nswp

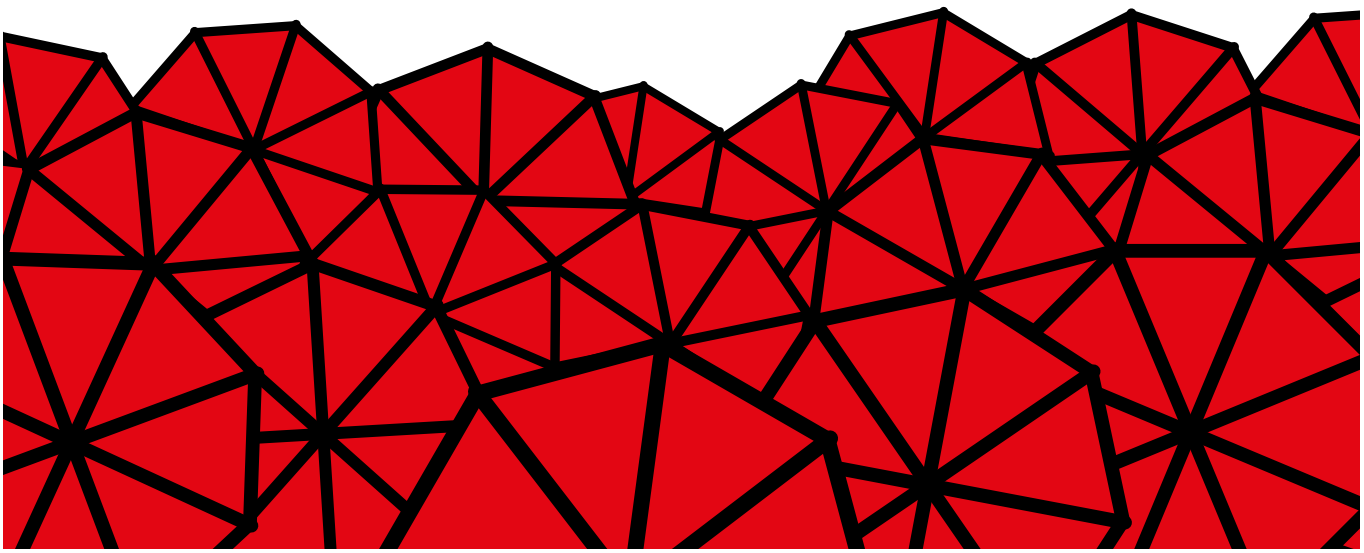
Global Network of Sex Work Projects

Promoting Health and Human Rights

BRIEFING PAPER

#04

New prevention technologies and their implications for sex workers



New prevention technologies and their implications for sex workers

"Sex workers need as many ways as possible to practice safer sex".[1] Starting with this premise, Cheryl Overs' book, *Sex Work and the New Era in HIV Prevention and Care*,[2] explores how HIV prevention technologies currently under development are likely to impact female, male and transgender sex workers. She cautions that emerging prevention tools hold both promise and potential risks for sex workers. Since they are liable to be less effective than condoms, the risks may be higher, she argues, "where sex workers are not able to resist demands by clients and sex business owners to use microbicides or PrEP instead of condoms".[3]

…it explores how sex workers' advocacy can influence the development and introduction of these tools in ways that maximise usefulness and minimise risk to sex workers

Building on this premise, this paper provides an overview of the new HIV prevention tools on the horizon, including microbicides, pre-exposure prophylaxis (PrEP), vaccines, and 'treatment for prevention'. It details the possible positive and negative impacts of these as identified by sex worker organisations. Finally, it explores how sex workers' advocacy can influence the development and introduction of these tools in ways that maximise usefulness and minimise risk to sex workers. An update on the current status of research on each new prevention option is provided at the end.

Many of the points raised in this article are discussed thoroughly in Overs' book and in other publications.[4, 5, 6] Original input for this paper was gathered from sex workers in interviews with NSWP member organisations conducted in June 2011.

