AVAC
Global Advocacy for HIV Prevention

A Cascade of Hope and Questions

Volume 1

Anticipating results of ARV-based HIV prevention trials

Key messages

- No single trial will provide a definitive answer about ARV-based prevention.
- A positive result would require further exploration.
- A trial result that shows no effect from one ARV-based strategy cannot be extrapolated to other trials of the same or similar strategies.

Background

In the coming months and years, data will be released from a range of clinical trials of antiretroviral (ARV)-based prevention. These include trials of oral pre-exposure prophylaxis (PrEP) and topical ARV-based microbicides. Each of these trials will provide a piece of the puzzle of how antiretrovirals could be used by HIV-negative people to reduce their risk of acquiring HIV. Positive results from any of these trials would be cause for excitement, as there is an urgent need for additional biomedical HIV prevention strategies. Any single trial that showed a positive result would also raise additional questions. This document is designed to provide advocates with a "big picture" of the ARV-based prevention landscape, with a focus on trials in HIV-negative people. It covers the decisions and processes that might be triggered by data from individual trials of PrEP and ARV-based microbicides, and describes how these trials fit together.

There is also ongoing exploration of how ARVs could be used by HIV-positive people to reduce their infectiousness. Terms used to refer to such strategies include "test and treat", "treatment as prevention" and "TLC Plus." The guiding principle being explored in these approaches is that initiating ARVs early—i.e., before the treatment thresholds of most clinical guidelines used in developing countries—would reduce an individual's viral load and, therefore, his or her risk of transmitting HIV. While this document focuses on ARV-based prevention in HIV-negative people, AVAC is also monitoring treatment as prevention. Please visit our website at *www.avac.org* for more resources on these topics as well as information on our work on the full range of new biomedical prevention strategies.

This document will be updated as new data become available.

In this document:

What's going to happen in the next week—and in the next six to 12 months in ARV-based prevention research?

Data from a range of larger-scale safety and effectiveness trials will begin to emerge over the coming year, beginning with the results of the CAPRISA 004 trial on July 20, 2010. Each announcement is likely to trigger questions and suggestions about what to do next.

Each of the ongoing trials is regularly monitored by an independent committee to ensure the safety of the participants. Trials that run to scheduled completion are not generally expected to yield a finding that the product is unsafe, therefore, this document focuses largely on next steps after a result that is positive or shows no effect. Here, the most important messages that advocates can work to understand and share with their communities are:

- No single trial out of the current array of ongoing trials will provide all the information that would be needed to guide decisions about large-scale introduction of a new ARV-based prevention strategy.
- If any single trial shows benefit, there will still need to be research to confirm the trial result and explore important related questions.
- If any single trial shows that there is no impact from an experimental strategy, there is still the possibility that other trials—even ones testing the same experimental strategy—will show evidence of benefit.
- Safety is of the utmost importance. All of the ARV-based strategies in effectiveness trials have been evaluated in early-stage research, which indicated they were safe for further testing in HIV-negative people. If there is evidence of effectiveness, additional data on safety and potential resistance issues must be gathered as part of follow-up research and potential implementation.

Which trials will announce their results first?

Several trials will release data at the upcoming International AIDS Conference in Vienna (AIDS 2010):

- Data from the CAPRISA 004 Phase IIb trial that evaluated the *safety and effectiveness* of 1% tenofovir gel in 889 urban and rural South African women at risk of HIV infection acquired through vaginal sex will be released by the trial's research team. Women enrolled in CAPRISA 004 were asked to use gel before and after sex (no more than 12 hours before and as soon as possible after sex, but no more than 12 hours later).
- The US Centers for Disease Control and Prevention (CDC) will release data from a *safety and behavioral* trial, known as CDC 4323, of daily use of oral tenofovir in gay men and other men who have sex with men in the United States. This trial was not designed to provide data on the effectiveness of PrEP for HIV prevention.
- The International AIDS Vaccine Initiative (IAVI) and its collaborators in Kenya and Uganda will present preliminary results of two small *safety and acceptability* studies of intermittent PrEP, known as IAVI E001 and E002. HIV-negative participants were asked to take oral PrEP in the form of tenofovir and emtracitibine (TDF/FTC), often referred to by its brand name, Truvada. These trials compared daily PrEP with an intermittent dosing schedule of one tablet twice a week plus a tablet within two hours of sex, with no more than one tablet taken per 24-hour period. These two trials will not provide any data about possible effectiveness.

