

PrEP Primer

An introduction to pre-exposure prophylaxis (PrEP) research for HIV prevention

MAY 2010

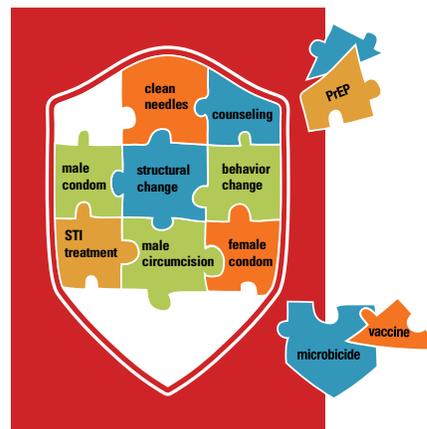
This primer provides an introduction to pre-exposure prophylaxis (PrEP) research for HIV prevention, including basic information on PrEP strategies being studied, the scientific rationale for PrEP, the state of the research, who is involved in PrEP, what additional research may be needed, and how to prepare for upcoming trial results.

What is PrEP, and why do we need it?

PrEP refers to an experimental HIV prevention strategy that, if proven effective, would use antiretrovirals (ARVs) to reduce the risk of HIV infection among HIV-negative people. In this intervention, individuals would take a single drug, or a combination of drugs with the hope that it would lower the risk of infection. PrEP is not yet proven to work. Trials are ongoing to test whether PrEP can reduce the risk of HIV infection via different routes of transmission.

There is an urgent need for additional HIV prevention options along with expanded scale-up of proven interventions. PrEP is one of several experimental biomedical HIV prevention strategies being studied today. If proven effective, PrEP would provide an additional method to help individuals reduce their risk of HIV infection. One of the potential advantages of PrEP is that an individual could use it without negotiation with his or her partner, so those who are unable to negotiate condom use with their sex partners would still be able to reduce their risk of HIV infection. Because PrEP is unlikely to be 100% effective, it would not replace other proven prevention strategies and would likely be most effective when used in combination with current HIV prevention methods,

The Proven and Possible Puzzle Pieces of Prevention



From AVAC Report 2009: *Piecing Together the HIV Prevention Puzzle*, www.avac.org

including safer sex practices, use of male and female condoms, treatment of sexually transmitted infections, risk-reduction counseling, clean needles, and male circumcision. PrEP would not replace any of these current strategies, but it could be a powerful additional tool in the fight against AIDS.

What do we already know about PrEP, and why might it work?

There is a scientific rationale for studying PrEP for HIV risk reduction. Studies of different PrEP

strategies in animal models have shown high levels of protection when ARVs were administered before being challenged with virus. There is also relevant evidence from humans:

- ARVs are given to HIV-positive mothers and their infants as part of effective strategies to reduce the risk of HIV transmission to the infant.
- Post-exposure prophylaxis (PEP) is an HIV risk-reduction method in which someone who may have recently been exposed to HIV (e.g., through a needle stick or an unprotected sex act) takes an ARV regimen for a limited time period to reduce the risk of acquiring HIV.

No one knows whether PrEP will work, but the evidence from animal studies and other uses of ARVs for prevention provide a rationale for studying PrEP in human clinical trials. There are currently a range of trials going on worldwide to learn whether PrEP reduces risk of infection in HIV-negative individuals.

How will we know if PrEP works?

In order to know if PrEP works, it needs to be tested in human clinical trials. Several types of research came before PrEP moved into these safety and efficacy trials in humans. The ARVs being tested as a PrEP strategy for HIV-negative people were first developed and licensed for treatment of HIV-positive people. There is extensive data on the safety and long-term effects of these medications in HIV-positive people. Additional studies to look at safety and tolerability in HIV-negative people have taken place or are ongoing. Animal studies have also shown that the PrEP drugs appear generally safe and have provided a scientific rationale for looking at PrEP in humans.

