. More recently, but certainly before the publication of the Swiss statement, a study demonstrated that a small minority of gay men were using the strategy of ‘reliance on undetectable viral load’, that is, dispensing with condoms when engaging in anal intercourse within serodiscordant regular/committed relationships when the HIV-positive partner’s viral load was undetectable [18]. This finding was confirmed [19, 20], particularly for HIV-negative men whose HIV-positive partners’ viral load was consistently undetectable for a period of two years or more.

These findings highlight that sexual practice is modified in response to biomedical information including information about potential reduction of HIV transmission risk in cases where the HIV-

positive person has an undetectable viral load. The genie is out of the bottle—and indeed had escaped before the publication of the Swiss statement.

Although some heterosexual couples remain sceptical, a similar turn to unprotected sex has been found among some serodiscordant heterosexual couples in Sydney, Australia [21]. As Persson notes, decisions by heterosexual couples to use condoms are not solely based on calculations of risk but by intimacy, a desire to reproduce, and a range of emotional and relationship priorities. The Swiss Statement, she argues, will be of benefit to those who are committed to protected sex as information about ARV therapy and undetectable viral load may alleviate anxieties in the case of condom breakage. While for those already practising unprotected sex, it will outline the conditions that will enable them to do so more safely.

Given that social research evidence indicates that people act on the basis of what they understand about ARV therapy and viral load, then people need to be informed about ARV therapy and its preventive effects. As Garnett and Gazzard [5] point out: ‘Denying an effect of treatment on risk of transmission would be dishonest and futile’ (p. 270). As Vernazza et al. [4] rightly argue, it is important for HIV physicians to respond and, when counselling and advising patients, provide a balanced estimate of risk over the course of many sex acts.

There is a relatively straightforward policy outcome when the focus is on individuals and the protection of serodiscordant couples, but what of the ‘test and treat’ strategy proposed by Granich et al. where the focus is on ARV therapy as a public health prevention measure rather than as an individual harm reduction strategy?

The public health argument: Population protection

Using the South African HIV epidemic, Granich et al. [1] model the impact of testing all adults annually and immediate ARV therapy for all persons diagnosed with HIV. They conclude that such a strategy, now referred to as ‘test and treat’, would reduce annual HIV incidence and mortality to less than one case per 1000 people within ten years and would reduce the prevalence to less than 1% within 50 years. In a follow-up paper [22], they elaborate their argument for treating early and argue that starting earlier—CD4 counts at above 200 or 350 cells/mm compared with lower than 200 cell/mm—is better in terms of mortality and TB rates. They also claim that in cases of acute illness, treatment should be started as soon as possible. However their major claim is that prevention is possible with universal testing followed by immediate ARV therapy for all those diagnosed as HIV positive. This claim is a very seductive one because if correct the test and treat strategy would lead to at the very least a dramatic reduction in HIV transmission.

“Social research has demonstrated that people are influenced by biomedical research findings and indeed many people interpret and act on such research findings before their clinicians or health promotion experts have recommended that they do so.”

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“This claim is a very seductive one because if correct the test and treat strategy would lead to at the very least a dramatic reduction in HIV transmission.”

Because it is so seductive, it is this claim that needs careful scrutiny.

A number of researchers have raised concerns about the assumptions of the model used by Granich et al., some others have voiced concerns in relation to human rights, while still others have raised questions about the long-term effectiveness of the ‘test and treat’ strategy. With regard to the modelling, a number of epidemiologists have argued that the model does not show that HIV elimination is possible [23–26]. Ruark et al., (2009), Wagner and Blower (2009), Wilson (2009), and Dodd et al. (2010) all argue that the assumptions of the Granich model depend on the epidemiological context and that failure to capture important features of the context can generate over-optimistic projections .

The human rights issues are significant. A group of independent experts advising UNAIDS on HIV and human rights [27] voiced concerns that: ‘the ... model does not really address the issues of acceptability and safe applicability of universal testing and treatment in the face of widespread stigma and discrimination. Nor does it address the risk that governments will fund and implement coercive biomedical and other approaches instead of empowering individuals through information, education and access to a range of HIV-related services’ (p.1).

Dodd et al. point to the importance of incorporating local behavioural data into more detailed models of HIV transmission [26]. In a paper that addresses the use of ARV therapy for both people living with HIV—the ‘test and treat’ strategy, and people who are uninfected by HIV—the pre-exposure prophylaxis strategy, Cohen and Gay provide ‘a sober view of the actual potential of [ARV therapy] for prevention of HIV infection’ [28] (p.S85). In their review of the literature the authors point to the possible preventive benefit of the use of ARVs being undermined by behavioural disinhibition, and to problems associated with ARV resistance. Others too have noted that the effect of ‘test and treat’ is likely to be a function not only of biological and clinical factors, but of behavioural and social factors [29, 30]. One recently published paper referred to above [10] assessing the impact of treating the infected partner in a serodiscordant couple does attempt to address the issue of behavioural disinhibition. While their study showed that initiation of ARV therapy did not lead to either increased sexual activity or decreased condom use in the heterosexual couples studied, the authors note that the follow-up time in their study was short when compared with the lifetime duration of treatment needed by those who begin ARV therapy. As Donnell et al. note: ‘Reliable information is needed about the long-term transmission benefits and behavioural risks associated with [ARV therapy]...’ [10] (p.2097). It should also be noted that the participants living with HIV and who initiated ARV therapy

in this cohort study reported very low rates of unprotected sex: unprotected sex was reported at only 6.2% of all follow-up visits before initiation of ARV therapy and this proportion fell even further to 3.7% after starting ARV therapy.

The best and the worst of public health

There are two major questions that fuel the debate between those urging caution and those urging action with regard to ‘test and treat’. The first concerns what Garnett and Baggaley rightly refer to as a conflict between individualism and utilitarianism [31] (p.10). As they argue, the ‘test and treat’ strategy ‘reflect[s] public health at its best and its worst’ (p.11). Assuming that the model is correct, at its best the ‘test and treat’ strategy would reduce morbidity and mortality for the population, both through better treatment for people living with HIV and a reduced spread of HIV. At its worst, the strategy would lead to over testing, over treating, resistance problems, and for those on ARV therapy, the risk of additional side effects, both in the long and short term. In short the public health gains for populations at large are likely to place large number of individuals at risk—of side effects, resistance problems, and discrimination and stigma. For as Garnett and Baggaley also point out, the partial success of the ‘test and treat’ strategy could lead to infection becoming concentrated in those at high risk of infection, with an increased danger of stigma and coercion [31].

Notwithstanding the above arguments and while noting that more research is needed to investigate the efficacy of ARV therapy as prevention, the relationship between stage of infection and transmission, the development of drug resistance, behavioural disinhibition, the ability to reach populations and implement annual universal testing, and the cost effectiveness of ‘test and treat’, a number of researchers support the strategy—at least in a qualified fashion, e.g. Dieffenbach and Fauci [32]. In the influential IAVI Report, Fauci outlines a triumvirate of HIV prevention strategies: the development of a preventive HIV vaccine; ‘test and treat’, which calls for universal HIV testing and immediate treatment of those infected; and pre-exposure prophylaxis, which involves delivering ARVs orally or in a microbicide gel to uninfected individuals [33].

The ‘test and treat’ approach is also supported by WHO and CDC: both bodies have endorsed the strategy as a way of reducing if not eliminating HIV transmission—especially in developing countries. And it is interesting to note that while these two bodies were ‘luke-warm’ in their response to the Swiss Statement, they are far less cautious about the ‘test and treat’ strategy as outlined by Granich and others. A Fact Sheet released by WHO in 2009, stated that: ‘A large majority of people living with HIV remain undiagnosed. This probably remains the largest

barrier to prevention and treatment efforts.’ [34] (p.2). Furthermore an editorial published in the Bulletin of the World Health Organization states that: ‘There is little doubt that [ARV therapy] has preventive effects; what is uncertain is how best to apply it and combine it with other evidence-based prevention interventions for maximal synergy and benefit.’ [35] (p.488).

In part because HIV prevention is being seen as stalling or failing [36] and HIV prevention research, including vaccine evaluations, have produced discouraging results [35], the response of some countries has been to roll out testing as prevention or as an aid to prevention. While the proposed change in policy is highly controversial, the pressure is mounting to ‘test and treat’ as an HIV public health prevention strategy.