Participants were tested for HIV throughout these trials and immediately stopped taking study product (either the active product or placebo) if diagnosed. However, the CDC and IAVI trials were too small—and not designed—to provide any information on PrEP effectiveness.

It is expected that more safety and effectiveness data will be presented later in 2010 and early 2011 from additional oral PrEP studies. See the ARV-based prevention timeline at *www.avac.org.*

CONNECT THE DOTS

What upcoming results from selected tenofovir-based prevention trials will tell us—what they won't—and when

	Results announced	Results available in next 12 months					Results available 2012-2013		
	CAPRISA 004	CDC 4323 US safety	CDC 4370 Bangkok tenofovir	CDC 4940 (TDF2)	IAVI E001, E002	iPrEx	Partners PrEP	FEM-PrEP	VOICE
Oral		●	●	●	●	●	●	●	●
Topical (Vaginal)	●								●
Topical (Rectal)									
Tenofovir (Viread)	●	●	●				●		●
Tenofovir/ Emtricitabine (Truvada)				●	●	●	●	●	●
Daily dosing		●	●	●	●	●	●	●	●
Intermittent dosing					●				
Coitally related dosing	●				●				
Safety	●	●	●	●	●	●	●	●	●
Effectiveness	●		●			●	●	●	●
Women	●		●	●	●		●	●	●
Heterosexual men			●	●	●		●		
Gay men and other MSM		●			●	●			
Injection drug users			●						
Serodiscordant heterosexual couples					●		●		
Safety and effectiveness in real-world settings with less frequent monitoring	These questions and many others —which can't be answered in a randomized clinical trial—will be of critical importance if any ARV-based prevention strategy shows a benefit.								
Optimal strategies for delivering to key populations including poor and marginalized communities									

What kind of results might come from these trials?

Each of the trials releasing data at AIDS 2010 will provide a different piece of the ARV-based prevention puzzle.

- CAPRISA 004 will provide the first data on the effectiveness of an ARV-based microbicide for protecting HIV-negative women from HIV transmission via vaginal sex. The results could show evidence of risk reduction in women who received 1% tenofovir gel; there could be no evidence of benefit; or the results could be indeterminate, perhaps giving some sign of effectiveness but with such a high degree of statistical uncertainty that it is hard to tell whether the finding is "real" or not. The trial was monitored by an independent data and safety monitoring board for any safety issues. A finding that gel use was associated with harm—such as an increased risk of HIV among users—would have likely triggered an early stop to the trial. However, advocates should always be prepared for the full range of findings that can come from a trial.
- CDC 4323 followed 400 gay men and other men who have sex with men over a two-year period to gather information about the safety and acceptability of daily use of oral tenofovir in HIV-negative people. Although oral tenofovir has an extensive history of use in HIV-positive people, data on daily use among HIV-negative people are still being collected. Participants in the trial were also asked about their HIV risk behaviors throughout the course of the study, providing some information about how daily oral PrEP use relates to behavior. This trial will not provide any information on whether PrEP reduces the risk HIV infection. It was not designed to answer this question. Although information about the rates of HIV infection in the different groups of trial participants may be presented, these cannot be interpreted as evidence about whether PrEP is effective in reducing the risk of HIV infection.
- The intermittent PrEP trials of oral TDF/FTC conducted by IAVI and its collaborators will provide information on whether people can correctly and consistently follow an intermittent PrEP regimen (twice weekly plus within two

How does an HIV prevention trial like CAPRISA 004 measure protection against HIV infection?

In ARV-based prevention trials that enroll HIV-negative volunteers, all of the participants receive a standard HIV prevention package. The exact components vary by trial. One group of participants receives the experimental intervention—such as a microbicide or PrEP—and the other group receives a placebo that is indistinguishable from the experimental product. Participants are followed over time. Those who test positive for HIV are immediately taken off of the study product—they stop taking placebo or experimental product. At the end of the trial, the research team compares rates of HIV infections in the group of participants who received the experimental product plus the prevention package to HIV rates in those who received the placebo plus the prevention package. A finding of lower rates of infection among participants using the experimental product could indicate that the product has an HIV prevention benefit.