In a PrEP efficacy trial, each participant receives a basic package of proven HIV prevention interventions, including treatment for sexually transmitted infections, male and female condoms, and behavior change counseling. Some of the trial participants are randomly assigned to also receive PrEP drugs, while the other participants receive a “placebo”—a pill that has no effect on the body

THE KEY POINTS:

- Pre-exposure prophylaxis (PrEP) is a potential new HIV prevention intervention that could have an important impact on HIV prevention globally.
- The ARV drugs tenofovir disoproxil fumarate (TDF) and a combination of TDF and emtricitabine (FTC) are currently being tested in clinical trials for use as PrEP. Other agents may be tested in the future—investment is needed to support this additional research.
- Clinical research is taking longer than originally anticipated, but initial results from current PrEP efficacy trials are expected in the second half of 2010.
- Current PrEP trials will leave important questions unanswered, requiring additional research.
- PrEP should be placed high on the AIDS advocacy and global health agendas. Action is needed now to:
 - Ensure current clinical trials have the best chance of producing decisive results.
 - Identify and invest in additional research that is needed.
 - Plan for optimal use of PrEP.
 - Provide adequate funding for PrEP research and planning.

or on HIV. Participants are reminded at every study visit that they do not know whether they are receiving the experimental drug or the placebo; they are also counseled to keep using all proven risk-reduction strategies since the PrEP strategy is not proven to have a benefit. These messages are designed to reduce the risk that participants will assume they’re protected by the intervention and change their levels of risk behavior.

Over the course of the trial period, some volunteers get infected even though they are being counseled

and receiving prevention services. This is consistent with what we know about the AIDS epidemic: even with information and services, not everyone can protect himself or herself all the time. At the end of the trial, researchers compare the rates of new infections in the participants who received PrEP drugs and in those who received a placebo. If the number of infections in the group that received PrEP plus the standard prevention package is significantly lower than the number of infections in the group that received the placebo plus standard prevention, then this can be an indication that PrEP helps reduce the risk of HIV infection. The term statistically significant describes a finding—like a difference in HIV rates between two groups—that is too great to be explained by chance.

Current state of the research

There are a number of ongoing PrEP trials enrolling over 20,000 participants (see table on p.4). Oral PrEP trials are testing either tenofovir disoproxil fumarate (TDF), sometimes called tenofovir, or a combination of TDF plus emtricitabine (FTC). TDF is marketed under the name *Viread*, and TDF/FTC is marketed under the name *Truvada*, both made by Gilead Sciences, Inc. There is also ongoing research on tenofovir gel, which is a topical vaginal microbicide.

Researchers are also looking at other antiretrovirals for PrEP, including TMCZ278A, which is currently being tested as an injectable in a small study in the UK.

Scientists have focused on TDF and TDF/FTC in oral PrEP studies because they require only a single daily dose, have relatively low rates of side effects and because there is significant data on their long-term safety and resistance profiles in HIV-positive people.

Additional ARV agents are being considered for both topical microbicides and oral PrEP, and there is ongoing discussion about whether there should be a special “PrEP pipeline” for new ARVs that are intended for prevention only.

The suite on ongoing PrEP trials are testing different formulations and combinations, in

different populations. Positive or negative results from any one of these trials will not be the final answer on whether or not PrEP works. Each current trial is designed to answer a specific question, or set of questions, and the results from each trial will inform the broader field. While it is impossible to predict the future, it is highly likely—based on experiences with other biomedical HIV prevention strategies—that other efficacy trials would continue even if a single trial showed benefit. It is critical to answer questions about the safety, acceptability and efficacy of different product formulations and combinations, in different populations in which the routes of transmission differ.

In addition, even if several of the ongoing efficacy trials find that PrEP is safe and effective in reducing HIV risk, there will still need to be additional research on long-term safety, use in pregnant women and adolescents, and to understand the potential effectiveness of other dosing and delivery strategies.

All of the current efficacy trials of oral PrEP are testing once-daily dosing, but there is increasing discussion of and research around intermittent PrEP (iPrEP). AVAC and partners have led a number of discussions around iPrEP including think tanks and global teleforums. (Visit www.avac.org/prep for meeting reports and call recordings.)

Where is PrEP research happening and in which groups?

PrEP clinical trials are currently underway in countries in Africa, Asia, Latin America and North America, with nearly 20,000 trial participants involved. See page 5 for a map of ongoing PrEP trials.

