

February 18, 2005

**A public statement from the Global Campaign for Microbicides and
the AIDS Vaccines Advocacy Coalition
on the impact of stopping PREP trials in Cambodia and Cameroon**

Recently clinical trials have been launched in Africa, Asia and the United States to explore the potential use of oral Tenofovir as a “once a day” pill to prevent HIV in uninfected individuals—an intervention known as pre-exposure prophylaxis (PREP). Yet concerns from a few activists opposed to these efforts have resulted in government decisions to halt the trials in Cambodia and Cameroon.

The decisions to halt the trials have generated a firestorm of controversy in the HIV/AIDS treatment, prevention, advocacy, and research communities. In both countries, the public allegations criticizing the trials were not completely evidence-based, and the media’s coverage was highly provocative. As a result, the government decisions to stop the trials may have been premature.

Left unchecked, these forces threaten to undermine future trials. The cost is paid in people’s lives--the lives of those who might benefit from new technologies or treatments. This is not to say that unethical research should proceed. But derailing trials without high levels of evidence to support the claim that they are unethical is a costly practice.

The Global Campaign for Microbicides and the AIDS Vaccines Advocacy Coalition (AVAC) are international networks of advocates who have worked to forge meaningful collaborations between researchers, communities and activists. Both organizations are committed to ensuring that as science proceeds, the public interest is protected and the rights and interests of trial participants, users, and communities are fully represented and respected. Good prevention research must be accelerated, must be ethical, must involve communities and must result in products accessible and acceptable to the people who need them most.

We are convinced that the concerns raised by those who oppose the trials are solvable and need not have resulted in stopping trials. Issues can and should be addressed by researchers and sponsors working collaboratively with local communities and governments. Controversy over the ethics of research is an opportunity to engage communities in partnership. As Gregg Gonsalves of Gay Men’s Health Crisis recently noted, shutting down an HIV prevention study “is not a victory – it is a defeat. A victory would have been to be able to craft a solution to fix the local study.”

In this spirit, the Global Campaign and AVAC are planning to generate various materials that accurately reflect current events, assist all stakeholders with working through these issues and provide specific recommendations to accelerate ethical development of new technologies. Among the materials we will produce, are:

- A fact-sheet designed to correct some of the common misperceptions and errors of fact that have been made in the course of public discussion of these trials. This fact sheet will be available on our websites (www.global-campaign.org and www.avac.org) in the next few weeks.
- A background document that attempts to articulate the basics about Tenofovir, the current PREP studies and the various issues involved (available in early March).
- Two on-the-ground case studies to document what actually happened in Cambodia and Cameroon from each sector’s perspective, to identify lessons learned that could help prevent similar situations in the future. This project is already underway, and we hope to have these materials available in the coming three months.

The following key principles are pivotal:

1. The HIV pandemic creates an incredibly urgent demand for additional safe and effective tools with which to treat HIV infection and stop transmission. This can only be achieved by responsible, credible scientific studies.
2. Research to create these tools must be done in a way that protects the rights of vulnerable populations and contributes to overcoming the global imbalance in access to health care resources.
3. Communities affected by research must be actively involved in its conceptualization and implementation.
4. The rights of trial participants should be respected and participants should be admired for their contribution to helping others.

5. Researchers and funding agencies must be held accountable for their studies, and advocates must demand that problems be resolved.

AVAC and the Global Campaign are dedicated to developing effective collaborations among a broad range of civil society actors, researchers and sponsors.

We cannot combat AIDS effectively without research and development of new technologies. Without clinical trials, we cannot know what does and does not work – or how different drugs and interventions work in various populations and settings. This means wrestling, collectively and collaboratively, with the complexities of designing trials that are simultaneously ethical and scientifically rigorous. Simply objecting to existing trial designs and shutting down trials is not a solution. We must, instead, proceed with the much harder job of shaping a research standard we can support and then demanding that trials be designed and adequately funded to meet that standard.

For more information:

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