

Study proves that a pill a day reduces the risk of HIV infection amongst men who have sex with men

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SECTION27 and the Treatment Action Campaign (TAC) welcome the results of the Pre-exposure Prophylaxis Initiative (iPrEX) trial. Published yesterday in the *New England Journal of Medicine* (NEJM), the study is the first to establish that pre-exposure prophylaxis (PrEP) ? taking antiretroviral (ARV) medicines before sex ? reduces the risk of HIV infection. It follows closely on the heels of the CAPRISA 004 trial, which demonstrated that the use of tenofovir 1% gel reduced the risk of HIV infection amongst women at increased risk.

The iPrEX trial enrolled 2499 men who have sex with men (MSM) at 11 sites across the world (including Cape Town). Half of the trial participants were randomly assigned to take a daily dose of two ARV medicines ? tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) ? combined into a single pill. The other half, also randomly assigned, received a daily placebo. All received a comprehensive package of HIV prevention services, including regular HIV testing, risk-reduction counselling, condoms, and the treatment of symptomatic sexually transmitted infections.

In summary, the iPrEX trial showed that ?

- Those taking TDF/FTC were on average 43.8% less likely to be infected than those taking the placebo;
- Amongst those taking TDF/FTC, better adherence meant better protection:
 - Those who took the pill at least 50% of the time were 50.2% less likely to become infected than those who took the placebo; and
 - Those who took the pill at least 90% of the time were 72.8% less likely to become infected than those who took the placebo;
- The side effects of the drugs were generally mild, infrequent and passed within a few weeks of starting to take the ARVs;
- Not one study participant who contracted HIV developed resistance to TDF;
- The two study participants taking TDF/FTC who developed resistance to FTC appear to have been infected before they entered the trial; and
- Over the course of the study, those who had receptive anal intercourse reported ?
 - Having fewer sexual partners; and
 - Increased condom use by their partners.

Whilst a significant breakthrough, iPrEX does not address all the questions that need to be answered. For example ?

- We still don't know what the most effective regimen for PrEP will be, and whether it will be possible to move away from daily to intermittent dosing;
- We have yet to work out how best to ensure adherence;
- We still need to get longer-term safety data due to the potential for side effects such as bone loss and kidney dysfunction;
- We don't know if the risk of drug resistance will be greater in real world ? as opposed to clinical trial ? settings, where HIV testing is less frequent; and
- The data from this study cannot be applied to other groups of people ? for example, we don't yet know what

this means for heterosexual women and their sexual partners.

Some of these questions are being addressed in other ongoing PrEP studies ? including amongst heterosexual men and women, and in follow-up studies in MSM. It is estimated that up to 20,000 trial participants are currently or expected to be enrolled in PrEP trials across the world, including in South Africa.

Globally, MSM are at increased risk of HIV infection. Even in South Africa, with its generalised HIV epidemic, MSM have the highest rates of HIV infection. SECTION27 and TAC will work with our partners to ensure that the iPrEx results lay the foundation for an enhanced response to the epidemic amongst MSM. And armed with this knowledge, we look forward to the results of other PrEP trials. We now have every reason to believe that PrEP may indeed offer protection to all people who ? for whatever reason ? are unable to use condoms consistently and correctly.

The iPrEx results underscore the urgent need for the development in South Africa of a comprehensive evidence-based prevention strategy that takes advantage of all we now know about effective HIV prevention tools. Amongst other things, an effective prevention strategy should include a focus on communications, including plans to disseminate the results of HIV prevention clinical research to the population as a whole. Almost 30 years into the epidemic, we cannot continue to accept the absence of a comprehensive and effective prevention strategy. With just a week to World AIDS Day 2010, SECTION27 and the TAC call for the development and implementation of such a strategy to be made an utmost priority in early 2011.

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