In the case of CAPRISA 004, the standard prevention package included HIV and STI counseling and testing, free broad-based STI treatment without diagnosis of specific infections (syndromic STI treatment) for participants and their partners, risk-reduction counseling and condoms. In CAPRISA, half of the participants also received the active product, 1% tenofovir gel, while the other half received a placebo gel (an inert gel with no antiretroviral that was indistinguishable from 1% tenofovir gel). Neither the participants nor the research team knew who had received the tenofovir gel or the placebo. All of the participants received ongoing counseling and HIV testing at monthly study visits. At these visits, all participants were counseled that they should not assume that they had received the experimental product; that there was no guarantee that the product would provide any protection; and that they should continue using proven HIV prevention methods such as condoms.

hours of sex), which might be preferable to daily dosing should PrEP show effectiveness overall. These trials will not provide any information on whether intermittent PrEP reduces the risk of HIV infection and were not designed to answer this question. While information about rates of HIV infection in the different groups of trial participants may be presented, these shouldn't be interpreted for their evidence about PrEP effectiveness.

Each of these trials has been closely monitored by independent data safety and monitoring boards (DSMBs), and to date, there have been no safety concerns.

These sound like very different trials—how do they all relate to each other?

Each of the trials described in this document would provide a piece of information about how ARV-based prevention strategies might work. More information will come from the additional trials summarized on page nine. Together, the data from these trials will form a more complete picture than any single trial could on its own.

This being said, it can be challenging for researchers and advocates to follow all the different permutations of ARV-based prevention research. For example, as stated above, the two oral PrEP trials being presented at AIDS 2010 in Vienna are safety studies that won't give any data on effectiveness of tenofovir or TDF/FTC for HIV prevention. CAPRISA 004 will provide data on 1% tenofovir gel's safety and effectiveness in South African women at risk via vaginal sex. But even if there is evidence of benefit, it is likely that one or more confirmatory trials will be needed.

Tracking the main types of information that could come from each trial will help advocates reduce confusion and manage expectations. It is important to develop clear messages that distinguish between these different types of findings.

Finally, it's important to look beyond these trials to other ongoing research. CAPRISA 004 will provide information on whether1% tenofovir gel provided any protection to South African women in urban and rural settings. Additional data would be needed to understand if and how the gel worked for women from other socio-cultural and geographic contexts, as well as its ability to protect during anal sex.

CAPRISA 004 was designed to detect whether 1% tenofovir gel provided 33 percent protection or higher—what does this mean?

CAPRISA 004 was designed with the statistical power to detect whether the gel reduced risk of HIV infection by 33 percent or more. The research team will make this calculation by looking at the numbers of HIV infections in the group of women who received 1% tenofovir gel plus the standard prevention package, compared to the women who received placebo gel plus standard prevention package. (See box on page four for more details.)

For example, if the gel reduces HIV risk by 33 percent, it means that there were 33 percent fewer infections in the group of women who received the experimental gel compared to those who received the placebo gel. If there is a finding that the 1% tenofovir gel provides partial protection, further research aimed at understanding reasons why some women were protected or women were protected some of the time might be used to fine-tune recommendations about when and how the product could be used for optimal benefit. The goal from any single trial is to make progress and learn to build upon those successes to make an even more effective approach. For more information on understanding some of the statistical issues involved in trials, refer to AVAC's Advocate's Guide to Statistics at *www.avac.org/statsguide*.

If CAPRISA 004 shows evidence that 1% tenofovir gel could reduce a woman's risk of HIV infection, what would happen next?

Until the actual data are known, and depending on the level of protection observed, it is difficult to predict exactly what additional steps would be needed to further develop 1% tenofovir gel. But there are several broad issues and processes that advocates can consider in advance. These include the following:

- **Designing additional clinical trials:** Any data from CAPRISA 004 would very likely need to be confirmed by another clinical trial. Right now the only other effectiveness trial looking at tenofovir gel is MTN 003, or VOICE, a multi-arm effectiveness trial evaluating 1% tenofovir gel, oral tenofovir and oral TDF/FTC. VOICE is

Exploring the Terms: Phase IIb trial

Phase IIb is the term used to describe a trial that has been designed to provide an initial indication of whether an experimental strategy has a benefit. Data from a Phase IIb trial can be used to decide whether to proceed to a confirmatory trial, usually a Phase III trial. None of these distinctions are absolute. Phase IIb trials can be designed with the statistical power to support licensure of candidates that show very high levels of effectiveness.

testing a different dosing schedule for tenofovir gel (once-daily) and enrolling women in several African countries, so it will provide additional information to complement CAPRISA 004 results. The results from VOICE are expected in 2013. If CAPRISA 004 shows a benefit, then a confirmatory trial might be launched. The specific details of dosing regimen and other aspects would be guided by the strength of the benefit observed in CAPRISA 004.