The current PrEP trials are designed to produce results in diverse populations, representing multiple routes of transmission:

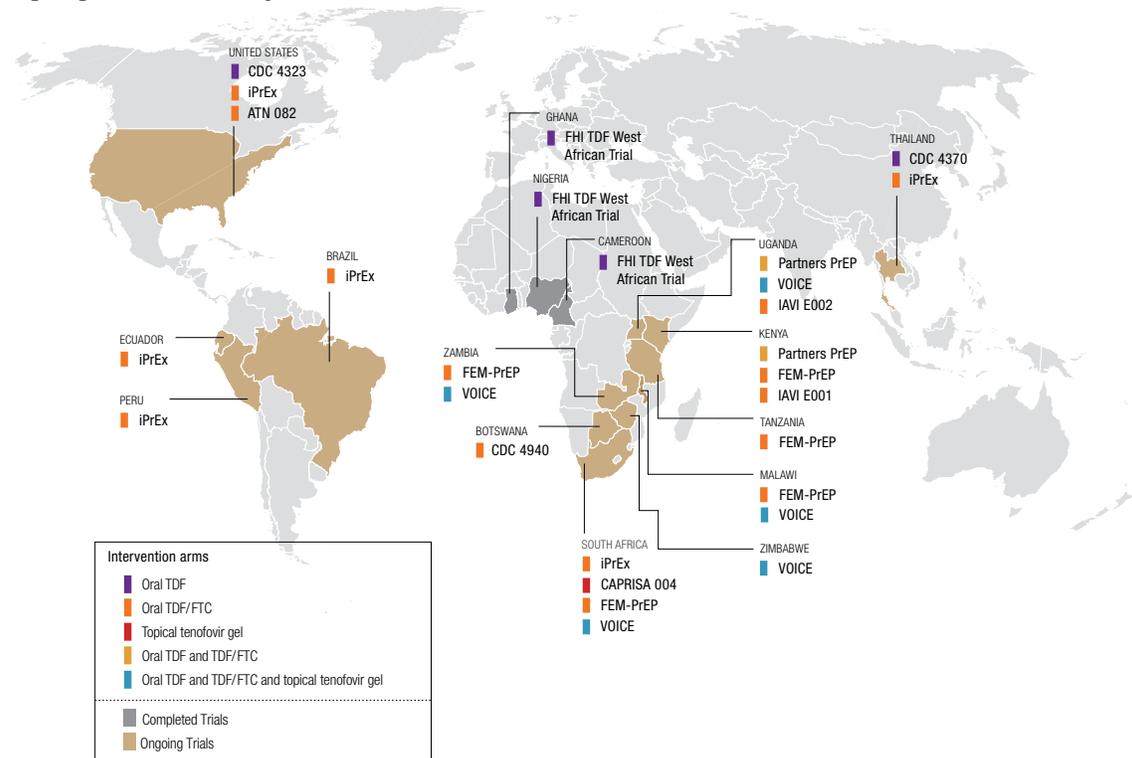
- Heterosexual men and women in high-prevalence locations
- Serodiscordant heterosexual couples (one partner is HIV-positive and one is HIV-negative)
- Injection drug users
- Gay men and other men who have sex with men (MSM)

Ongoing PrEP Trials (May 2010)