Social Voice

What have social researchers to say—especially about: 1) evidence regarding the effectiveness of the ‘test and treat’ strategy; and 2) the concern about stigma?

While the debate with regard to modelling is essentially a debate about whether certain assumptions are justified or not, there are few studies that have addressed the effectiveness of the ‘test and treat’ strategy in the ‘real world’. Clearly some in public health are concerned about behavioural disinhibition and ‘context’ [26, 29, 30]. Advocacy Director of the AIDS Foundation of Chicago, Jim Pickett, has also recently expressed his concern about the current moves in San Francisco to offer ARV therapy to all patients testing HIV positive. He asks: where is the evidence that starting people living with HIV on ARV therapy when their CD4 count is 500, 700 or 900 t-cells is good for their health; and where is the evidence that putting everyone on ARV therapy will reduce HIV transmission and eradicate or greatly reduce HIV infection? [37]

Turning to the issue of reduction/eradication of HIV transmission, even if the assumptions of the model are met, the effectiveness or otherwise of the ‘test and treat’ strategy relies on a very large number of factors. Some of these relate to the capacity of health systems to provide the necessary treatment, monitor viral load, respond to treatment resistance, and decrease rates of sexually transmissible infections in population/s, and so on. Others relate to social factors including: the patterning of sexual practice and rates of protected and unprotected intercourse in population/s; changes in sexual practice as information about ‘test and treat’ becomes widespread; rates of HIV testing; and attitudes towards people living with HIV, and associated levels of stigma in population/s.

While Donnell et al. report a 92% reduction in HIV transmission amongst their serodiscordant couples on ARV therapy [10], a recent study found that in the Australian context of affordable

access to ARV therapy, the per-contact risk of HIV transmission in gay and bisexual men had not significantly changed since before the introduction of ARV therapy in 1996 [38]. As the authors put it: ‘Despite a more than 10-year gap from the last estimation of HIV transmission risk in homosexual men and the substantially improved treatment availability, the per-contact risk of HIV transmission with an HIV-positive partner does not seem to have reduced.’ (p. 912). While the unexpected absence of a downturn in HIV transmission in this population may be because HIV transmission by anal intercourse is not as closely related to viral load as it is in vaginal intercourse, or because of the relatively high levels of sexually transmissible infections in this population, it may also be because of behavioural disinhibition. Given the findings from the earlier studies referred to above demonstrating the influence of biomedical knowledge on sexual practice—among gay men and among heterosexual men and women—it is likely that behavioural disinhibition is playing some role.

We clearly need more research monitoring the potential impact of the ‘test and treat’ HIV prevention strategy on sexual practice, especially in relation to behavioural disinhibition but also with regard to the understandings that people—those living with HIV and those not, as well as those in regular and committed relationships and those not—have about the preventive impact of ‘test and treat’.

The second issue on which social scientists have something to offer is in relation to the impact of an increased pressure to test as part of the ‘test and treat’ strategy. First of all, how are high rates of HIV testing achieved and sustained—at least in sub-Saharan Africa, if not elsewhere? Indeed in low and middle income countries, the proportion of people never tested for HIV remains high at around 80% [39]. Even if and when HIV testing coverage and rates increase, researchers will need to monitor closely the impact of increased testing on sexual risk as well as the impact of HIV testing—particularly if it is provider initiated—on levels of stigma in the community. With regard to sexual risk taking, while counselling in association with HIV testing ‘appears to provide an effective means of secondary prevention, i.e. decreasing the likelihood of infected individuals infecting others, it does not appear effective in primary prevention ...’ [40]. Shelton notes that although there is some evidence supporting an effect if counselling and testing is done well, the approach is limited [41]. More disturbingly, there is evidence from Zimbabwe indicating that not only is counselling and testing ineffective for people who test HIV negative, but that it may have the serious unintended consequence of increasing risk behaviours [42]. What will be the impact of repeat HIV-negative test results? It is possible that increased testing will lull those who continually test HIV-negative into a false sense of security.

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“...what is the potential that increased testing—particularly provider-initiated testing—will increase stigma and discrimination?”

With regard to stigma, what is the potential that increased testing—particularly provider-initiated testing—will increase stigma and discrimination? In many countries such as in sub-Saharan Africa, testing uptake remains poor and many continue to avoid testing because of fear of discrimination and stigma [43, 44]. As noted above, the independent experts who serve on the UNAIDS Reference Group on HIV and Human Rights have expressed concern and have called for ‘full consultation with and participation by people living with HIV who are fully aware of the daily realities of stigma, violence and discrimination ...’ [27] (p.2). At present no such consultations have occurred and indeed at least one person living with HIV, Jim Pickett, has expressed concerns about the current state of affairs regarding access to care and treatment in the US, where he claims that half of all people in need of HIV treatment—around 500,000—do not have such access. Although the economic feasibility of the ‘test and treat’ strategy is not taken up in this paper, the costs of ARV therapy and related health infrastructures needed to implement this public health strategy of ‘test and treat’ will certainly raise issues about discrimination in relation to access to treatment and care.

Conclusions

The voice of social science has been relatively quiet, in part I believe because social science has been increasingly marginalised in HIV-related research [45]. However I do believe it has something to offer. With regard to ARV therapy as prevention in the context of an individual focus and protection of HIV-negative partners in serodiscordant couples, the social science findings, taken together with the biomedical and epidemiological findings, indicate unequivocally that people living with HIV and those with whom they have sex need to be properly informed so that they can make decisions with regard to preventing the transmission of HIV. Clearly the evidence to date indicates that such decision-making is influenced not only by the wish to avoid the risk of unprotected sex, but also by the desire for reproduction, as well as reasons associated with intimacy and pleasure. Although not 100% safe, the harm reduction strategy of negotiated safety developed on the basis of the knowledge of one’s own serostatus and the associated educational program, ‘talk test test trust’ [46] has enabled many to sustain ‘safe’ sex. If this strategy for dispensing with condoms under certain very strict conditions can be made ‘safe’ as the evidence suggests [47], there is no reason that the same cannot be done in the context of knowing one’s viral load. However a strategy and associated educational program needs to be developed by health carers, educators, those living with HIV and their sexual partners, and the special conditions specified to ensure that the strategy is as safe as possible.

“...people living with HIV and those with whom they have sex need to be properly informed so that they can make decisions with regard to preventing the transmission of HIV.”

“...The way in which peoples and populations will interpret the biomedical findings is likely to vary depending on how testing is rolled out and the conditions under which treatment is initiated.”

With regard to questions relating to a public health focus and population protection, the issue is more complex and the need for social science greater. In relation to behavioural disinhibition, for example, a number of scenarios are possible. The way in which peoples and populations will interpret the biomedical findings is likely to vary depending on how testing is rolled out and the conditions under which treatment is initiated. In the worst case scenario, on the basis of a universal ‘test and treat’ strategy, people are likely to believe that they and/or their sexual partners—either regular or casual—have an undetectable viral load and that they can dispense with condoms. The best case scenario would be if people dispensed with condoms only under very strict conditions as set out, for example, in the Swiss Consensus Statement [4]. While clearly the concept of ‘treatment as prevention’ implies changes in screening and testing for HIV, as Dabis et al. note, the sorts of changes that are needed have not been specified [48]. Indeed no conditions have been specified, rather there appears to be a push to test and treat all.

Social and political science input is central if an HIV ‘test and treat’ population strategy is to be effective. While the strategy may give rise to some positive unintended outcomes, it is imperative that any negative consequences, such as behavioural disinhibition, risk compensation and increases in stigma and discrimination, be avoided [49]. For ‘treatment as prevention’ to have the desired effect, that of a dramatic reduction in HIV transmission, policies need to be informed not only by the work of Vernazza et al. [4] and Granich et al. [1]. A successful response needs the expertise of social and political scientists to ensure that ‘undetectability’ is not misunderstood by individuals who will make decisions to test and to treat, by communities in which norms regulating responses to test and treat will emerge, and by governments who will make decisions about whom to test and treat—as well as when and how.

Social scientists must continue to challenge some of the taken-for-granted assumptions in these debates. The relationship between prevention and testing and treating is a complex one. The move, which began with the advent of ARV therapy in 1996, to collapse prevention into treatment is, I believe, a factor in the so-called ‘failure of HIV prevention’ in many countries ... but that’s an argument for another paper, or book.

