

# Not PrEPared to wait any longer: Advocating for the use of PrEP in a HIV prevention strategy

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Pre-exposure prophylaxis (PrEP) is a protective measure in the form of a pill (Brand name Truvuda), taken to reduce the chance of contracting HIV sexually. WHO guidelines currently recommend that oral PrEP should be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination HIV prevention approaches. This paper advocates for the use of PrEP in clinical practice in a UK setting to reduce transmission rates amongst men who have sex with men (MSM). I discuss the evidence surrounding the effectiveness of treatment and some of the potential parallel benefits and costs of treatment, as well as some of the cost implications for a health system. I argue that we should move beyond current HIV strategies offered to MSM and that PrEP should be available in the framework of a HIV prevention strategy.

In the UK Men who have Sex with Men (MSM) are disproportionately affected by HIV accounting for over 40% of those living with HIV in the UK (1). The transmission of HIV in this group remains a key challenge for policy makers with new diagnoses increasing from 2,450 in 2004 to 3,250 new cases in 2013 (2), suggesting that current preventative measures to stem the spread of HIV are not working in this group. The mainstay preventative measure to protect against HIV transmission is routine and regular use of condoms, but with only 55% of MSM reporting use of condoms with their last sexual partner, this message is failing (1). Looking beyond condom use to prevent the spread of HIV is essential to reducing the inequalities between heterosexual and MSM groups.

Pre-exposure prophylaxis (PrEP) is a protective measure in the form of a pill (Brand name Truvuda), taken to reduce the chance of contracting HIV sexually. WHO guidelines currently recommend “Oral PrEP containing TDF [PrEP] should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches” (3). This piece will be advocating for the use of PrEP in clinical practice in a UK setting to reduce transmission rates amongst MSM. I will discuss the evidence surrounding the effectiveness of treatment and some of the potential parallel benefits/costs of treatment before going on to analyse some of the cost implications for a health system. I will argue we should move beyond current HIV strategies offered to MSM, and PrEP should be available in the framework of a HIV prevention strategy.

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## EFFECTIVENESS OF TREATMENT

Truvuda was proven to be efficacious in early placebo controlled studies of African heterosexual couples conferring a 75% reduction in HIV seroconversion between serodiscordant couples (4), while a 63% effectiveness (despite follow-up and logistical problems) was recorded by (5). Following the success of placebo trials it was expected that transferring PrEP into a real-life setting would be less effective. Qualitative research by Wheelock et al. found that effectiveness was a key challenge for offering this treatment (6). Converse to expectations, when transferred to open label trials in the Botswana's setting, Truvuda was proven to be 100% effective at preventing HIV with a high adherence rate to treatment (7).

Successes in African trials were replicated in high income settings. The PROUD study – an open label treatment trial for MSM in a real-life setting – conferred an 86% protection level (8), which was matched by 86% in the French/Canadian IPERGAY placebo study (9). It should be noted that in the PROUD study, of the three men in the study group who seroconverted, one is thought to have contracted HIV before the study began while the two other men were not taking PrEP at the time of infection. “These findings suggest that there were no breakthrough HIV infections in participants who were taking PrEP” (8). This finding was replicated in the IPERGAY study: the only men who seroconverted were those who had stopped taking PrEP (10). In the USA, where Truvuda is currently licenced, recent research in San Francisco showed no seroconversions in MSM groups taking PrEP despite high levels of STI's, indicative of high levels of unprotected sex (11). In terms of effectiveness, PrEP has been proven, when taken regularly, to confer protection against HIV infection.

## COST EFFECTIVENESS

Cost effectiveness has been found to be a major factor for acceptance of PrEP as found by Wheelock et al. (6). The current lifetime cost of treating an HIV patient is estimated to be £360 000 (12). At 86% effectiveness, only 13 people per year would have to be treated with PrEP to prevent one HIV transmission. (McCormack et al. 2015) With the Truvuda patent expiring in 2017 and a likely drop in cost associated with this (13), PrEP has been modelled to be cost effective in a UK setting (14).

However, more conservative modelling has proven PrEP to not be cost effective (15). This model assumed a 60% efficiency, lower than PROUD and IPERGAY (seroconversions were all due to inconsistent dosing of PrEP), a 20% risk compensation which as discussed later is not evidenced, a lower background incidence of HIV than PROUD and IPERGAY (incidence amongst potential PrEP users – whose sexual engagement is high risk – is likely to be higher than population incidence), and a drop in cost of HIV treatment in the forthcoming years while the price of Truvuda remains unchanged. However, were the model to be used with an 86% efficiency, with all other inputs remaining unchanged, PrEP would be cost saving (15). Furthermore, externalities such as the economic benefit of a healthier workforce or an increased life-expectancy of those prevented from seroconverting were not taken into account.