New prevention tools

Microbicides and PrEP are 'primary prevention strategies' designed to help HIV negative people to reduce their risk of getting HIV. 'Treatment for prevention' is a secondary prevention strategy. It allows people living with HIV to reduce the risk of transmitting the virus to others. HIV vaccines are being developed for both primary and secondary prevention.

Anything that kills or disables microbes (such as viruses or bacteria) can be called a microbicide. In the world of HIV prevention, 'microbicide' refers to any product that is applied to the vagina or rectum before sex to reduce the risk of HIV infection or transmission. Microbicides work by either killing or disabling HIV directly, or by blocking the virus from attaching itself to vaginal or rectal cells. They are being formulated as gels, dissolving tablets and films, and in other formats (see Microbicide research section below). No microbicide is available yet on the market but dozens are being tested and in other stages of development.

1 C. Overs (2007), *Sex Work and the New Era of HIV Prevention and Care*, Bangkok: Asian Pacific Network of Sex Workers.

2 *ibid.*

3 *ibid.*

4 A. Forbes (2010), *Sex Workers and Microbicides: An Advocacy Brief*, Microbicides 2010 conference, abstract #455. Online at http://www.plri.org/resource/microbicides-and-sexworkers-advocacy-brief

5 C. Overs (2010), *Tenofovir as a Microbicide Gel: Where are sex workers in the CAPRISA calculations?* Paulo Longo Research Institute. Online at http://plri.wordpress.com/2010/08/31/tenofovir-as-a-microbicide-gel-whereare-sex-workers-in-the-caprisacalculations

6 M. Richter, C. Gay, F. Venter, J. Vearey & D. Murdoc (2011), *Antiretroviral-based HIV prevention, including 'Treatment-as-Prevention', should be embraced by sex workers*, Editorial Response, Paulo Longo Research Institute. Online at http://www.plri.org/story/antiretroviral-based-hiv-preventionincluding-'treatment-prevention'-should-be-embraced-sex-work

PrEP is the term given for taking a medicine while healthy to prevent getting a disease or condition. Some people call microbicides 'topical PrEP' because they work this way, although they are applied locally (to a body surface) rather than swallowed or injected. Anti-malaria pills are an example of PrEP. People start taking the pills before travelling to places where they could be bitten by mosquitoes carrying malaria. If they are bitten, the risk that they will get sick is lowered by the anti-malaria medicine already in their system. Hormonal contraceptives can be regarded as a form of PrEP. A woman using birth control pills is unlikely to become pregnant if exposed to sperm because the hormones in the pill are designed to keep her egg from being released.

In the context of HIV, PrEP refers to a regular intake of an anti-retroviral drug (ARV) by an HIV negative person to stay negative. If exposed to HIV while taking PrEP, the drug may prevent the virus from multiplying rapidly and taking hold of the body

In the context of HIV, PrEP refers to a regular intake of an anti-retroviral drug (ARV) by an HIV negative person to stay negative. If exposed to HIV while taking PrEP, the drug may prevent the virus from multiplying rapidly and taking hold of the body. Using ARVs to prevent vertical, or 'mother to child', transmission is a form of PrEP already proven to be highly effective.

No HIV vaccine exists yet but several candidate vaccines are currently being developed. They are designed to train a person's immune system to identify HIV and take steps to disable or suppress it. Work is underway to develop preventive and therapeutic HIV vaccines. People living with HIV would receive a therapeutic vaccine to help control their infection. No vaccine can eliminate HIV from the body. But a successful therapeutic vaccine could lower a person's viral load (amount of virus in the body) by slowing down the process of HIV replication in the body.