Study phase Study phase	Location	Sponsor Funder	Population (mode of exposure)	Intervention arm(s)	Status / Results expected
US Extended Safety Trial (CDC 4323) Phase II, safety	US	CDC	400 gay men and other men who have sex with men (<i>penile/rectal</i>)	Daily oral TDF	Completed / Q3 2010
iPrEx Phase III, safety and effectiveness	Brazil, Ecuador, Peru, South Africa, Thailand, US	NIH, BMGF	2,499 gay men and other men who have sex with men (<i>penile/rectal</i>)	Daily oral TDF/FTC	Fully enrolled / Q4 2010
Bangkok Tenofovir Study (CDC 4370) Phase II/III, safety and effectiveness	Thailand	CDC	2,400 injecting drug users (<i>parenteral</i>)	Daily oral TDF	Enrolling / Q4 2010
TDF2 (CDC 4940) Phase II, safety and adherence	Botswana	CDC	1,200 heterosexual men and women (<i>penile and vaginal</i>)	Daily oral TDF/FTC; switched from TDF Q1 2007	Fully enrolled / Q4 2010
Partners PrEP Phase III, safety and effectiveness	Kenya, Uganda	BMGF	4,700 serodiscordant heterosexual couples (<i>penile and vaginal</i>)	Daily oral TDF; daily oral TDF/FTC	Enrolling / 2012
FEM-PrEP Phase III, safety and effectiveness	Kenya, Malawi, South Africa, Tanzania, Zambia	FHI, USAID, BMGF	3,900 heterosexual women (<i>vaginal</i>)	Daily oral TDF/FTC	Enrolling / 2013
VOICE (MTN 003) Phase IIb, safety and effectiveness	Malawi, South Africa, Uganda, Zambia, Zimbabwe	MTN, NIH	5,000 heterosexual women (<i>vaginal</i>)	Daily oral TDF; daily oral TDF/FTC; daily topical tenofovir gel	Enrolling / 2013
IAVI E001 & E002 Phase I/II, safety, acceptability, adherence	Kenya, Uganda	IAVI	150 serodiscordant couples and men and women (<i>vaginal and penile/rectal</i>)	Daily oral TDF/FTC; intermittent oral TDF/FTC (twice weekly + coital dosing)	Fully enrolled / Q4 2010
PrEP in YMSM (ATN 082) Phase II, safety, acceptability, feasibility	US	ATN, NICHD	99 young men who have sex with men (YMSM) (<i>penile/rectal</i>)	Daily oral TDF/FTC	Enrolling / 2011
CAPRISA 004 Phase II, safety and effectiveness	South Africa	CAPRISA, FHI, CONRAD, USAID, LIFElab	900 heterosexual women (<i>vaginal</i>)	Coitally dependent topical tenofovir gel	Completed / Q3 2010
PrEP Using TMC278LA Phase I/II, safety and pharmacokinetics	United Kingdom	St. Stephens AIDS Trust	100 men and women (<i>vaginal and penile/rectal</i>)	TMC278LA injected intramuscularly	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; FHI – Family Health International; FTC – emtricitabine; IAVI – International AIDS Vaccine Initiative; 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; US – United States; USAID – United States Agency for International Development

Ongoing PrEP Trials (May 2010)



It is important to get data from a range of populations as different routes of transmission pose different challenges in reducing infection risk.

When will we get results?

Results have been reported from one completed phase II PrEP trial to-date: a safety study that enrolled women in several countries in West Africa—Cameroon, Ghana and Nigeria. In this trial, once-daily TDF was safe and well-tolerated by participants over the course of their study participation.

Data from a PrEP extended safety trial in gay men and other men who have sex with men is expected in the third quarter of 2010. This trial will answer important questions about the safety of TDF while assessing the effects of taking a daily pill on HIV risk behaviors, adherence to and acceptability of the drug regimen, and in cases where participants become infected, the resistance characteristics of the acquired virus.

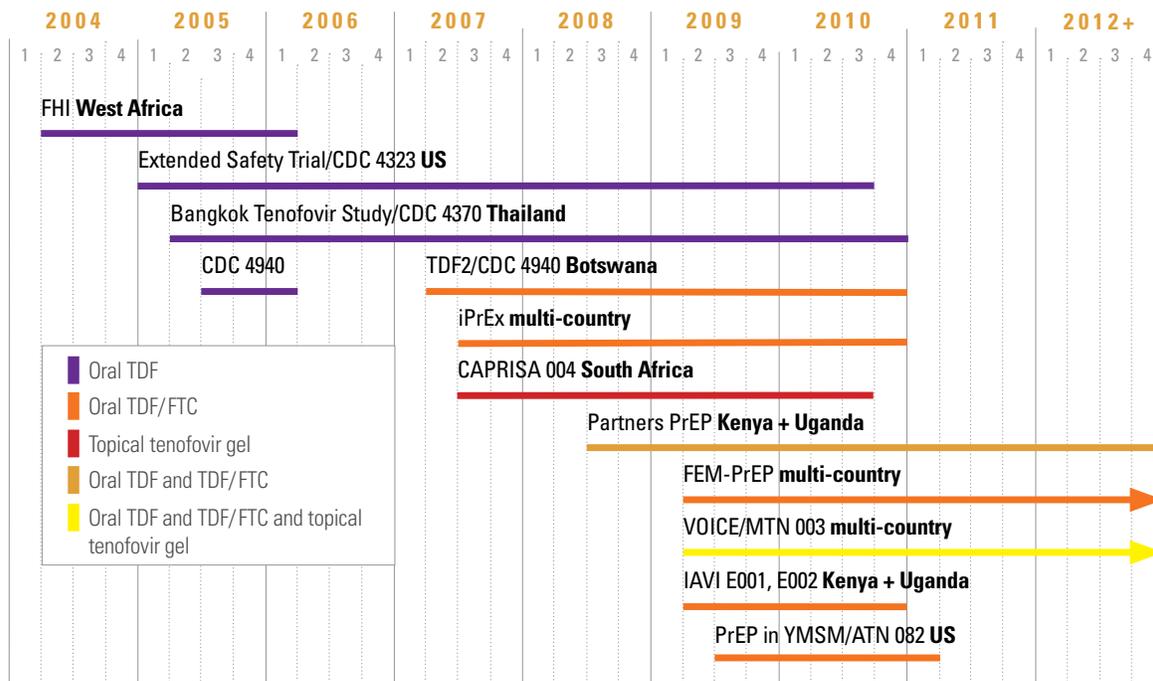
As the timeline on page 6 shows, we will begin to have results from a range of populations and PrEP strategies in late 2010 and early 2011.