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Abstract

The release of the 'Swiss Statement' in early 2008 re-initiated an international debate about the impact of antiretroviral (ARV) therapy on reducing the probability of sexual transmission of HIV. This debate quickly moved beyond the focus of the statement, which was about the risk of transmission among serodiscordant couples in certain limited circumstances, and now encompasses the role of treatments in arresting the growth of the HIV pandemic. This article reviews some of the key responses to the Swiss Statement, and the advice given to serodiscordant couples and people living with HIV (PLHIV). The Australian response to the statement is considered in relation to the history of messages about HIV treatments and infectivity.

The controversy created by the statement has overshadowed the good news story about the significant role of effective HIV treatments in reducing HIV transmission risk from PLHIV. This controversy has meant missed opportunities in reducing the stigma associated with HIV. It may be that the intense attention to the question of transmission in the context of treated PLHIV has distracted HIV educators and policymakers from factors that may make a much greater contribution to new HIV transmissions.

The ‘Swiss Statement’: policy and health promotion responses

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Introduction

In January 2008 the Swiss National AIDS Commission released a statement outlining their view that under certain conditions people living with HIV (PLHIV) on effective antiretroviral (ARV) therapy were not sexually infectious [1]. The statement was intended as information for Swiss doctors who were providing advice for people in stable serodiscordant relationships about assessing HIV transmission risks. The required conditions were:

- perfect adherence to the antiretroviral therapy regimen
- regular monitoring by the treating physician
- viral load undetectable for at least six months (i.e. below 40 copies/ml)
- no concurrent sexually transmissible infections (STIs)

The authors of the statement also emphasise that the decision whether or not to suspend the use of condoms is incumbent on the seronegative partner. This is based on the understanding that it is s/he who is ultimately taking the risk, however small, of potentially becoming infected with HIV. This aspect of the statement has received surprisingly little attention from those who joined the debate about it.

When the ‘Swiss Statement’ was released, it caused controversy around the world. Could it be true that PLHIV on effective antiretroviral therapy cannot infect others, and what are the implications of that on HIV education and health promotion for PLHIV? In responding to the statement from Australia, from the view of HIV education and health promotion, I’ll address it head-on but also look at where a response could lead us.

The first problem in responding to the statement is that the most crucial part of the statement—that is that people on antiretroviral therapy are not sexually infectious—is contested by other HIV experts. The only agreement is that there is strong evidence about the relationship between an individual’s viral load levels and infectivity [2]. There is disagreement about the degree of benefit from successful antiretroviral therapy in reducing sexual transmission risk, and about the durability of this benefit. The following have been identified as challenging the conclusions in the Swiss Statement:

- breakthrough viral blips
- genital shedding of HIV
- intermittent STIs (e.g. herpes)
- treatment failure and variations in viral load between clinical visits [3]

There has also been debate about whether there is a viral load level below which transmission is just not possible—or whether sexual transmission is possible at any level of HIV viremia [4]. Additionally, in Australia and other countries with large gay HIV epidemics, there have been concerns raised that there is not enough data to establish whether anal sex is in a different category of risk to vaginal sex—even in the context of undetectable viral load—and should therefore be excluded from interpretations of the Swiss Statement [5, 6]. Critics of the Swiss Statement point out that the studies of serodiscordant couples reviewed by the Swiss National AIDS Commission were studies of heterosexual couples only [7, 8].

So, if the role of HIV education is to interpret scientific data and understandings about biology, and to use these to craft advice for our communities, then responding to the Swiss Statement presents some challenges—particularly because the available data does not allow a definitive position in relation to anal sex. Much of the debate about the statement has focused on the question of its applicability to anal sex—mainly in relation to gay men and other men who have sex with men (MSM), but also among heterosexuals. The lack of an explicit reference to anal sex in the statement added to confusion in this debate. While the initial statement implicitly included all modes of sexual transmission, the authors only later made clear their intent that anal sex and MSM were included in their analysis [9]. The Swiss Statement authors based their position on the absence of reported cases of sexual transmission from PLHIV with undetectable viral load levels in European epidemiological studies; these studies of approximately 300,000 PLHIV include MSM and heterosexuals practising anal sex.

Key HIV or health organisations in various countries issued responses to the Swiss Statement, each taking different positions on aspects of the statement.

“The authors of the statement also emphasise that the decision whether or not to suspend the use of condoms is incumbent on the seronegative partner.”

“...it is important to differentiate between the role of treatment as prevention within serodiscordant couples and the preventive effects of treatment in the population.”

Australia

In July 2008, an Australasian response was published on the website of the Australasian Society for HIV Medicine (ASHM) in which ASHM, along with the National Centre in HIV Epidemiology and Clinical Research (NCHECR), the Australian Federation of AIDS Organisations (AFAO) and the National Association of People Living With HIV/AIDS (NAPWA), took the position that—at a population level—the effect of antiretroviral therapy on viral load, and STI control will not lead to a reduction in HIV transmissions, so consistent condom usage rates need to be maintained to reduce HIV infections [6]. The response is not inconsistent with the Swiss Statement, which in fact did not remove advice about continued use of condoms [10]. However, the Australasian response is more cautious about the potential benefit of ARV therapy in reducing infectivity, and therefore the risk of HIV transmission when condoms are not used.

Germany

In April 2009, Deutsche AIDS-Hilfe (DAH), the leading non-government HIV prevention organisation in Germany issued a position paper in response to the Swiss Statement [11]. The DAH response was broadly supportive of the Swiss Statement, and welcomed the increased public discussion its release had initiated on the relationship between viral load and infectivity, and the opportunities this had created for reducing irrational fear and stigmatisation of PLHIV.

The DAH response also highlights the importance of the Swiss Statement for creating new possibilities for prevention within their pragmatic framework for approaching HIV prevention, which acknowledges that some people do not seek to minimise risk to the greatest extent, but rather weigh risks against sexual pleasure.

On the question of how the Swiss Statement may apply to anal sex and MSM, the DAH statement acknowledges the lack of scientific evidence from cohort studies of serodiscordant MSM couples, but challenges the position taken in the Australasian response that the relationship between viral load and infectivity may be fundamentally different to that among heterosexuals. The DAH statement cites an epidemiological study of MSM which verified a reduction in infectivity following the introduction of antiretroviral therapy [12], and in arguing that the ‘viral load method’ is in any case safer than condoms, questions the position of those who would exempt MSM from the implications of the Swiss Statement. The DAH statement notes that for 25 years HIV organisations accepted a ‘residual risk’ in condom use (in the absence of treatments) that is higher than the estimated risks of unprotected sex in the context of undetectable viral load.

France

The French response to the Swiss Statement welcomes the contribution that widespread use of HIV treatments may make in altering the dynamics of the HIV epidemic [13]. The response acknowledges that behavioural prevention approaches have not been sufficient to arrest the spread of the HIV epidemic, and that the prospect of additional downward pressure on new transmissions from reduced infectivity provides hope that the epidemic may be sufficiently slowed so that prevalence will begin to fall. For this reason, the French response declared that the Swiss Statement created a paradigm shift in the role of HIV treatments; treatments now offer more than a therapeutic response for PLHIV. The response therefore calls for greater resources for HIV testing and treatments access, and even that physicians should consider offering HIV treatments outside current guidelines to PLHIV who have trouble sticking to safe sex. This is intended as a positive option for PLHIV, and coercion to take treatments is explicitly rejected.

The impact on attitudes to responsibility for HIV transmission is also addressed. The French response warns that greater reliance on ARVs for prevention would place responsibility for avoiding transmission solely on PLHIV. Their statement therefore suggests that the responsibility of presumed HIV-negative people is to get tested—and treated if diagnosed HIV positive. Despite the optimism about the population-level benefits of treatments, the French response rejects the proposition that PLHIV with undetectable viral load cannot sexually transmit HIV.

United States

The Centres for Disease Control and Prevention (CDC) response to the Swiss Statement notes the impact of HIV treatments in reducing HIV transmission at a population level [12], but cautions that individuals should not rely on undetectable viral load in decisions about condom use [14]. This response refers to studies which show that viral load levels in genital fluids and plasma are not always correlated, and that PLHIV on treatments may experience transient increases in viral load. The response also refers to an Australian mathematical modelling analysis which suggests that repeated exposures over time create a high probability of HIV transmission [15].

The CDC response goes further than many other responses in that it also recommended use of condoms for seroconcordant HIV-positive couples, to reduce the risk of superinfection. Like the French response, the CDC recommends that physicians consider transmission risk to others in decisions about whether to offer treatments to PLHIV.