Additional research questions would also need to be explored. These might include: new research on rectal safety; safety on pregnancy; safety and effectiveness with different dosing strategies; use in adolescents; and safety for HIV-positive women and men. Additional research would also be needed to answer operational, implementation and marketing questions. The precise set of questions asked as part of a follow-up research agenda will depend on guidance from regulatory agencies as well as priorities set by various stakeholders engaged in HIV prevention and public health decision-making at international and national levels. Given the relatively limited supply of 1% tenofovir gel, if additional trials are to be conducted, there will be challenging decisions about how to use these supplies.

- **Ensuring post-trial access to the product or HIV treatment for trial participants:** If the trial shows unequivocal benefit, there would need to be discussions among the trial collaborators and sponsors about providing 1% tenofovir gel to HIV-negative participants in the trial. The timing for delivering 1% tenofovir gel to participants would depend on several factors, particularly the speed with which additional gel can be manufactured, tested for safety and quality and ultimately approved by regulatory authorities for use in humans. This process could take several years. It is possible that some product could be made available to trial participants through pre-introductory studies. *The Good participatory practice guidelines for biomedical HIV prevention trials* (UNAIDS/AVAC, 2010) state that plans for eventual access to experimental products that show effectiveness for trial participants, their communities and countries should be developed as part of every trial planning process, in collaborative dialogue among community stakeholders and the trial team. It is critical to document and debate the CAPRISA 004 approach to this issue—whether 1% tenofovir gel shows benefit or not.

  Women who acquired HIV during CAPRISA 004 were invited to enroll in one of the long-term CAPRISA Acute Infection Cohort Studies that offer oral ARVs as part of a package of treatment and care, and also track the impact of prior use of 1% tenofovir gel on viral load, drug resistance and treatment options. Participants who did not enroll in a follow-up study were referred to local ARV treatment and care programs.

- **Expanding product supply and manufacturing capacity:** If CAPRISA 004 shows a benefit, there will be a need to learn more about how the gel works and, therefore, a need for more gel. Right now there are limited quantities available—and the existing supply is committed to the VOICE trial that is studying 1% tenofovir gel as well as two different oral PrEP regimens. Manufacturing additional supplies of gel will be one of the priorities if a follow-up trial is warranted.

- **Understanding regulatory pathways:** Should CAPRISA 004 show benefit, it is likely that tenofovir gel would need to be evaluated in a confirmatory trial before licensure is sought. The trial team, manufacturers and other national and international stakeholders would need to

collaborate to map the process for seeking regulatory approval by the relevant South African bodies, such as the South African Medicines Control Council (MCC), as well regulatory agencies in other countries.

Why can't a single trial provide all—or most—of the answers about ARV-based prevention?

It's highly unusual for a single clinical trial of any intervention to be used as definitive evidence for regulatory, manufacturing and health policy decision making among all populations. Even when there is a high level of benefit shown in a single trial, there is still almost always the need for additional, confirmatory research. An additional trial or trials would build evidence that the observed effect is similar to that reported in the first trial. Follow-up trials can also ask more specific questions sparked by the first study, such as the impact of different dosing regimens or counseling messages to support product adherence. Because every clinical trial asks its research question in a specific way, with a particular population, and over a finite period, multiple studies are the best way to understand whether the result is "generalizeable"— a key prerequisite for pursuing large-scale introduction.

A recent example of this was the sequence of three trials of male circumcision for HIV prevention. Even after a South African trial found that medical male circumcision reduced HIV-negative men's risk of HIV infection via vaginal sex, trials in Uganda and Kenya continued to provide additional data on how the procedure worked when it was performed using different techniques on men of different ages who lived in urban and rural settings. Taken together, the three trials provided strong evidence that was used as the basis for WHO and country-level policy making and rollout of medical male circumcision for HIV prevention.

What are some of the important differences between the trials?