What questions will likely remain even after the current PrEP trials are completed?

All of the stakeholders involved hope that the current PrEP trials will produce consistent, positive results on the safety and effectiveness of PrEP. But, even if they do, current effectiveness trials will also leave several other important questions unanswered:

- Are there dosing strategies other than ongoing, once-daily dosing that could be used with oral PrEP drugs to reduce individuals' risk of HIV?
- Can safe and effective PrEP strategies be developed for adolescents and pregnant women—two groups not included in current effectiveness trials?
- Can other compounds be developed for potential PrEP drugs?
- What are the long-term safety consequences of PrEP use?
- What are the rates of drug resistance associated with individuals using PrEP who become HIV infected? How does this impact future treatment options?

Timeline for Ongoing PrEP Trials* (May 2010)



* The trial end-dates listed in this table are estimates. Due to the nature of clinical trials the actual dates may change. AVAC will continue to monitor trial progress and will update the timeline accordingly. To view or download an updated timeline visit www.prepwatch.org.

What if PrEP works? What are the possible implementation challenges?

Positive results from ongoing PrEP trials would be an exciting development for biomedical HIV prevention. However, even if the efficacy trials show benefit, there would be many challenges in translating this benefit into an impact outside of the trial setting. These challenges include: communicating what the new tool does and does not do; developing programs that deliver it as part of a comprehensive prevention package; and ensuring adequate and sustained financing for new programs. Given that PrEP involves ARV use in HIV-negative people, introduction—if the trials show benefit—would require careful integration with HIV testing, safety monitoring and referrals to other services.

Planning must happen now to address these issues. Stakeholders must:

- Identify and invest in additional research priorities including research on delivery, impact, safety, alternative dosing and other issues

- Plan now for optimal use of PrEP by developing tools and consultations to explore
 - Which settings would be appropriate for PrEP?
 - What level of PrEP efficacy would warrant widespread delivery?
 - Which populations would benefit most from PrEP?
 - What is the right mix of prevention interventions, in addition to PrEP, to ensure the biggest impact on the HIV epidemic?
 - What other interventions are needed to ensure that risk behavior does not inadvertently increase due to PrEP?
 - Where would targeted or more generalized delivery be more appropriate?
 - What other services (e.g., regular HIV testing, counseling) would need to be delivered with PrEP?
 - How much would PrEP cost?
 - Who would pay for PrEP?
- Prepare for procurement and delivery of PrEP
- Provide adequate financing
- Increase HIV testing capacity

Key questions

While there is great enthusiasm for PrEP, it is important to remember that it has not been proven and that there are a number of questions—some unanswered and some with complex explanations. Here are some frequently asked questions and the corresponding messages that can be the start of a conversation around these often complex issues:

Is it safe to give ARV drugs to HIV-negative people?

- We don't yet know what the long-term safety implications are for once-daily PrEP (TDF or TDF/FTC) in HIV-negative people. Data from the one completed PrEP trial (in women in several countries in West Africa) showed that once-daily TDF was safe and well tolerated by participants over the course of their study participation. However, this was only one trial, in one population, over a limited period of time. Additional research is needed to determine the safety of long-term use of PrEP.

Would people adhere to daily PrEP for long periods?