The feasibility of using treatment for prevention has been hotly debated in recent years. Known under several names (including 'treatment as prevention', 'prevention for positives' and 'test and treat'), this is the practice of starting those who test positive for HIV on ARV treatment immediately, regardless of whether they are ill or not. Doing this can lower the amount of virus in semen, vaginal secretions and blood, greatly reduce the risk of transmitting HIV to another person.

What this means for sex workers

Let's talk about treatment for prevention first. This strategy, if implemented, could have far-reaching implications for sex workers. Two contrasting articles on the specific implications of treatment for prevention have been recently published by the Paulo Longo Research Institute. Readers are encouraged to read these articles for different views on ways that treatment for prevention might affect sex workers.[7, 8]

The following section highlights the foreseeable effects that microbicides, PrEP and HIV vaccines may have when they become publicly available. It reflects both positive and negative opinions of sex worker organisations. Some points are substantiated by commentaries, meeting reports, and other published materials cited.

7 C. Overs (2011), Treatment as Prevention: How might the game change for sex workers? *Paulo Longo Research Initiative Newsletter*, 1. Online at http://www.plri.org/newsletter/newsletter-number-1

8 Richter, Gay, Venter, Vearey & Murdoc, *op. cit.*

Potential positive impacts of microbicides, PrEP and/or vaccines

These tools would provide some protection when condom use is impossible to negotiate

Back-up protection

Having prevention tools that sex workers could use in addition to condoms would reduce risk if the condom tears or slips off. These tools would provide some protection when condom use is impossible to negotiate when sex workers are coerced into providing free sexual services by police, managers, etc or when rape occurs.

Alternative to post-exposure prophylaxis (PEP)

PEP is difficult to obtain in many countries and may be unaffordable even when available. Sex workers may feel less need for PEP after sex without a condom if they are using another relatively effective prevention tool.

Demand

Despite having concerns, some sex workers maintain that they would use a microbicide, PrEP, or vaccine if it were safe, effective, and available at an affordable price. Out of 250 female Kenyan sex workers participating in focus groups, 225 said they would use a 60% effective microbicide[9] if one were available for 50 Kenyan shillings per dose or less.[10] Some described microbicides as "friendlier to the ladies" than PrEP. All said they would use it in conjunction with condoms.[11]

Free access to PrEP

In places where ARVs for treatment are already provided free of charge by public health systems, it may be possible for some sex workers to access free ARVs for prevention, if PrEP is prescribed.[12, 13] Unfortunately, it is possible that access in government clinics may be denied to suspected sex workers due to stigma. Some clinics may be likely to provide PrEP only to "regular married women".[14]

Covert protection

Microbicides in gel form may increase lubrication that is noticeable during sex. The visibility of non-gel microbicides, PrEP and vaccines will be negligible. This means that sex workers will have a better chance of being able to use them without a client or partner's knowledge.[15]

Long-lasting protection

A prevention tool that requires minimal attention (as in the case of PrEP, a long-lasting microbicide, or a vaccine) could benefit sex workers who have difficulty with products that must be applied shortly before sex. They might especially help street-based sex workers who have less privacy and control over situations.[16]

9 G. Kamau, Bar Hostesses Empowerment and Support Programme (Kenya), personal communication.

10 50 Kenyan shillings is about $0.54 U.S. or €0.38. A male condom costs about 10 Kenyan shillings.

11 Kamau, *op. cit.*

12 F. Strack, DAVIDA (Brazil), personal communication.

13 N. Akers, St. James Infirmary (U.S.A.), personal communication.

14 Kamau, *op. cit.*

15 S.J. Bleviss, Sex Workers Organizing Project – New York (U.S.A.), personal communication.

16 Akers, *op. cit.*

Separate tool for prevention with a partner versus a client

Some sex workers use condoms with clients but not with their romantic partners. Barrier-free sex may provide a greater sense of intimacy with partners.[17] Others want to reduce HIV risk with partners but do not want to eliminate the possibility of pregnancy.[18] PrEP, non-contraceptive microbicides and vaccines may offer ways to do this.