“...also highlights the importance of the Swiss Statement for creating new possibilities for prevention within their pragmatic framework for approaching HIV prevention...”

“The response therefore calls for greater resources for HIV testing and treatments access, and even that physicians should consider offering HIV treatments outside current guidelines to PLHIV who have trouble sticking to safe sex.”

“Like the French response, the CDC recommends that physicians consider transmission risk to others in decisions about whether to offer treatments to PLHIV.”

Implications

So what does all this mean for our work with people living with HIV and at-risk communities in Australia? Clearly, our work with individuals and communities will need to be more nuanced than the broad position taken in the Australasian response to the statement. As Holt and Lee outline in their chapter in this monograph, the number of serodiscordant couples in Australia who fit all the criteria required by the Swiss Statement is actually very small. Because the size of this audience is so small, there probably isn't going to be a social marketing campaign targeting them.

However, doctors, sexual health nurses, counsellors, treatment officers, and HIV educators will need to field questions from people who do meet the criteria of the Swiss Statement—if they are not already doing so. These workers will have to address the specific situations of their clients, and, apart from considering the Australasian response, they will need to address issues like adherence, viral breakthrough, STI exposure risk and more.

HIV educators will also need to work with other HIV-positive people who don't meet the criteria of the Swiss Statement, but who may be wondering what relevance the statement has for them. They will need to address the broader contexts within which sex happens, including sex in casual settings, where STIs prevalence is high. The capacity for the statement to be misinterpreted and applied to settings beyond its intended scope is real—and possibly dangerous—although we are not yet sure how dangerous. And, rather than just dismissing the Swiss Statement, if we are to be credible, then educators will also will need to engage with the content of the statement, and include clarifying information about the relationship between viral load and transmission probabilities, particularly in relation to factors where transmission risk is increased.

Clinical markers and risk reduction strategies

Concerns have been raised that the Swiss Statement will lead HIV-positive people on treatments to abandon condom use. While it will be important that researchers monitor for any such effect, I think that a sudden big change in behaviour is unlikely because the general relationship between viral load and infectivity has been known for a long time.

We have also known for a long time that a proportion of gay men have already been using this information about clinical markers of HIV—alongside other risk reduction strategies such as strategic positioning—to inform decisions about whether and when to use condoms. Rosengarten et al. [16] were the first

to document these practices—and many other Australian researchers have built on their work over a long period [17–19]. Although there is less data, this is also true for serodiscordant heterosexual couples [20].

Health promotion campaigns

The development of risk reduction strategies in response to new understandings about HIV has a long history in gay men's sex cultures—it dates back to the adoption of condoms for anal sex as a risk reduction alternative to abstinence. Researchers like Michael Hurley [21] and Sue Kippax (see chapter in this monograph) have noted that such responses usually precede responses from health promotion and policymakers.

Debate among HIV educators about appropriate responses to gay men's deployment of risk reduction strategies relying on reduced viral load preceded the publication of the Swiss Statement. Some educators supported a harm reduction approach i.e. to assist those using risk reduction strategies to do so as safely as possible. Others supported approaches that challenged the validity or reliability of risk reduction strategies and encouraged returning to condom use to eliminate risk. The latter approach has been adopted in most Australian social marketing campaigns addressing risk reduction.

An early response to risk reduction strategies based on viral load was the *Consider This* campaign, released by the AIDS Council of NSW (ACON) in 2001. This campaign was unusual compared to its successors in that it did not suggest a re-adoption of condoms. The campaign implicitly acknowledged a link between treatments, viral load and HIV transmission risk, but it challenged risk reduction by questioning whether participants could be sure about the true viral load of their partners. The campaign addressed men who '...sometimes fuck without condoms..' and asked them to consider the question: 'he might be on treatments but do you know the viral load of the guy you are fucking with?'

Apart from *Consider This*, most Australian HIV campaigns addressing this issue have challenged the proposition that relying on undetectable viral load to avoid HIV transmission is safe. For example, the *No Worries?* Campaign produced by the Australian Federation of AIDS Organisations (AFAO) in 2001, while implicitly acknowledging the relationship between lowered viral load levels and reduced HIV transmission risk, challenged the reliability of risk reduction strategies based on that relationship.

The campaign posed the rhetorical question: 'Can I still pass on HIV if my last viral load test was "undetectable"? A response ('Yes')

“Some educators supported a harm reduction approach i.e. to assist those using risk reduction strategies to do so as safely as possible.”

was given, along with a number of statements challenging the proposition that an undetectable viral load level may preclude HIV transmission:

- an ‘undetectable’ test result doesn’t mean you’re HIV negative—it means the amount of virus in the blood is less than current tests can measure
- viral load in semen is not the same as in blood
- viral load can fluctuate rapidly due to other infections such as gonorrhoea that do not show any symptoms
- we don’t know how much HIV in semen or blood is needed for transmission

The message concluded with ‘Lower risk does not mean no risk: Condoms and water-based lube prevent HIV and other sexually transmissible infections’.

Although Australian social marketing campaigns addressing risk reduction strategies that relied on viral load have been rare since 2002, the approach of challenging the validity of the strategy and promoting condoms as the sanctioned alternative has continued. A recent development (in late 2009) has been a partial embrace of harm reduction principles in advice on risk reduction. Positive Life NSW and AFAO have released detailed specific factsheets on the Swiss Statement for PLHIV. While these resources do ultimately promote condom use in serodiscordant couples, they also provide advice on steps that can be taken to reduce harm if the couple decides to have unprotected sex [22].

Rises in HIV diagnoses and risk reduction

Why did we reduce our focus on work that addressed gay men’s use of risk reduction strategies? Around the time that AFAO and the AIDS Councils were running the *No Worries?* campaign in 2002, it became apparent that the data on rises in HIV diagnoses was looking like a national trend, rather than just a rise in one or two states. The response to this new situation of rising diagnoses was a renewed emphasis on promoting condom use. While work on risk reduction in relation to viral load continued in peer education and outreach settings, it largely disappeared from social marketing campaigns.

However, the use of risk reduction strategies by gay men has not gone away. Even if the Swiss Statement had never been released, I would suggest we would have needed to return to this discussion. Recent social research data has shown that some of the ways that gay men are deploying risk reduction strategies may be increasing HIV transmission risks. For example, recent work has suggested that HIV-positive and HIV-negative men in serodiscordant relationships may have different understandings of the role of viral load in decisions about condom use and

strategic positioning [23]. In this analysis, among HIV-negative men in serodiscordant relationships, beliefs about their partner’s viral load did appear to be a factor in decisions about unprotected sex. Unprotected sex was more likely to be practised when their HIV-positive partner’s viral load was believed to be undetectable, and this was often in combination with strategic positioning. However, HIV-positive men were just as likely to engage in UAI when their viral load was detectable as when it was undetectable. Also, strategic positioning was not used when viral load was detectable.

These findings trouble one aspect of the advice of the Swiss Statement—that it should be the HIV-negative partner that decides whether condoms are used at times when the positive partner’s viral load is undetectable. The implication of this study may be that HIV-positive and HIV-negative gay men have different perceptions of the implications of viral load levels for decisions about condom use.

Considering innovative responses to STIs

The inclusion of STIs as an exclusion in the Swiss Statement criteria has refocused discussion of their contribution to HIV transmissions, and morbidity among PLHIV. Paul Kidd has recently suggested that part of our response to the Swiss Statement should be to look at innovative new strategies to reduce the prevalence of STIs, such as chemoprophylaxis and presumptive treatment [24]. Further, he has highlighted the opportunities that the Swiss Statement provides for promoting the benefits of HIV treatments to PLHIV who may have outdated fears about side effects.

The next 1,000 infections

It is important that debate about the Swiss Statement in Australia should not distract us from identifying the most significant current drivers of increased HIV transmissions in Australia and developing innovative and appropriate responses. Epidemiologists suggest that a good way to identify the drivers of HIV epidemics is to understand the factors that contributed to the most recent 1,000 infections.

Recent work by David Wilson and others suggests that we need to better address areas where HIV transmission risks may be higher than in unprotected anal intercourse involving people on ARV therapy. In Australia it is estimated that 31% of new HIV infections may be from the 9–13% of men with undiagnosed HIV infection [25]. These significant numbers of undiagnosed PLHIV combined with rising rates of serosorting among presumed HIV-negative men creates a dangerous mix. It may be that more attention to these areas of our work will result in a bigger reduction in new transmissions than worrying whether 10, or 40, or 400 copies of HIV per millilitre might enable transmission to occur [26].