- Right now, we don't know. The current trials will provide adherence data for participants over the length of the trial. If PrEP shows efficacy and moves to implementation, it will be critical to develop and monitor pilot programs and do additional research to learn about how to optimize adherence outside of the clinical trial setting.

Would PrEP increase risk behavior rates?

- We don't know yet. Ongoing efficacy trials will provide data about rates of risk behaviors among trial participants. Overall, in biomedical prevention trials, rates of risk behavior tend to drop among all trial participants, likely due to the prevention counseling and services provided by the trial. The more important questions will concern shifts in risk behavior that might happen if there is a positive finding from a PrEP trial. The impact of risk compensation (for example, a decrease in condom use if lower risk is perceived) depends on how effective the strategy is and how that may affect behavior. Given these unknowns, risk compensation should be anticipated and planned for with appropriate counseling and programs that ensure that, if PrEP does have a prevention benefit, its promise is realized.

If once-daily PrEP shows efficacy, would it be possible to explore whether other dosing strategies (sometimes called intermittent dosing) could be used?

- If there is evidence of benefit from efficacy trials testing once-daily dosing, it would still be possible to evaluate intermittent dosing strategies. These could include daily dosing for specific periods of time, or dosing at less frequent intervals. For example, one current trial is looking at adherence to and drug levels of PrEP in people taking it Monday, Friday and whenever they have sex. This trial is also looking at the acceptability of this type of intermittent strategy. For more on intermittent PrEP research visit www.avac.org/prep.

Would those who get infected while taking PrEP have HIV that is resistant to the PrEP antiretrovirals? Would this affect subsequent care and choice of ARV treatment?

- Right now, we don't know. PrEP is testing the use of ARVs in people who are HIV-negative. Resistance would only become an issue for people who become infected with HIV while taking PrEP drugs. This is because the current trials are testing single- or dual-drug regimens that are suboptimal treatment for HIV-positive people. In the current trials, participants are tested on a regular and frequent basis, minimizing the time that people might spend on suboptimal therapy if they become infected while on the study drug. These studies will provide data on the rates of HIV resistance among participants who seroconvert while in a PrEP trial. Long-term follow-up could give some indication of whether the resistant virus, if any, remains detectable once the study drug has been stopped, and whether PrEP use at the time of infection affects subsequent treatment options. But as with the issues discussed above, the current trials will provide incomplete answers. If PrEP shows benefit in current trials, carefully planned research and monitoring will be needed to gather information on resistance issues related to PrEP over time and outside the clinical trial context.

How often would HIV testing be needed for people taking PrEP?

- Individuals interested in using PrEP, or ARV-based microbicides, would need regular HIV testing to determine whether they are eligible. Once using PrEP, individuals would need testing

to find out if they have become infected so that use of PrEP drugs as suboptimal therapy is minimized. The frequency of this testing is already being discussed in the scientific literature. It's important to remember that the current trials are using regular and frequent testing and that this schedule will be the only one for which data are available if regulators consider PrEP for introduction. Community perspectives on testing and other aspects of service delivery for PrEP should help shape context-specific programs, if they are warranted by clinical trial data. Effective PrEP delivery would depend on expanded opportunities for HIV testing and thorough training of health care personnel in settings around the world.

Where would PrEP fit with other prevention tools—proven and in development?

- PrEP would be one additional HIV prevention tool. It would not replace any proven options and regardless of whether PrEP is found to reduce the risk of HIV infection, additional options and combination approaches will still be needed. Right now, people need continued and vastly expanded access to proven options. The additional benefit of any new strategy has to happen in the context of a well-funded, comprehensive response to the epidemic.

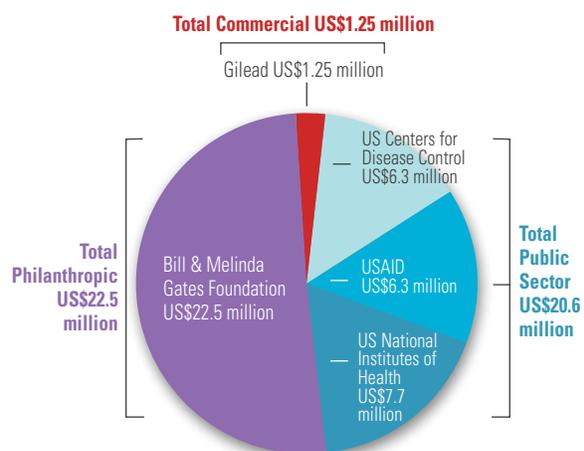
Who is investing in PrEP research?