Extra lubrication

Microbicidal gels provide additional lubrication that may make sex more comfortable. This can also reduce the risk of a condom bursting due to excess friction.[19]

Potential negative impacts of microbicides, PrEP and/or HIV vaccines

Pressure to skip the condom

Brothel owners, managers, or clients may exert pressure on sex workers to forego condom use and rely solely on partially effective prevention tools

Brothel owners, managers, or clients may exert pressure on sex workers to forego condom use and rely solely on partially effective prevention tools. Since condoms will continue to provide maximum protection, this will increase a sex worker's risk to HIV.[20] The bottom line is that it is safer to keep HIV out of the body than to try to disable it once it is there.

Less motivation for condom use

Some sex workers may feel less strongly about the need to insist on condom use if they are using one of these prevention tools. This may be especially tempting when clients offer more money for sex without a condom.

Non-multi-purpose

Male condoms are multi-purpose. They can be used for oral, anal, or vaginal sex. PrEP and vaccines may reduce risk regardless of the kind of sexual activity practised but a microbicide will not. Thus, a sex worker who purchases a vaginal microbicide instead of a condom will be unprotected if she has anal sex.

Expense

If a sex worker cannot afford to buy multiple HIV prevention tools, she or he will have to choose between condoms and other tools. Expense has been cited as a major concern by sex workers.

[17] Akers, *op. cit.*

[18] Kamau, *op. cit.*

[19] *Idem.*

[20] Bleviss, *op. cit.*

Side effects

This is another universal concern. The Nonoxynol-9 (N-9) trials held in the nineties left a legacy of distrust, since the product's ineffectiveness was finally proven in a trial among sex workers. The trial found that N-9 increased, rather than decreased, HIV risk among the participants. Although safety in testing has improved in the last decade, several interviewees expressed concerns about long and short-term side effects and said that many sex workers are wary about using new HIV prevention tools.

Although safety in testing has improved in the last decade, several interviewees expressed concerns about long and short-term side effects and said that many sex workers are wary about using new HIV prevention tools

Access

ARVs are not always available, even in countries where they are provided free to people living with HIV. Access to ARV for PrEP may be sporadic when stocks run out. Access may be difficult or impossible in rural areas where HIV testing and treatment services are minimal.[21]

Lack of information

Teaching correct condom use is relatively easy. Teaching people how to use microbicides or PrEP correctly is likely to be more difficult. Materials in multiple languages and graphic form, as well as the efforts of skilled peer educators, will be needed.

Forfeiting the psychological barrier

Condoms can provide a psychological, as well as physical, barrier between sex worker and client. Other tools may not meet this need as effectively.

'Real world' use – testing and the risk of coercion

New prevention products are being developed through research, including clinical trials in which people use the test product under very controlled conditions. But 'real world' use of a product can be very different from clinical trial use. Trial participants are given the product, condoms, HIV testing and regular medical check-ups. They meet with the trial staff to discuss problems or ask questions. Clearly, most people do not have access to this kind of support outside a trial setting.

PrEP, ARV-based microbicides and treatment for prevention are only effective if people get frequent HIV testing and regular, uninterrupted access to the tools. To use them successfully, people need to:

1. be tested for HIV regularly so that those who become HIV positive stop using PrEP or an ARV-based microbiocide immediately, since these can be harmful if used by people living with HIV, and
2. take their ARVs regularly, if they are HIV positive, to keep their viral load low.

[21] Strack, *op. cit.*

These conditions may be impossible to meet in many parts of the real world. But the absence of such safeguards incurs the serious risk of developing an HIV strain that is resistant to the drugs being used. For example, if a person is using PrEP then sero-converts (becomes HIV positive), and keeps taking the PrEP because she is unaware that her status has changed, she may develop HIV that is resistant to the PrEP drug she is using. This not only makes her HIV infection harder to treat, but it also means that that she could pass the drug resistant virus to other people.

