Report: Now Is Time to Prepare for PrEP

August 5, 2008 By Tim Horn

A new report issued by the AIDS Vaccine Advocacy Coalition (AVAC) at the XVII International AIDS Conference in Mexico City calls for increased action while preparing for initial results—expected as early as 2009—from the first trials of antiretroviral (ARV) drugs being tested for HIV prevention, known as pre-exposure prophylaxis (PrEP). The report, *Anticipating the Results of PrEP Trials*, also provides information about ongoing and planned PrEP research and lays out an agenda for action on key issues that the organization says must be addressed as research on PrEP moves forward.

PrEP clinical trials are currently planned or under way in Africa, Asia, Latin America and North America. These studies are looking at the safety and efficacy of PrEP, an unproven strategy in which HIV-negative people could take an ARV, or combination of ARVs, on a regular basis to reduce their risk of acquiring HIV.

"We cannot wait for the study results to begin to prepare for the optimal use and delivery of PrEP," says Pedro Goicochea, an investigator of a PrEP study currently taking place in Peru and Ecuador. "Instead, we should look ahead to consider all of the possible outcomes of these trials and make real plans for making PrEP available to those who can benefit from it, as quickly and safely as possible if it is proven effective."

The report identifies five priority issues that AVAC claims need attention now.

First, steps should be taken to ensure that current clinical trials have the best chance of providing results. AVAC says that clinical trials occurring now in Thailand, Africa, Latin American and the United States could establish the safety and effectiveness of PrEP, but only if the trials produce clear answers. AVAC argues that study sponsors, regulatory agencies and the global health community must work together to ensure that these clinical trials are supported to produce the data needed to determine next steps on the possible use of PrEP.

Identifying and investing in additional research is another priority, AVAC says. The group suggests that additional studies, such as those looking at intermittent PrEP dosing (current studies are exploring long-term use of PrEP to prevent infection), are needed and will require additional funding.

A third priority is developing a plan for using PrEP that would have a maximum public health impact. AVAC says that such a plan should address the issues set out in a July 2007 Lancet paper that called for assessing appropriate settings and populations for PrEP use, determining what level

of efficacy would warrant widespread delivery and finding out where targeted vs. more generalized delivery would be more appropriate.

The report also stresses that PrEP must be considered a global prevention initiative—one that requires a strategy to streamline funding, procurement and delivery on a global level.

Adequate funding is another point. According to AVAC, underinvestment in PrEP is hampering progress and needs to be corrected by government and private funders committed to global health.

“Although still unproven human clinical research, PrEP is considered one of the promising clinical interventions against HIV currently in development,” say AVAC executive director Mitchell Warren. “By mid-2009, more people will be enrolling in PrEP studies than in both HIV vaccine and microbicide efficacy trials combined. Advocates and communities affected by HIV need to understand PrEP and its implications for the AIDS advocacy and global health agendas, and government and private funders committed to global health must step forward now to ensure that PrEP research is fully funded.”

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http://beta.docker.poz.com/article/HIV-prep-prevention-15032-5078