



A Statement of Support for HIV Prevention Research on Pre-Exposure Prophylaxis

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Pre-exposure prophylaxis, or PrEP, is one of several experimental prevention interventions (including microbicides and vaccines) which could potentially provide additional modes of minimizing the risk of HIV infection¹.

PrEP has not yet been proven to have any efficacy or to be completely safe. Moreover, unlike the microbicide and vaccine fields, which have widespread community support as well as investment from global research entities, PrEP research appears to lack either a scientific leader or a vocal community constituency.

In addition, there have been ethical questions regarding community consultation and access to HIV treatment and health care raised about early PrEP trials in Cambodia and Cameroon, which have been halted.

We believe wholeheartedly that ethical research must engage communities in substantive, responsive and ongoing dialogue about the risks and benefits of trial participation. We also believe that trials should not be conducted without community buy-in as well as opportunities for involvement in outreach, education and monitoring.

We also believe that it is vital to continue to investigate new, next-generation prevention interventions, and that communities are critical stakeholders and advocates for prevention research. We are concerned that PrEP research has not yet developed a community constituency and therefore make this statement of support for PrEP research as a call to action to people with HIV and other HIV prevention activists, researchers, industry, AIDS service and prevention organizations, and other community groups.

We must swiftly and ethically answer the question: Does PrEP work and is it safe? A New York Times Magazine article on January 22 focused on the possibility of behavioral disinhibition (increased risk-taking) which might be associated with the news that PrEP was an effective prevention intervention. The same article also cited limited reports that HIV-uninfected gay men in the United States are already using tenofovir in hopes that it will prove effective as a prevention modality, in spite of the lack of scientific evidence that this is the case.

The risk of behavioral disinhibition cannot be discounted, and must be studied. Neither can reports of informal use of tenofovir PrEP. But these issues should not deter research, and in fact, give further urgency to the need to answer the question: ***Does PrEP work, using tenofovir, other drugs, or drug combinations?***

In fact, the answer may vary by mode of transmission. It is therefore crucial that scientifically rigorous and ethical trials are expedited to explore this question for gay *and* straight men *and* women *and* for injection drug users.

We therefore call for roll-out of a full panel of well-conducted trials with the statistical power to answer questions about PrEP efficacy and safety in a range of populations.

In addition, we further ask that the sponsors of the planned or ongoing trials provide the community with an update which addresses:

- the statistical power of the current trials to answer questions about safety and efficacy in various populations and with respect to various modes of transmission
- plans for future trials if preliminary data suggest efficacy
- status of regulatory discussions about how the product would be labeled if it proved effective against one mode of transmission or in one population

This information is vital to building an informed and supportive constituency for PrEP research in the United States and internationally. It should be provided immediately and updated on a regular basis.

This will help ensure that the individuals and communities who could benefit most from an answer about PrEP are able to act as advocates, volunteers and educators in this important field.

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¹ For background, see "Will a Pill a Day Prevent HIV?" on the AIDS Vaccine Advocacy Coalition website: <http://avac.org/pdf/tenofovir.pdf>.