“...among HIV-negative men in serodiscordant relationships, beliefs about their partner’s viral load did appear to be a factor in decisions about unprotected sex.”

“In Australia, a useful outcome of this debate has been renewed focus on appropriate responses to gay men’s use of risk reduction strategies.”

Conclusion

While the Swiss Statement has led to a vigorous debate about appropriate health promotion and policy responses for PLHIV and their partners, it has also re-initiated a global debate about the role of HIV treatments in the prevention of HIV transmission. With PrEP trial results expected soon, this debate will soon take on new dimensions. In Australia, a useful outcome of this debate has been renewed focus on appropriate responses to gay men’s use of risk reduction strategies. Part of this reassessment will raise questions like whether our aims should be to promote a return to condom use in all contexts of serodiscordant sex, or whether a harm reduction approach is more realistic.

This article is based on a paper presented at the 20th Annual Conference of the Australasian Society for HIV Medicine, Perth (September, 2008).

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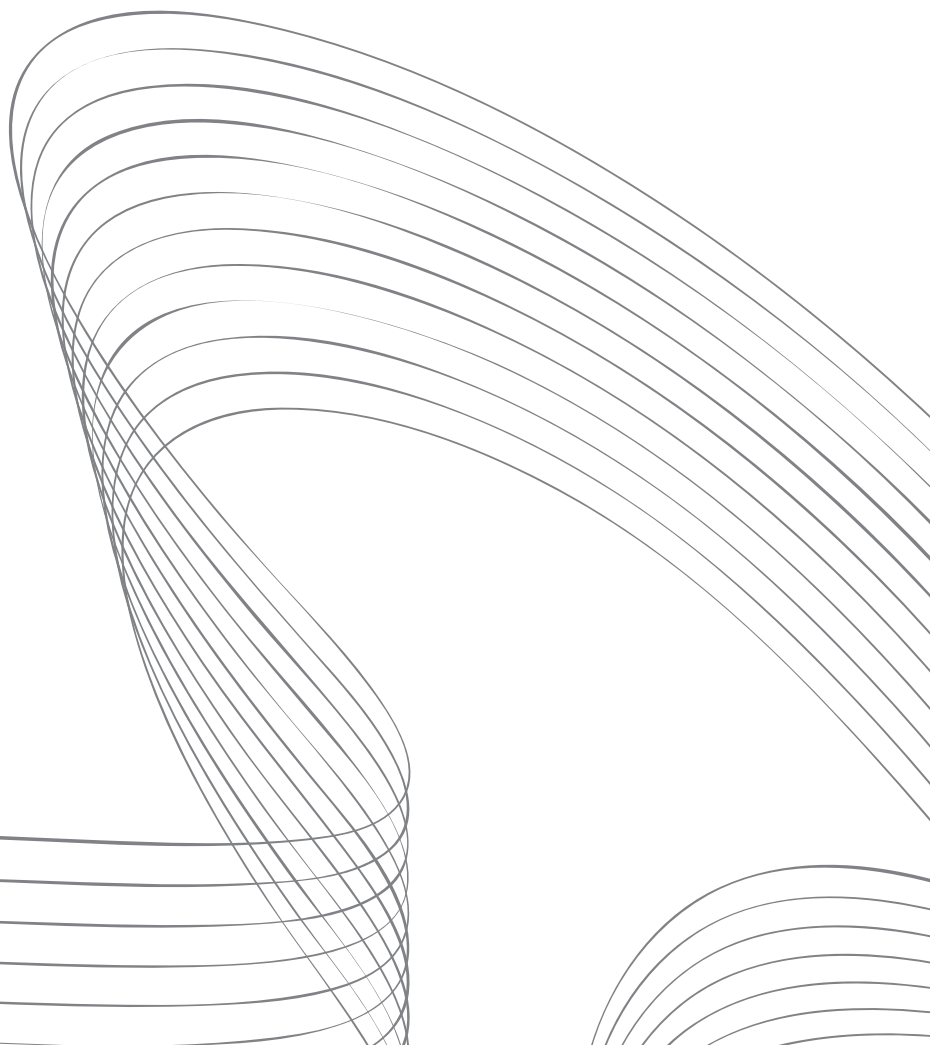
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Abstract

This paper explores HIV-positive women's accounts of using antiretroviral (ARV) therapy during their pregnancies, and of providing ARVs to their newborn babies. In-depth interviews were conducted in 2001 with 34 HIV-positive women who were diagnosed during their childbearing years. This paper reports on the 16 women who gave birth after being diagnosed with HIV. Whilst most women accepted the use of ARVs during their pregnancies and to their babies, many expressed concerns about potential toxicity and harmful effects on their babies. Three women rejected the use of ARVs during their pregnancies and several women rejected or altered the use of ARVs or prophylaxis prescribed to their babies after birth. To maximise the benefit of ARV therapy to mothers and babies, thereby reducing the risk of vertical transmission, it is imperative to understand a woman's explanation of what therapy means to her, and advisable to presume that she wants the best for her baby.



‘What about the baby?’ Women’s accounts of antiretroviral use for the prevention of mother-to-child transmission

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“HIV-positive women have the double burden of confronting threats to their own health and deciding what is best for their children...”

Introduction

Women make up only 8.6% of the population of people living with HIV (PLHIV) in Australia—a total of 1,854 women [1]. Due to Australia’s large area and moderate-sized population, these women are widely dispersed, often isolated, and almost invisible. Nevertheless, the consequences of an HIV-positive diagnosis for women are highly significant [2–3] because most women are diagnosed during their reproductive years, with the median age of diagnosis being 30 years [4]. The diagnosis of HIV in a woman of reproductive age has extensive ramifications for her life and the wellbeing of her existing and future children. HIV-positive women have the double burden of confronting threats to their own health and deciding what is best for their children, both of which are framed by the medical discourse of HIV. The HIV diagnosis also poses dilemmas for women’s clinicians in managing the best interests of women and infants.

Mother-to-child transmission can occur throughout pregnancy—in any trimester, as well as during the delivery and via breastfeeding. Without treatments, mother-to-child transmission rates are estimated to be between 15–30%. However, in 1994 the Pediatric AIDS Clinical Trial Group (PACTG) 076 study revealed that a three-part zidovudine (AZT) regime could significantly reduce the chance of mother-to-child transmission from by up to two thirds (from 25.5% to 8.3%) [5]. This finding had an enormous effect on the lives of HIV-positive pregnant women and provided many with great hope. In 1996, the introduction of combination antiretroviral (ARV) therapy further reduced mother-to-child transmission to less than 2% when used in conjunction with other interventions [6].

Use of these interventions has been shown to result in minimal vertical transmission of HIV in Australia. Ann McDonald and her colleagues reported that, in Australia between 1982 and 1999, 204 children were born to 162 women with diagnosed HIV infection [7]. Among the 50% of women who were diagnosed antenatally, use of ARV therapy increased from 14% for women whose babies were born in 1982–1993 to 88% for women whose babies were born in 1994–

1999. Mother-to-child transmission occurred in women diagnosed antenatally at 25% during 1982–1993 and 19% during 1994–1999. The rate of mother-to-child transmission was significantly lower among women who used ARV therapy in pregnancy (11% versus 36%). Notable were the 52 women who were diagnosed antenatally and whose exposed children were born between 1994 and 1999. Of these women, only 11 made use of all three recommended interventions: 1) ARV therapy during pregnancy and prophylaxis to the baby; 2) caesarean delivery; and 3) avoidance of breastfeeding. All of these women’s babies were HIV negative. Since 1996, more than 150 HIV-positive women have given birth to more than 200 babies. Most of these women were diagnosed before the birth of their baby and less than 1% of these babies were HIV positive [4].

Despite numerous clinical trials and considerable public discussion of the effects of advances in ARV therapy during pregnancy and childbirth, little attention has been paid to the perspectives of the focal population: women living with HIV and AIDS. Within a larger project studying the impact of an HIV diagnosis on women’s experience of motherhood, the research reported here aimed to understand women’s accounts of their use of antiretroviral therapy during pregnancy and as prophylaxis for their babies.