Four funders provide the majority of financial support for PrEP research today: the Bill & Melinda Gates Foundation, the US National Institutes of Health (NIH), the US Centers for Disease Control and Prevention (CDC) and the US Agency for International Development (USAID). Gilead, the manufacturer of both TDF and TDF/FTC, has provided in-kind support for PrEP research.

Global resources dedicated to PrEP in 2008 totaled US\$44.3 million, about 10% more than in 2007. However, even with this increase, there is still a gap between what is needed and what is available. More involvement and investment is needed from industry to expand the “pipeline” of new ARVs that could be evaluated for PrEP. Funding is needed

for preparedness activities at global, national and regional levels so that PrEP research findings are presented to stakeholder groups that are prepared to understand and act on them. Current and future trials need to be designed and funded so that they get answers in a timely manner. This means close attention to recruitment, retention and incidence rates, and responsive action when trials start to fall short of any of their targets in these areas. PrEP research is complex, expensive—and promising. It must become a priority in health research funding.

Investment in PrEP R&D 2008 by Funder and Sector



* See *Adapting to Realities: Trends in HIV Prevention Research Funding 2000 to 2008* for more on PrEP financing and funding trends for biomedical HIV prevention research at www.hivresourcetracking.org.

Next Steps

Combination ARV therapy is a key element of HIV treatment. Today the hope is that a highly effective approach to combination HIV prevention can be developed and implemented with the same dramatic effects that ARV rollout has had in many parts of the world. Right now, the world is far from meeting this goal—even with the tools available today. Expanding access to proven strategies is one priority. Finding additional strategies is another one. The introduction of male circumcision as part of comprehensive HIV prevention and sexual and reproductive health services for men and women is one example of how combination prevention might work. But as experience with male circumcision introduction is showing, achieving these goals

takes time, funding and commitment at every level. If PrEP is found effective, it would need this same commitment to develop programs that delivered it alongside behavioral interventions, male and female condoms, clean needles, HIV testing, male circumcision and access to HIV treatment.

PrEP may prove ineffective. Or it may turn out to be a unique and important new opportunity for the world to reduce HIV infection and help change the course of the epidemic. People at risk of HIV cannot afford to let PrEP research be delayed unnecessarily. Nor can we wait for definitive results before laying plans to utilize PrEP to maximize public health impact against the pandemic.

FOR MORE INFORMATION

Background

- “Anticipating the Results of PrEP Trials: A powerful new HIV prevention tool may be on the horizon. Are we prepared?” AVAC, 2008, www.avac.org/anticipating_results_prep.2008
- Centers for Disease Control and Prevention (CDC) PrEP webpage, www.cdc.gov/hiv/prep/
- Family Health International PrEP backgrounder webpage, www.fhi.org/en/Topics/preexposure_prophylaxis.htm
- “Introduction to PrEP”, Global Campaign for Microbicides, 2009, www.global-campaign.org/clientfiles/GCM_IntroToPrEP.ppt
- “Pre-Exposure Prophylaxis: Could It Work?” presentation by Sharon Hillier at CROI 2009, www.retroconference.org/2009/data/files/webcast.htm
- “PrEP 101” slide set, AVAC, 2009, www.avac.org/prep/resources
- PrEP Fact Sheet: An introduction to PrEP research, AVAC, www.avac.org/prep/resources
- PrEP Watch website – a comprehensive resource on PrEP for HIV prevention research, www.prepwatch.org (also available via the AVAC website at www.avac.org/prep)
- “PrEP: What Does It Mean for Women?” Global Campaign for Microbicides, 2009, [www.global-campaign.org/clientfiles/FS-PrEP\[E\].pdf](http://www.global-campaign.org/clientfiles/FS-PrEP[E].pdf)
- Preparing for PrEP: A Stakeholder’s Dialogue, webcast of daylong session in advance of 2009 National HIV Prevention Conference (August 2009), www.avac.org/meetingreports
- “Will a pill a day prevent HIV? Anticipating the results of the tenofovir PrEP trials.” AVAC, 2005, www.avac.org/anticipating_results_prep.2005