But the absence of such safeguards incurs the serious risk of developing an HIV strain that is resistant to the drugs being used

Drug resistance may also occur if someone is using an ARV-based microbicide while HIV positive. The risk of this, however, is lower than the risk of developing resistance while on PrEP. This is because a much higher dose of the ARV enters the bloodstream when it is taken orally (as with PrEP) than when it is applied topically.

Obviously, treatment for prevention can only be effective if people living with HIV, who choose to try it, have affordable and uninterrupted access to ARVs.

Further, there is a risk that government health authorities could use coercive strategies to ensure that the two conditions above are met. These may include mandatory HIV testing (which is already being imposed on sex workers in some areas) or mandatory 'directly observed therapy' – where people are required to take their daily medication in the presence of a public health worker. Such actions are not only ethically wrong but wasteful and counter-productive from a public health standpoint. They increase people's impulse to avoid HIV testing and treatment. Only human rights-based strategies and universal access to ARVs can make people seek HIV testing and adhere to treatment and prevention guidelines.

Advocates can lobby their governments to assure successful use of these interventions. This could include making voluntary access to ARVs truly universal, eradicating stigma, funding support services that encourage HIV testing and treatment, and decriminalising sex work.

Conclusion

Given all the above points expressed, there is a critical need for sex workers' organisations to be involved in shaping how clinical trials are conducted to assure users that products will meet sex workers' needs. For example, they need to be safe for frequent use, non-intrusive and affordable.

Without [sex worker] involvement, there is no assurance that the positive impact of new prevention technologies will be realised, and that negative impacts will be minimalised

Sex workers need to be present at policy-making and planning meetings that will guide the introduction and rollout of new prevention tools. Without involvement, there is no assurance that the positive impact of new prevention technologies will be realised, and that negative impacts will be minimalised. Globally, experience has taught that failure to involve sex workers as research and planning partners diminishes HIV prevention efforts. Despite this, there is every reason to

believe sex workers' unique contributions, and their specific needs and risks, will be ignored if sex workers do not insist on participation.

To bring about this level of involvement two conditions are necessary. They are:

1 Sex worker organisations need to educate themselves about these new tools, including how they are being developed and how they are likely to work. Investing time in educating NSWP members about these pending options is an essential first step to undertaking advocacy efforts around them.

2 HIV prevention researchers and policy makers must be convinced that involvement of sex workers' groups is essential and that public health goals cannot be realised without it. Though difficult, this is an area in which sex workers have had previous success.

...sex workers have the ability, unique expertise, and right to play an important role in HIV prevention, research and policy

Sex worker activism stopped major PrEP trials in 2004 and 2005.[22] This sent a strong message that sex workers have the ability, unique expertise, and right to play an important role in HIV prevention, research and policy. In Brazil[23] and South Africa, sex workers are recognised as important partners in HIV prevention programming and currently participate in their countries' HIV policy-making bodies.

Research update: how products are being developed and tested

Microbicide research

Numerous 'candidate microbicides' (the term for products in development) have been tested over the past two decades. All candidates go through extensive safety testing designed to ensure that they will not harm end users or trial participants.

In July 2010, South African researchers found that a vaginal gel containing 1% of tenofovir (an ARV commonly used to treat people living with HIV) was safe and effective in preventing HIV. This study, named CAPRISA 004, enrolled 889 HIV-negative volunteers all of whom received monthly HIV counseling and testing, free condoms, and STI treatment for themselves and their partners. Those who became HIV positive during the trial receiving on-going care, treatment and support services.

At every monthly visit, trial participants were reminded to use condoms for protection since no one knew if the test product would work. In addition to condoms, half of the women received the tenofovir gel and half received a placebo gel. At the end of the trial, the women who used tenofovir gel during at least 80% of their sex acts had lowered their HIV risk by 54%. This means they were half as likely to have become HIV positive as those using the placebo.[24] The study found that regular tenofovir gel users had reduced their risk of getting HSV (genital herpes) by 51%. While this is a much lower level of protection than condoms, even this degree of risk reduction could be helpful for women who cannot insist on condom use.