Research and methods

This paper presents some of the results from my PhD research, ‘What about motherhood?’: Women’s journeys through HIV and AIDS [8]. Thirty-four HIV-positive women who were diagnosed during their childbearing years were interviewed in 2001. Among other things, women described and explained their use of and attitudes to ARV therapy during pregnancy. Interviews were conducted at a location of their choice, recorded with permission, and transcribed. Participants volunteered after seeing a notice about the research distributed among AIDS Councils and organisations that support and provide services to HIV-positive women in Victoria, New South Wales, South Australia, Western Australia, Queensland, and the Northern Territory, or after being told about the research by another participant.

Participants were sent copies of their own transcript and asked to verify and update the account and intermittent contact was continued for six years to enable participants to update information and validate interpretations of their accounts. The iterative qualitative analysis employed a thematic framework approach [9]. Analysis was underpinned by an understanding of the narrative mode of thought [10–11], in which people make sense of their experiences through the construction of explanatory accounts. Meaning was derived from the interview as a whole rather than from isolated extracts. La Trobe University Human Research Ethics Committee approved the research. Participants gave written consent. Their confidentiality is protected by the use of pseudonyms and the concealment of identifying details in reporting results. Information about counselling and referral services was offered to each participant.

The participants

Sixteen women had given birth to 23 children after becoming aware of their HIV status. All but two of these children were born after 1994 and the introduction of the PACTG 076 protocol [5]. Only one child, born in 1994, was HIV positive. Two women were pregnant with their first child at the initial interview and updated details about their use of ARV therapy in postnatal interviews. Four women had been diagnosed during a pregnancy; all proceeded to term. Fourteen women were Australian-born—they ranged in age from 25 to 47 years and 12 women had completed high school or had tertiary qualifications. Women had been diagnosed between 1–16 years previously and only two were using ARVs at the time of the interview. Twelve women said they had acquired HIV via heterosexual sex and the remaining four via heterosexual sex and/or injecting drug use. Thirteen women were married or in defacto relationships.

Treatments during pregnancy

Most women expressed gratitude for their access to ARV therapy and acknowledged its role in improving health and longevity for many PLHIV as well as in reducing vertical transmission. Their gratitude, however, was coupled with anxiety about the toxicity of treatment for themselves and potential detrimental effects on their babies. They tended to frame treatments as experimental, referring to themselves and their children as ‘guinea pigs’. Yet, despite their concerns about adverse effects of ARV therapy, most women reported being prepared to take ARV therapy during pregnancy.

Women who had had other children in the era before ARV therapy usually embraced the opportunity to reduce the chance of vertical transmission. For example, Miranda’s second child was born in 1998 and, despite still worrying about vertical transmission, she found the

experience much easier because, ‘When we decided we wanted to have Jack, I knew about all the medication and the triple therapy so I did that, and had a booked-in Caesar, and it was much better.’ Similarly, Sophie had given birth to one HIV-negative child and was pregnant with her second when she heard about the role of AZT in reducing vertical transmission and that AZT was about to be made available in Australia. Sophie said that she seized this opportunity to increase the chances of having a second negative baby and immediately contacted the hospital to begin treatment.

Using treatment during pregnancy, however, did not free women from worry that it might have adverse effects on their unborn children. In the context of pregnant women being advised to avoid most medications, recreational drugs and alcohol, and some foods, it is not surprising that many women worried about the potential for ARVs to harm their unborn babies. Some women also expressed concern about the limited information on any long-term effects on babies of ARV therapy treatment. Olivia said, ‘They don’t know what the drugs are doing, because the kids are still small. So the girls may be infertile. I don’t know.’

However, not all women accepted treatment for either their pregnancy or for their babies. Three women, Polly, Lily and Carol, expressed grave concerns about the use of ARV therapy during their pregnancies and refused to use it. Polly was living overseas, and was diagnosed at 20 weeks’ gestation. Although treatment was advised and available, she decided it was too expensive and preferred to spend her money on ‘good food’ for herself and her growing baby. Despite being told by a doctor about a government agency that supplied free treatment during pregnancy and reading fact sheets on vertical transmission and the recommended interventions, Polly interpreted treatment as ‘pretty toxic’ and probably harmful. She said, ‘Am I going to give this sort of toxicity to my child, with some repercussion for her?’

Lily also did not trust the information she was given about the use of AZT to reduce vertical transmission. She too was concerned about the potential for the treatment to harm her unborn child, particularly given the side-effects she was experiencing:

They gave me the medicine and I took it home but I wouldn’t take it. Because they weren’t listening to me; they were just giving it and ordering me to take it. So ... [I] took it home and threw it out. I did take it for a little while but it made me sick and I told them that, but their attitude was just, ‘Bad luck’ I was saying, ‘I’ve got a baby in my body. Look what it’s doing to me. What’s it doing to him’ ... I was worried that it was going to make him deformed, but all they focused on was the HIV. But they couldn’t be sure and, as far as I knew, AZT was a killer for lots of people with HIV and they wanted me to take it.

“They tended to frame treatments as experimental, referring to themselves and their children as ‘guinea pigs’.”

“Using treatment during pregnancy, however, did not free women from worry that it might have adverse effects on their unborn children.”

“From the women’s perspective, it makes sense not to let their babies become experimental subjects.”

Carol had given birth to two children as a positive woman since the availability of ARV therapy. She also disagreed with her doctor’s advice to take ARVs during both of her pregnancies. She had a low viral load, which she continued to monitor during her pregnancies, and therefore decided that treatment was unnecessary for her babies and herself. She said, ‘During the pregnancy, they respected my decision not to take treatments. They would always re-hash: “Are you still not wanting to go on treatment?” But that was really about it.’ Carol believed she was allowed to act on her own judgement and that the risk of toxicity from the treatments to her unborn children was greater than the risk of vertical transmission. She said that if it only affected her she might have considered it but that because it could cross the placenta she ‘found that too scary.’

From the women’s perspective, it makes sense not to let their babies become experimental subjects. Taking the treatments during pregnancy and giving them to their babies represents a threat, not a solution. AZT still carries its reputation from the late 1980s and early 1990s, when excessive doses proved toxic for people living with HIV. When this is added to the psychological implications of initiating HIV treatment, at a time when women are most conscious of their health and their bodies as safe vessels for their babies, you have a powerful force of resistance against antiretroviral treatment [12].

Treatments for babies

At the time of the study, the PACTG 076 protocol and National Institutes of Health guidelines adopted in Australia recommended that babies born to HIV-positive women be given a six-week course of AZT followed by six weeks of prophylaxis to prevent PCP (Pneumocystis carinii pneumonia) should the baby be HIV positive. All but three women gave their children the full recommended treatment, although some expressed concern about toxicity and potential long-term side-effects. Most women accepted that giving the treatment was one of the final steps in pursuit of a healthy and negative baby. The accounts given by the majority of women did not dwell on their thoughts and feelings about giving their baby AZT (and, in some cases, other treatment in combination, such as 3TC). Mary’s account was typical of most women when she explained that, ‘Joel was really good with the medication. Because in the beginning we had to put it through a teat and he’d take it all right like that.’

Even women who had not disclosed to their family members found inventive ways to explain the medication with little or no questioning from their family. For example, Monica told her mother, sister and in-laws that the AZT vials were a ‘new vitamin that they recommend you use for babies who are not breastfed.’

Even among the women who were adamantly opposed to or sceptical of treatment for themselves, most were willing to comply with treatment advice for their babies. The explanation for this apparent contradiction was that they did not have enough knowledge to challenge the advice they were being given and, because it was not their own body, they could not act upon how the medication was making them feel. Lily, the only mother of an HIV-positive child in this study, had refused treatment for herself, but when it came to her son she understood this decision as not hers to make:

My body was my responsibility but as far as Zach was concerned, a child with HIV, I did not have knowledge so I had to go along with the doctors. So Zach has been on constant medication for his five years.

As mentioned in the previous section, most of the women in the study were prepared to comply with recommended treatment regimens during their pregnancy. However, this acquiescence did not always extend to giving their babies prophylaxis after birth. Brooke’s account demonstrates her interpretation of HIV medicine as an inexact science. To avoid any medical scrutiny, Brooke did not discuss her decision with her doctor:

[After a six-week course of AZT] I was supposed to give her Bactrim which I didn’t actually do but I said that I did because ... I don’t know I just thought it would be easier if I didn’t say anything. Because Bactrim doesn’t stop them from getting HIV anyway. But I just went along with it. They give it to them in case she is positive to stop her getting PCP but she might not get PCP even if she is positive so it’s a real like, if, if, if. So I just thought, Oh no, she’s not going to have it anyway, I am pretty sure.’ And it was sort of scary with the AZT. Why is it six weeks you have to give it to her, why is it not four or why not eight? Apparently it’s just from previous tests that have worked so why change it if it works but I was thinking, oh maybe I should skip the last week but then when it comes to it I was a bit scared to do it. But I think she missed the last day. Because you think, she might not even need the AZT, she might be negative anyway. You just don’t know.