PrEP Clinical Trials

- For information on ongoing and past PrEP trials visit www.avac.org/trials/prep to find:
 - PrEP trials map
 - PrEP trials table
 - PrEP trials timeline
 - Centers for Disease Control and Prevention fact sheet: CDC Trials of PrEP for HIV Prevention
 - FEM-PrEP trial newsletter
 - iPrEx trial newsletter
- “Preventing Prevention Trial Failures: A Case Study and Lessons for Future Trials from the 2004 Tenofovir Trial in Cambodia.” Global Campaign for Microbicides, 2009, www.global-campaign.org/clientfiles/Cambodia.pdf
- “Research Rashomon: Lessons from the Cameroon Pre-exposure Prophylaxis Trial Site.” Global Campaign for Microbicides, 2009, www.global-campaign.org/clientfiles/Cambodia.pdf

Implementation

- “Anticipating the Efficacy of HIV Pre-Exposure Prophylaxis (PrEP) and the Needs of At-Risk Californians,” Center for HIV Identification, Prevention, and Treatment Services (CHIPTS), www.aidspartnershipca.org/pubs.html
- AVAC Think Tank on PrEP Financing in the US – What are the key regulatory, legal and financial challenges to PrEP implementation, if it proves effective? Meeting summary available at: www.avac.org/meetingreports
- “Pre-exposure prophylaxis for HIV infection: what if it works?” Paxton, LA, et al. *Lancet* 2007; 370: 89-93, [www.lancet.com/journals/lancet/article/PIIS0140-6736\(07\)61053-8/fulltext](http://www.lancet.com/journals/lancet/article/PIIS0140-6736(07)61053-8/fulltext)
- “The PrEP Implementation Puzzle: Many missing pieces.” from AVAC Report 2009, www.avac.org/avacreport

Selected Studies

- “Circulating HIV Type 1 drug resistance will have limited impact on the effectiveness of preexposure prophylaxis among young women in Zimbabwe” Van de Vijner DA, et al, *Journal of Infectious Diseases* 2009;199:1310-1317, www.ncbi.nlm.nih.gov/pubmed/19301982
- “HIV pre-exposure prophylaxis in the United States: impact on lifetime infection risk, clinical outcomes, and cost-effectiveness.” Paltiel, AD, et al, *Clin Infect Dis.*, 2009 Mar 15;48(6): 806-15, www.ncbi.nlm.nih.gov/pubmed/19193111
- “Modeling the impact of HIV chemoprophylaxis strategies among men who have sex with men in the United States: HIV infections prevented and cost-effectiveness” Desai K, et al, *AIDS* 2008;22(14): 1829-1839, www.ncbi.nlm.nih.gov/pubmed/18753932
- “Potential Impact of Antiretroviral Chemoprophylaxis on HIV-1 transmission in resource-limited settings.” Abbas, UL, et al, *PLoS ONE*, September 2007, Issue 9, e875, www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0000875
- “Prevention of rectal SHIV transmission in macaques by daily or intermittent prophylaxis with emtricitabine and tenofovir.” Garcia-Lerma, JG, *PLoS Medicine*, February 2008, Vol 5, Issue 2, www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0050028
- “Tenofovir disoproxil fumarate for prevention of HIV infection in women: a phase 2, double-blind, randomized, placebo-controlled trial.” Peterson, L, et al. *PLoS Clinical Trials*, May 2007, www.pubmedcentral.nih.gov/picrender.fcgi?artid=1876601&blobtype=pdf

Intermittent PrEP

- Reports from a series of think tanks on intermittent PrEP, the first convened by AVAC in December 2008 and the second convened by amfAR and AVAC in December 2009:
 - Consultation on the Intermittent PrEP (iPrEP) Research Agenda and research priorities in biomedical and behavioral iPrEP research (December 2009), www.avac.org/meetingreports
 - Trials of Intermittent Dosing of Pre-Exposure Prophylaxis (PrEP) - Preparing for PrEP: Policy, Practice and Politics (December 2008), www.avac.org/meetingreports
- The Intermittent PrEP (iPrEP) Research Agenda teleforum (April 2009), call recording available at: www.champnetwork.org/iprep-research-agenda
- What is iPrEP? To learn more about what the field is considering, check out the iPrEP glossary: A Lexicon of Intermittent PrEP Possibilities, www.avac.org/prep

Notes

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