22 A. Forbes & S. Mudaliar (2009), *Preventing Prevention Trial Failures: A Case Study and Lessons Learned for Future Trials from the 2004 Tenofovir Trial in Cambodia*, Washington: Global Campaign for Microbicides. Online at http://www.global-campaign.org/clientfiles/Cambodia.pdf

23 Strack, *op. cit.*

24 Q. Abdool Karim, S. Abdool Karim, J.A. Frohlich, et al. (2010), Effectiveness and Safety of Tenofovir Gel, an Antiretroviral Microbicide, for the Prevention of HIV Infection in Women, *Science, 329*(5996), pp. 1168–1174.

Since no product is approved for public use on the basis of a single trial's results, additional trials are underway to gather more data on the use of tenofovir gel. One study, VOICE (Vaginal and Oral Interventions to Control the Epidemic), has enrolled 5,000 women to test both tenofovir gel and tenofovir in pill form as PrEP. The VOICE study is expected to produce results by mid-2012.

Yet another study is testing the effectiveness of a microbicide contained in a vaginally inserted ring. Made of molded plastic, this flexible ring is similar in size and shape to NuvaRing™, a contraceptive device. Instead of containing contraceptive hormones, the microbicidal ring slow releases an ARV called dapivirine over a one-month period. Many women say they would prefer a product that offers continuous protection and only has to be changed monthly (with no action required before or after sex). The ring trial is scheduled to enroll 3,000 women and to produce results in 2015.

Many women say they would prefer a product that offers continuous protection and only has to be changed monthly (with no action required before or after sex)

While rectal microbicides are being developed, most microbicide research to date has focused on products for vaginal use. The primary goal of this research has been to create prevention options for women who cannot insist on condom use and/or prefer not to prevent pregnancy. If tenofovir gel is confirmed to be effective, the first microbicide could reach the market in some countries within the next few years.

Pre-exposure Prophylaxis (PrEP) research

Clinical trials to test the safety and effectiveness of PrEP are underway in several populations. In November 2010, the iPrEx study found that participants taking the PrEP drug were 44% less likely to contract HIV than those who took the placebo. As in the tenofovir gel trial, the participants who used the test product most consistently received the highest level of protection. Those who took pills on nine days out of ten reduced their risk of HIV infection by 73%.[25]

The ARV used in this study was Truvada, a combination of tenofovir and emtricitabine. The trial enrolled 2,499 HIV-negative male-to-female transgender women, gay men and other men who have sex with men (MSM) in Peru, Ecuador, the US, Brazil, South Africa and Thailand. As with the microbicide trials described above, all participants received regular HIV counseling and testing, free condoms, and STI treatment. Those who became positive during the trial are receiving on-going care, treatment and support services.

Given the iPrEx study results, it is surprising that the second major PrEP study showed no protective effect. In the FemPrEP study, 1,951 women in Kenya, South Africa, and Tanzania tested the effect of taking Truvada daily. In April 2011, the trial was halted because preliminary data showed that the number of HIV infections occurring among women who took Truvada was the same as those who took the placebo. As in other studies, participants were provided free condoms and urged to use them with every sex act.

The data from this study is currently under analysis to determine the reasons why results differed from the iPrEx trial. Several explanations are possible, including that many participants did not take the drug daily, as instructed. This may have occurred for a variety of reasons.

25 Grant RM, Lama JR, Anderson PL, et al. (2010) 'Pre-exposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men'. *New England Journal of Medicine* 363:2587–2599.