Miranda and Olivia’s thoughts were similar. Miranda gave her son the treatment but did not give him any of the prophylaxis, saying, ‘I didn’t even get the script filled ... In the end, I just thought, oh, he is having enough.’

When Carol was pregnant with her second baby, she and her husband decided not to treat their newborn baby. They believed the risk associated with the treatment was greater than the likelihood of their baby being HIV positive. Despite preliminary discussions with her specialist, Carol understood this decision as

hers to make. This disjunction between maternal and medical assessments of her baby's welfare resulted in legal proceedings and the involvement of community services in the administration of treatment to Carol's baby twice a day at her home for the first six weeks of her baby's life:

On the day of her birth, we actually ended up in court. The hospital was forcing treatment on her, so she was actually treated through a court order and we had hospital staff coming around twice a day to administer the AZT. ... It was four hours after she was born and we were ready to go home and they walked in with the detention order to detain her.

Carol also decided against giving her daughter the PCP prophylaxis, thinking it was extremely unlikely that her daughter was HIV positive. To avoid further medical or legal scrutiny, Carol filled the prescription, but didn't administer the medication.

Conclusion

Although women were largely willing to follow protocols to reduce the risk of vertical transmission, most of the women in this study explained ARV therapy as not unequivocally benign for either themselves or their babies. They described experiencing or being aware of debilitating side-effects and those taking ARV therapy discussed the lack of scientific explanation for many of their experiences with the treatment. It is not that these women did not understand the scientific discourse that drives the protocols for mother-to-child transmission. Rather, these women identified for themselves a primary role as protectors of their children, including protection against the medical fraternity. The history of ARV therapy is not one of clear and consistent efficacy and most women were very aware of the trial and error that has preceded the treatment that is available today [13].

The imposition of unwanted advice can violate the patient's autonomy as well as paradoxically driving the patient into a defiant rejection of the health-care worker's advice [14]. In order to provide effective and appropriate health care for women living with HIV and their babies, health care professionals need to consider the mother's perspective. What does ARV therapy mean to her? What is her previous experience with ARV therapy? What are the public discourses that may be influencing her to deal with therapy in ways that may seem in conflict with her medical advisors? The interpretive and explanatory systems of mothers need to be taken in to account in exploring the benefits of ARV therapy. This research indicates that confrontation is counter-productive; explanations that take account of the meaning of therapy to the woman and assume that she wants the best for her baby may be more beneficial to all concerned.

Limitations

Although this study is the largest national study of HIV-positive women in Australia, making available rich data from a hard-to-reach population, conclusions are inevitably based on a limited number of participants. Most women are Australian-born Caucasians. The interviews were conducted in 2001 (five years after the advent of highly active antiretroviral therapy) and more research is required in this area to confirm women's attitudes to treatments in the prevention of mother-to-child transmission.

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A full version of this paper has been accepted for publication in AIDS Care [15].

"...these women identified for themselves a primary role as protectors of their children, including protection against the medical fraternity."

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Abstract

Since the beginning of the HIV/AIDS epidemic in Australia the cornerstone of prevention messaging directed at gay men has been to emphasise the use of condoms and water-based lubricant when engaging in anal sex. With a variety of chemo-prevention options either being currently used (post-exposure prophylaxis, undetectable HIV viral load), or in development, (pre-exposure prophylaxis, microbicides) it would appear that sexual health promotion directed at gay men to prevent HIV acquisition and transmission may be about to undergo major change.

If these chemo-preventive options result in offering gay men protection against HIV acquisition and transmission that is equivalently effective as the use of condoms and water-based lubricant, the challenges these advances will pose for sexual health promoters will be complex since, in all likelihood, the circumstances under which gay men will be protected from onward transmission of HIV in this context will be highly conditional.

Defiance, imagination, guesswork and the real world: A sexual health promotion perspective on treatment as prevention

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“...it is timely to examine how gay men have adapted to prevention technologies and techniques other than condoms, and what those strategies have meant to health promotion.”

Introduction

We seem poised on the brink of a whole new world of chemo-prevention with the promise of PrEP, microbicides, recommendations for treating people living with HIV with antiretrovirals to prevent transmission to their partners, and the ongoing utility of PEP. Consequently, it is timely to examine how gay men have adapted to prevention technologies and techniques other than condoms, and what those strategies have meant to health promotion.

From the time when it was determined that gay men would need to use condoms to eliminate the risk of HIV transmission and/or acquisition it would be fair to say that our relationship with latex has been troubled. As health promoters we were never able to sexualise condom use in an erotic way and all the way through the 80s, 90s and into the new millennium we have qualified every risk reduction message with the caveat that condoms and water-based lube are the best protection from HIV and other sexually transmissible infections (STIs). In the absence of any equivalent form of protection, this strategy is not going to end anytime soon—even if chemo-prevention shows modest efficacy. This article outlines some reasoning behind this statement.

Then and now: 1993

As early as 1992 the Victorian AIDS Council / Gay Men's Health Centre implemented a campaign called *Because we want to be together*. In this campaign, health promoters, (or gay educators as we were then known) outlined the strategy that was to later become known as 'negotiated safety'. In the campaign material, peer education workshops, outreach and one-on-one interactions, we set out the pre-conditions for giving up condoms safely within primary relationships. These pre-conditions included:

- that anal sex with partners outside the primary relationship needed to be safe (i.e. with condoms and water-based lube at all times)
- both partners needed to be tested for HIV, if those initial tests came back negative
- anal sex within the primary relationship needed to maintain condom use for the next three months

- after three months, follow-up tests for HIV antibodies would be done
- if those tests came back negative and if each partner had maintained safe sex practices outside the relationship (and had committed to continue to do so), then—and only then—was it considered safe to stop using condoms in that relationship.

However, the campaign still advised that really, the best way to avoid transmission or acquisition of HIV was to use condoms and water-based lube when engaging in anal sex. The suggestion being, if you are faced with a choice between condoms on one hand, or relying on the honesty of your partner on the other, then perhaps it would be prudent to stick to latex after all.

Now and then: 2009

Leaving aside the cynicism of the previous approach mentioned above, it is instructive to compare the 1993 campaign to one created 17 years later, which also outlines a potentially safe way for couples to dispense with condoms, this time for men in serodiscordant relationships. In 2009, Positive Life NSW implemented a campaign called *Sero-disco* and it included an advertisement that was a response to the Swiss Consensus Statement [1] (the 'Swiss Statement'). The advertisement set out the pre-conditions¹ for the small proportion of gay men in serodiscordant relationships² to dispense with condoms in their primary relationships. They included:

- that the positive partner's viral load be stabilised beneath the level of detection for at least six months
- that the positive partner was adherent to their medication schedule at all times;
- that they have no concurrent STIs or viral infections that could cause a transient increase in HIV viral load;
- that all anal sex outside the primary relationship be with condoms and water-based lube.

The advertisement concludes that the most effective way for protecting yourself and your partner from HIV is to use condoms and water-based lube when engaging in anal sex. The campaign sensibly suggests caution when attempting to apply the suppositions found in the

¹ Assuming that the Swiss Consensus Statement conclusion about the negligible risk of HIV transmission in heterosexual individuals who are treating with antiretrovirals and who have undetectable viral load could be extrapolated to homosexually active men.

² See Holt and Lee article in this collection.

‘Swiss Statement’ based on heterosexual activity to gay men. Still, the condom caveat applied.

“...highly conditional prevention messages have limited comprehension when applied at a population level.”

Conditional messaging

If experience has taught us anything over the last 26 years of prevention initiatives, it's that highly conditional prevention messages have limited comprehension when applied at a population level. If we take the example of negotiated safety, even after 17 years of awareness, education and campaigning, the strategy is poorly understood and sometimes misapplied [2, 3]. And in the case of post-exposure prophylaxis (PEP) awareness, the same kinds of misunderstanding apply. The most recent periodic data referring to PEP awareness and comprehension indicates that 34% of gay men in the sample were not aware that PEP was available and of those who were aware of it 64% were unsure of when it needed to be taken [4].