Despite decreasing resources dedicated to health, cost-effectiveness should not be the only factor considered. For example, many drugs provided by the Cancer Drug Fund are still financed, despite not being cost-effective (16). Of course condoms will still remain the most cost-effective method to reduce transmission, but a HIV prevention framework which considers those who, for whatever reason, do not use condoms, should consider more radical methods. For example, the use of PrEP for the highest risk groups, with the prospect of eradicating HIV transmission rather than controlling it.

## IMPROVING THE SEXUAL HEALTH OF THE POPULATION

Further to preventing HIV, PrEP would encourage better access to testing for other STIs. Just as needle-exchange programmes may introduce IV drug users to cessation services (17) so PrEP may introduce MSM into STI testing, condom access and counselling into safer sex practices. Wheelock et al. captured this view by a national policymaker (6):

“The entry point for this truck driver was PrEP. He was eligible for PrEP but we tested him and testing is a very critical tool, we circumcised him, we screened him for STDs, we gave him condoms. This person has accessed more than PrEP.” (6)

Prior to PrEP being made available in the USA, research by Golub et al. (18) found that having arousal or pleasure barriers to condom use significantly increased the likelihood of prospectively using PrEP (18). This is supported by the remarkably high rate of HIV incidence in the control group of PROUD; those eligible to enrol in the trial and take PrEP, were at a higher risk of contracting HIV. By accessing PrEP a patient may be offered more sexual health services. Considering men at the highest risk of contracting HIV are also vulnerable to other STI's, screening and treating for these while receiving PrEP will prevent an infected patient being a vector of other infections. There is the potential to improve the sexual health of MSM, while preventing the transmission of HIV.

## SEXUAL DISINHIBITION AND RISK COMPENSATION

Wheelock et al. (2012) also found amongst policymakers a concern that those engaging with a PrEP program would risk compensate (engage in more risk behaviours due to perceived reduction in risk) (6). Apprehension that patients may engage sexually with more partners with reduced condom use was expressed, reducing the effectiveness of treatment and conversely increasing the incidence of HIV infection. However studies have not supported this view. Evidence from the IPERGAY study found no change in sexual behaviour (19), while the PROUD study found no increase in STIs compared to the control group “despite a suggestion of risk compensation among some PrEP recipients” (8). Volk et al. (2015) (11) found also that despite decreasing condom use, no seroconversions took place suggesting effectiveness if risk compensation takes place; this study however was not able to comment fully as there was no control group. Quantitative data from the IPrEx trial of MSM found no evidence of risk compensation (20), while qualitative research from the same trial supported PrEP not leading to more condomless sex (21). This study additionally suggested that not being burdened by the threat of HIV was a significant benefit to PrEP users (21).

Furthermore, as written by Collins in HIV i-base, “increased focus on HIV and sexual health that comes from engaging with a PrEP programme may in fact reduce their overall risk behaviour, and that this connection might have an additional prevention role in itself” (22), thus reducing transmission rates among the at risk groups.

## IMPROVING SEXUAL AUTONOMY

The advent of Highly Active Antiretroviral Treatment whereby somebody HIV positive on medication expects a near-average life expectancy, diluted the 100% condom-use messages of public health campaigns (23). To some extent, this led to sexual disinhibition. I reiterate, 100% condom use should remain the “Gold standard” in prevention; after all it is 100% effective. However, for higher risk groups, where this message has not been received, and for whom other STIs are still a natural risk of unprotected sex, PrEP provides a greater degree of sexual autonomy.

If we contrast the 100% condom use message to protect against STIs with the plethora of reproductive options available to women, we see a disparity in sexual health provision with a real lack of options for MSM to protect themselves. MSM are drastically underserved in protective measures due to a pregnancy bias. Evidently the 100% condom message has failed, so – looking beyond barrier protection – we must find suitable alternatives. Providing choice in sexual health will allow MSM to actively make autonomous health promoting decisions which may extend beyond HIV prevention. The qualitative research by Koester et al. (21) supports this with a quotient of participants taking PrEP describing a greater awareness of sexual practices and actions to prevent HIV transmission.

Furthermore numerous studies have proven that those at the highest risk of contracting HIV have the highest levels of adherence to PrEP regimes (24–26). This documents commensurate health promoting actions to perceived risk, while also displaying high cost efficiency to those who are most at need of HIV prevention services. Molina, at the Conference of Retroviruses and Opportunistic Infections, spoke to the audience: “gay men were capable of taking PrEP in a way that suited their lifestyle and maximised their safety, if offered the chance to do so.” (19).

Due to the recent advent of PrEP, qualifying the effectiveness at a population level is difficult due to a lack of long term studies following HIV incidence after the introduction of PrEP. However in clinical trials, PrEP has proven to reduce the incidence when taken consistently. While reducing HIV transmission, PrEP also has the potential to reduce other forms of inequality in MSM such as the burden of STIs and giving the opportunity to be greater actors in shaping their own health outcomes. Without PrEP the incidence of HIV amongst MSM in the UK is likely to continue to grow with current trends; considering more diverse strategies within a framework should therefore be considered.

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