Some key differences among the studies are:

- Trial population
- Dosing strategy
- Mode of delivery
- Drug being tested
- Study design

Trial population

Each of the large-scale ARV-based prevention trials is taking place in a different population at high risk of acquiring HIV: gay men and other men who have sex with men, injection drug users, serodiscordant heterosexual couples and heterosexual women in sub-Saharan Africa. People in these different groups are likely to get exposed to HIV in different ways. For example, in heterosexual women, the primary route of exposure is likely to be vaginal sex. For injection drug users, the primary route is through shared needles. (Heterosexual women may also have anal sex, just as gay men and other men who have sex with men may have female partners—this is why we say "primary" route of exposure, not only route of exposure.) The risk of acquiring HIV is different depending on the route of exposure. The tissues of the vagina, rectum and penis each have unique characteristics. As a result, the risk of acquiring HIV from an infected partner is different during anal and vaginal sex and through injection of drugs with an HIV-contaminated needle. A trial that shows PrEP is effective in

Why tenofovir-containing candidates?

All of the effectiveness trials of ARV-based prevention strategies for HIV-negative people are currently studying either tenofovir (TDF) or tenofovir and emtricitabine (TDF/FTC).

These drugs were selected for clinical study in humans on the basis of animal studies that showed effectiveness in blocking infection with the HIV-like viruses that infect non-human primates. Other positive factors included their safety, side effect and resistance profiles. Other drugs that could be used for ARV-based prevention are in the earlier stages of clinical development, as are novel delivery strategies such as vaginal rings.

reducing HIV risk during anal sex provides indirect evidence that the same strategy could protect during vaginal sex or injecting drug use—but there would still be a need for additional research. This is one reason that other trials are very likely to continue, even if there are positive findings from the first trials to release results.

Drug being tested, dosing strategy and mode of delivery

All of the current effectiveness trials are evaluating either tenofovir (TDF) alone or combined with emtracitibine (TDF/FTC). As the table on page three describes, some of the current trials are looking at oral dosing, others are looking at topical application to the vagina or rectum. One percent tenofovir gel is being studied in once-daily and "around the time of sex" dosing strategies. (New longer-acting delivery methods such as vaginal rings and long-acting injectables are being evaluated, as are novel antiretroviral drugs. These strategies have not yet moved into effectiveness trials.)

Study design

Every clinical trial is designed to give a certain level of statistical power in its answer. Some trials are designed to give a general indication of whether a product reduces the risk of HIV infection; others are designed to give a very precise answer to this question. The level of precision is related to the size of the trial and the rate of new HIV infections (the incidence) in the population that is participating in the study.

Each trial also has its own strategies for supporting participants' correct and consistent use of the intervention; each has its own approaches to measuring adherence.

What additional research might still be needed even after current trials are completed?

Even if all of the current trials of ARV-based prevention show evidence of benefit, there will still be questions that need to be addressed. These include issues of intermittent dosing for oral PrEP, safety and effectiveness of topical and oral ARV-based prevention in pregnant and lactating women, adolescents and other vulnerable groups. If ARVs are approved for use in prevention there will be a need to determine optimal strategies for delivering antiretrovirals to both HIV-positive and HIV-negative individuals including comprehensive counseling messages on adherence and other issues, incorporation of VCT, resistance monitoring and potential impact of PrEP or other ARV-based strategy on future treatment options among users who acquire HIV, counseling and testing intervals, safety and effectiveness in "real world" settings and many other issues.

What can advocates do?

- Follow the research (see resource box below or visit *www.avac.org*).
- Ask questions—lots of them—and listen critically to the answers from trial sponsors, donors, research teams and other advocates.
- Convey key messages to your communities.
- Advocate at country and global levels for scale-up of services including HIV counseling and testing, and ARVs for HIV-positive people who are medically eligible based on current criteria as well as comprehensive prevention programming.
- Demand comprehensive field-wide coordination and development of a rationalized ARV-based prevention drug development plan.

Resources

- PrEP Primer at *www.avac.org/prepprimer*
- Microbicides: Ways Forward at *www.avac.org/microbicide_resources*
- ARV-based prevention trial timeline at *www.avac.org/prep_resources*
- ARVs Now and in the Future (from *AVAC Report 2009*) at *www.avac.org/arvs_now_future*