It is perhaps not surprising that this problem of communicating conditional public awareness messages is not limited to HIV or to gay men. The Transport Accident Commission in Victoria has indicated that the majority of drivers who are booked as being at .05 alcohol limit or just over, insist that they had stayed within the limit (of two standard drinks in the first hour and one standard drink per subsequent hour) when clearly, they had not [5].

The challenges of chemo-prevention

Given that there are a number of problems in communicating highly conditional prevention messages, any perusal of where gay men are in relation to their understandings of HIV, treatment and relative risk in 2010, make for sobering reading for those of us who are charged with the responsibility of negotiating the terrain of sexual health promotion, chemo-prevention and gay men. Recent research suggests that gay men do not hold overly optimistic views about the role of ARV therapy in reducing HIV transmission [6]. For example, only half (48%) of the men surveyed disagreed that undetectable viral load makes it unlikely that HIV could be passed on (32.8% said that they didn't know), and three-quarters (79.6%) disagreed that HIV-positive men who are on treatments are unlikely to pass HIV on if they fuck without condoms. Also, 83.9% did not believe that HIV treatments take the worry out of sex. In terms of their actual practices, more than three-quarters (79.3%) disagreed with the statement, 'I fuck without condoms more often because of HIV treatments' (pp. 90–91; 94).

So it would seem that fears about gay men using clinical markers to determine risk—and that perceptions of the reduced seriousness of HIV meant that they are also more relaxed about safe sex—are incorrect, or at least incorrect for the majority of gay men. Similarly, with regard to pre-exposure prophylaxis (PrEP), it has been suggested at community meetings and

prevention think-tanks that gay men are not waiting for clinical trials but are already using ARVs as pre-exposure prophylaxis. However, studies in the United States have shown low levels of awareness of PrEP among gay and bisexual men, and very low levels of non-prescribed use of antiretroviral drugs among HIV-negative men as a prevention strategy [7–9].

Potentially compounding the complexity of the task at hand is the possibility that a combination chemo-prevention approach may offer gay men the best chemical protection against HIV transmission and acquisition with potentially a level of protection equivalent to condoms—for instance, PrEP for the negative partner and a regimen of antiretrovirals that maintains the HIV viral load of the positive partner to below the level of detection. If this turned out to offer close to 100% protection, then it would be possible to dispense with the condom caveat for those people who wanted to use these forms of prevention. But even once that day dawns it would seem that there could be further issues raised which could muddy prevention messages. In 2009 the AIDS Vaccine Advocacy Coalition (AVAC) and the Centre for HIV Identification Prevention and Treatment Services (CHIPTS), as well as others, held a meeting to discuss issues related to the potential impacts of PrEP on communities and community-based organisations as the results of PrEP studies become known. At the meeting, concern was expressed by representatives from the Centres for Disease Control and Prevention (CDC) that if these forms of chemo-prevention were to be taken up by gay men (once they were proven to be efficacious) it would lead to what is termed 'behavioral disinhibition'. However, when asked, they could not articulate what 'disinhibition' would mean in the context of chemo-prevention where the intervention had been proven to work.

Engaging gay men

The future challenges set out for us in communicating these shifts in the prevention landscape aren't just in the complexity of the science or the fact that it is possible that these technologies may only be applicable for a small portion of gay men—the challenges lie at a more fundamental level in the ways we engage with gay men. Whilst it is right that we concentrate on the relativities of risk, the mechanics of transmission under various circumstances and the science that may provide protection—that is, after all our job—we run the risk, as sexual health promoters, of being considered irrelevant safe-sex technocrats unless we find ways of facilitating a real and substantive exchange with gay men about how we have sex and how we live.

In the vibrantly creative ways in which gay men have adapted safer sex information during the 27 years of this epidemic we can see that our role as sexual health promoters is important, but limited,

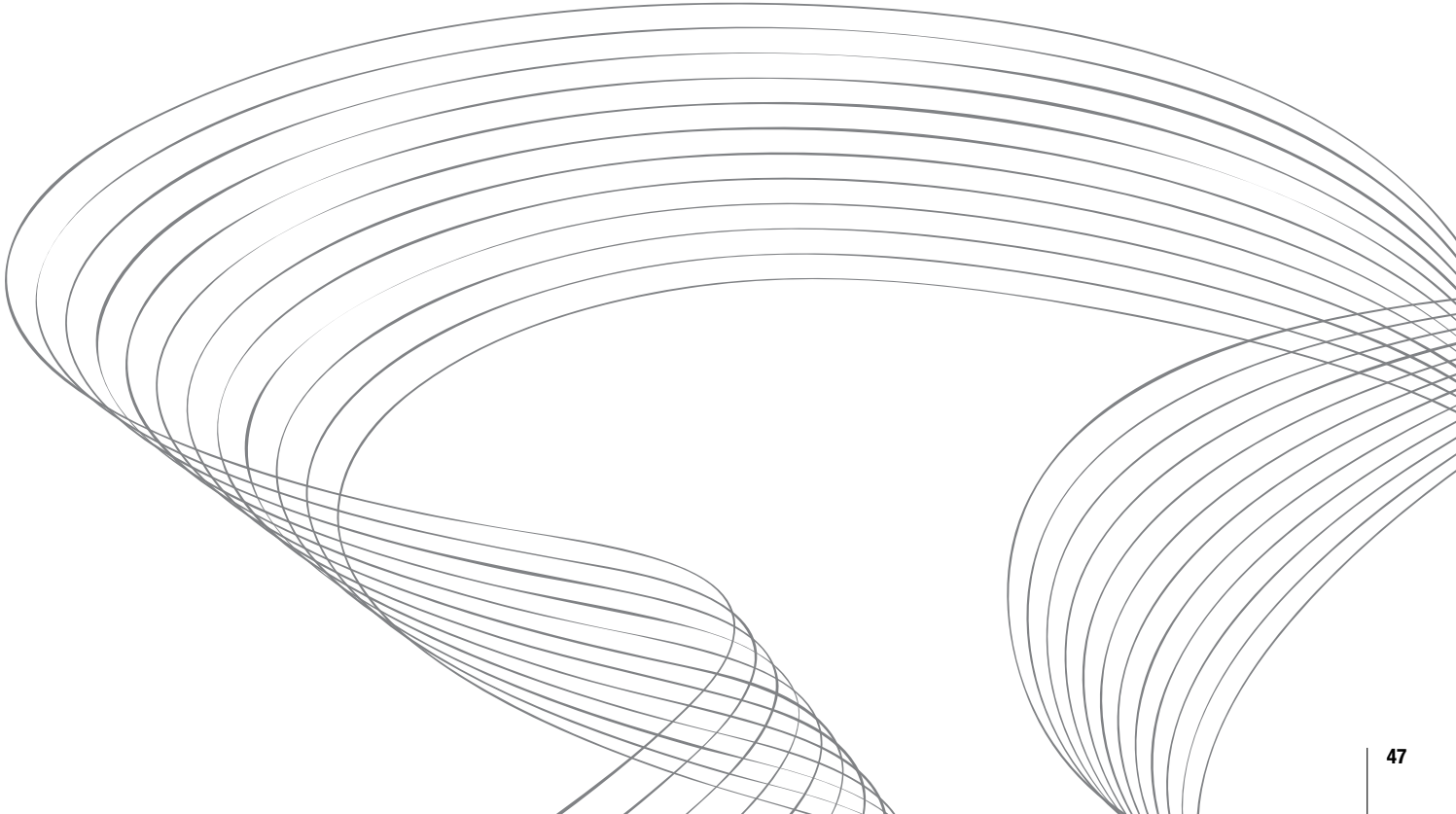
“Potentially compounding the complexity of the task at hand is the possibility that a combination chemo-prevention approach may offer gay men the best chemical protection against HIV transmission and acquisition with potentially a level of protection equivalent to condoms.”

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and in some instances it has become self-limiting. At times we have been uncomfortable with the defiant ways in which information is used in the real world and the troublesome ways in which gay men have applied guesswork and imagination in the ways in which they try to limit risk. We need to understand that the problem does not lie with gay men but rather our expectations and assumptions of them. It is going to be very important that if we are on the verge of a brave new world of chemo-prevention, that we not get bogged down or blinded by the science, but understand that these changes, any changes, need to be viewed through the complex lens of how gay men think, feel and live. This understanding needs to extend to listening to gay men talk about what they are willing to accommodate or give up in the quest for better sex and fuller, happier lives.

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