They may have given the dose to a family member with HIV or sold it to someone who needed treatment but could not access ARVs any other way. Since, the FemPrEP participants were primarily women in poor settings, this scenario is may have been more common than it was among those in iPrEx trails, who were primarily men living in somewhat more affluent settings. Other possible explanations could be differences in risk behaviours and the possibility that the drug may be absorbed differently in rectal and vaginal tissues. Participants who contracted HIV in the FemPrEP trial were likely to have been exposed to the virus during unprotected vaginal sex. In the iPrEx trial, exposure occurred primarily during unprotected anal sex. If Truvada provides better protection anally than vaginally, this could help explain the differing results.

The FemPrEP results have heightened interest in the VOICE trial mentioned above. In this, 5,000 women were divided into four groups. Two groups use a vaginal gel – either one containing tenofovir or placebo gel (one that contains no active drug) – and two groups take a pill daily, either Truvada or a placebo pill. The VOICE trial results in 2012 should offer more information about the potential feasibility of these tools for women.

Several other PrEP trials currently underway may also produce significant data for sex workers. These include a trial being conducted among 2,400 injecting drug users in Thailand, expected to produce results in early 2012, and a study among 4,700 serodiscordant heterosexual couples in Kenya and Uganda that will produce results in 2013.

Vaccine research

HIV vaccines are difficult to develop because HIV mutates rapidly as it reproduces. A vaccine that recognises one version of HIV is unlikely to be effective against other mutations of the virus.

HIV vaccines are difficult to develop because HIV mutates rapidly as it reproduces. A vaccine that recognises one version of HIV is unlikely to be effective against other mutations of the virus

In 2009 a large-scale trial in Thailand, RV144, enrolling 16,402 men and women, found that 30% fewer infections occurred among participants who received vaccine injections than among those who did not.

The trial was designed to see whether giving a vaccine to HIV negative people could reduce the impact of HIV if they eventually acquired the virus. The trial found that, overall, those who contracted HIV after being vaccinated did not have lower viral loads or higher CD4 counts than the unvaccinated participants who became HIV-positive. But some data from the study helped researchers identify particular characteristics in the blood of participants that may explain why the vaccine worked for some people and not others. This information may help guide researchers as they reformulate the vaccine, in the hope of making it more widely effective. New vaccine trials are currently being planned in Thailand and South Africa.

RV144 was a 'prime-boost' trial in which participants received two different vaccines, one after the other. The first vaccine 'primes' the immune system, and the second is designed to boost the body's ability to deal with HIV if it enters the body. A second prime-boost trial called HVTN 505 is enrolling over 1,300 MSM in twelve US cities. It is not yet known when that study will be completed.

Prospects for 'treatment for prevention' research

Debates are raging over the logistics, ethics, and medical implications of this approach. However, opinions about its effectiveness have been somewhat settled with announcement of results from the HPTN 052 trial in May 2011. This trial found that early ARV treatment could reduce the risk of HIV transmission by 97%. Initiated in 2005, the HPTN 052 trial enrolled 1,763 couples (96% were heterosexual) in nine countries. In each couple, one partner was HIV positive and the other negative. All the HIV positive participants had CD4 counts ranging from 350 to 550. This means they were relatively healthy. All couples were provided with the standard HIV prevention package, including free condoms.

This trial found that early ARV treatment could reduce the risk of HIV transmission by 97%

Half of the positive participants were started on ARVs 'early' – i.e. while their counts were above 350. The World Health Organisation (WHO) now cites 350 as the cut off below which ARV treatment is recommended. The remaining participants received ARVs when their CD4 counts fell to 250, or when they developed an AIDS-related symptom. These participants started treatment later than the currently recommended WHO guidelines, but earlier than previous (2006) guidelines, which advised starting ARVs at CD4 200.

Although scheduled to continue until 2015, the trial was halted when emerging data indicated that almost all newly infected participants were partners of those who were *not* in the early treatment arm of the trial. This provided substantial evidence that treatment for prevention might be the most promising strategy for slowing down the rate of HIV infections.