Selected Ongoing ARV-based Prevention Trials *(as of July 2010)* *					
Study **Study phase**	**Location**	**Sponsor** **Funder**	**Approximate # participants (mode of exposure)**	**Intervention arm(s)**	**Status / Results expected**
CAPRISA 004 Phase IIb, safety & effectiveness	South Africa	CAPRISA, FHI, CONRAD, USAID, TIA	900 heterosexual women *(vaginal)*	Coitally dependent topical 1% tenofovir gel	Completed / July 2010
US Extended Safety Trial (CDC 4323) Phase II, safety	US	CDC	400 gay men and other men who have sex with men *(penile/rectal)*	Daily oral TDF	Completed / Q3 2010 (Initial results July 2010)
iPrEx Phase III, safety & effectiveness	Brazil, Ecuador, Peru, South Africa, Thailand, US	NIH, BMGF	2,499 gay men and other men who have sex with men *(penile/rectal)*	Daily oral TDF/FTC	Fully enrolled / Q1 2011
TDF2 (CDC 4940) Phase II, safety & adherence	Botswana	CDC	1,200 heterosexual men and women *(penile and vaginal)*	Daily oral TDF/FTC; switched from TDF Q1 2007	Fully enrolled / Q4 2010
Bangkok Tenofovir Study (CDC 4370) Phase II/III, safety & effectiveness	Thailand	CDC	2,400 injecting drug users *(parenteral)*	Daily oral TDF	Fully enrolled / Q1 2011
Partners PrEP Phase III, safety & effectiveness	Kenya, Uganda	BMGF	4,700 serodiscordant heterosexual couples *(penile and vaginal)*	Daily oral TDF; daily oral TDF/FTC	Enrolling / 2012
FEM-PrEP Phase III, safety & effectiveness	Kenya, Malawi, South Africa, Tanzania, Zimbabwe	FHI, USAID, BMGF	3,900 heterosexual women *(vaginal)*	Daily oral TDF/FTC	Enrolling / 2013
VOICE (MTN 003) Phase IIb, safety & effectiveness	Malawi, South Africa, Uganda, Zimbabwe	MTN, NIH	5,000 heterosexual women *(vaginal)*	Daily oral TDF; daily oral TDF/FTC; daily topical 1% tenofovir gel	Enrolling / 2013
IAVI E001 & E002 Phase I/II, safety, acceptability, adherence	Kenya, Uganda	IAVI	150 serodiscordant couples and men and women *(vaginal and penile/rectal)*	Daily oral TDF/FTC; intermittent oral TDF/FTC (twice weekly + coital dosing)	Fully enrolled / Q4 2010 (Initial results July 2010)
PrEP in YMSM (ATN 082) Phase II, safety, acceptability, feasibility	US	ATN, NICHD	99 young men who have sex with men *(penile/rectal)*	Daily oral TDF/FTC	Enrolling / 2011
PrEP Using TMC278LA Phase I/II, safety & pharmacokinetics	United Kingdom	St. Stephens AIDS Trust	100 men and women *(vaginal and penile/rectal)*	TMC278LA injected intramuscularly	Enrolling / 2011
IPM 015 Phase I/II, safety & acceptability	South Africa; additional sites to be added	IPM	280 heterosexual women *(vaginal)*	Dapivirine vaginal ring releasing dapivirine for 28 days	Enrolling / 2011

ATN – Adolescent Trial Network; BMGF – Bill & Melinda Gates Foundation; CAPRISA – Centre for the AIDS Programme of Research in South Africa; CDC – US Centers for Disease Control and Prevention; FTC – emtricitabine; IAVI – International AIDS Vaccine Initiative; IPM – International Partnership for Microbicides; MTN – Microbicide Trials Network; NICHD – National Institute of Child Health and Human Development; NIH – US National Institutes of Health; Q1-4 – quarters 1-4; TDF – tenofovir disoproxil fumarate; TIA – Technology Innovation Agency; US – United States; USAID – United States Agency for International Development

*There are additional smaller-scale safety, adherence, feasibility and other trials going on which are not included in this table. A complete list can be viewed at *www.avac.org/trials.*

About AVAC

Founded in 1995 as the AIDS Vaccine Advocacy Coalition, AVAC is an international non-profit organization that uses education, policy analysis, advocacy and community mobilization to accelerate the ethical development and eventual global delivery of AIDS vaccines and other new HIV prevention options as part of a comprehensive response to the pandemic. For more information on AVAC's programs and work, visit *www.avac.org*.

AVAC
Global Advocacy for HIV Prevention

101 West 23rd Street
No. 2227
New York, NY 10011
USA

T +1 212 367 1279
F +1 646 365 3452
E avac@avac.org
W www.avac.org