

Policy and Practice Implications of HIV Pre-Exposure Prophylaxis (PrEP) in the United States

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Executive Summary

Pre-exposure prophylaxis (PrEP) is an HIV prevention strategy in which one or more antiretroviral drugs (ARVs) are used by an individual prior to/during potential HIV exposure, with the goal of reducing the likelihood of infection. The strategy is generally to take PrEP continually during a period of high risk for HIV acquisition. PrEP should be distinguished from postexposure prophylaxis (PEP), in which ARVs are taken soon after a potential HIV exposure to reduce the likelihood of infection.

It has been hypothesized that PrEP could be an effective HIV prevention strategy for those at high risk of infection, such as commercial sex workers, those in serodiscordant relationships, and members of high-risk groups who choose not to use condoms or for whom consistent condom use has proved difficult. Although behavioral interventions are likely to remain the cornerstone of HIV prevention for the foreseeable future, it is widely believed that biomedical approaches to HIV prevention, such as PrEP, vaccines, and microbicides, will also be necessary to control the spread of the virus.

Clinical trials are currently underway to evaluate the safety and/or efficacy of PrEP among heterosexual women (Botswana and West Africa); heterosexual men (Botswana); men who have sex with men (MSM) (Peru, Ecuador, and the United States); and injecting drug users (Thailand). Four of these studies are testing tenofovir disoproxil fumarate (TDF), a drug that is licensed to treat HIV infection; the other two are testing Truvada, a combination of TDF and emtricitabine, another anti-HIV drug. Results from these studies are expected to become available from 2006 until early 2010.

This monograph summarizes the PrEP studies currently underway, and considers three scenarios that were analyzed at a May 2006 PrEP think tank meeting in Los Angeles organized by the UCLA Program in Global Health. The scenarios include an optimistic one (in which all or a majority of the PrEP studies point in an efficacious direction); a pessimistic one (in which studies uniformly fail to show that PrEP is safe or effective); and a more complex “uncertain” scenario in which the evidence does not point strongly in either direction, either due to conflicting data from different studies, or from studies not providing clear outcomes.

For each of these scenarios, a detailed examination is presented as to what steps would need to be taken in the United States with regard to research priorities, prevention programming, funding, community relations/communication, and media relations, should that scenario come to pass. Although each scenario would come with its own set of particular challenges, an “uncertain” scenario may be the most complex to address, in that there may not be a clear mandate as to whether or to what degree implementation should occur. Confusion among communities, providers, and other stakeholders would be a likely result. An uncertain scenario may also be the most probable result of the current batch of clinical trials, however, and so it is important to prepare for this possibility. It is also necessary to recognize that many of the populations most in need of effective HIV prevention strategies in the U.S.—racial, ethnic, and sexual minorities; the economically disadvantaged; youth; substance users—are those who may be least likely to be able to access PrEP, should it prove to be safe and effective. Strategies would need to be developed to ensure access to PrEP and related HIV prevention services for those who need them.

This monograph provides recommendations that highlight important opportunities for taking action now to advance PrEP research, plan for future PrEP implementation and programming, engage communities and the media, and assume leadership for moving the PrEP and larger HIV prevention agenda forward.

Research priorities include advocating for additional studies, including alternative trial designs; investigating current patterns of PrEP use in communities; and conducting operational research to de-

termine the best ways to implement effective PrEP interventions.

Recommendations for prevention programming focus on bridging the divide between medical and non-medical HIV prevention providers, and finding ways for the two disciplines to work together more effectively at providing comprehensive HIV prevention services that include biomedical interventions such as PrEP.

Recommendations for community and media relations include developing simple, clear messages and fact sheets about PrEP for distribution to communities, providers, and the media; engaging the media in ongoing dialogue about PrEP; and fostering HIV prevention advocacy among at-risk communities.

Finally, a recommendation is put forth to convene a PrEP leadership group (or a larger HIV prevention leadership group for which a PrEP committee is one focus) that can move the PrEP research and advocacy agenda forward. Such a leadership group would help to ensure that the most promising research avenues are explored, that effective strategies are implemented as quickly and equitably as possible, and that the maximum benefit can be obtained from PrEP and other biomedical and behavioral HIV prevention strategies.

Introduction

Pre-exposure prophylaxis (PrEP) is an HIV prevention strategy in which one or more antiretroviral drugs (ARVs) are used by an individual prior to/during potential HIV exposure, with the goal of reducing the likelihood of infection. The strategy is generally to take PrEP continually during a period of high risk for HIV acquisition. PrEP should be distinguished from postexposure prophylaxis (PEP), in which ARVs are taken soon after a potential HIV exposure to reduce the likelihood of infection. It has been hypothesized that PrEP could be an effective HIV prevention strategy for those at high risk of infection, such as commercial sex workers, those in serodiscordant relationships, and members of high-risk groups who choose not to use condoms or for whom consistent condom use has proved difficult. Although behavioral interventions are likely to remain the cornerstone of HIV prevention for the foreseeable future, it is widely believed that biomedical approaches to HIV prevention, such as PrEP, vaccines, and microbicides, will also be necessary to control the spread of the virus. Clinical trials are currently underway to evaluate the safety and/or efficacy of PrEP in various risk populations in sub-Saharan Africa, Southeast Asia, Latin America, and the United States.

In November 2004, the UCLA Program in Global Health and the Center for HIV Identification, Prevention, and Treatment Services (CHIPTS) developed one of the first in-depth monographs on HIV pre-exposure prophylaxis. Funded by Northern California Grantmakers/AIDS Partnership California, the monograph, *Anticipating the Efficacy of HIV Pre-Exposure Prophylaxis (PrEP) and the Needs of At-Risk Californians* (<http://www.aidspartnershipca.org/assets/PrepReport1104.pdf>), explored the rationale for PrEP, summarized the state of PrEP knowledge, and outlined the key clinical, prevention, economic, and policy issues that would need to be addressed once PrEP data become available.

In May 2006, the UCLA Program in Global Health held a two-day PrEP think tank meeting (“Policy and Practice Implications of HIV Pre-Exposure Prophylaxis (PrEP) in the United States”) at the UCLA campus in Los Angeles. This think tank brought together approximately 60 leading PrEP researchers, community advocates, clinicians, industry representatives, foundation funders, and representatives from California and Federal government. The meeting served to review the PrEP clinical trials currently underway and make recommendations about the policy implications of various research outcomes (“optimistic”, “pessimistic”, and “uncertain” scenarios) for people and programs in the United States. This think tank meeting was instrumental in framing much of the discussion and many of the recommendations presented in this monograph; however, the views the monograph expresses and the conclusions it makes are those of the UCLA Program in Global Health, and are not necessarily those of any individual or agency represented at the meeting.

This monograph summarizes the current PrEP clinical trials and considers what the policy implications in the United States would be of three scenarios:

- an “optimistic” one, in which all or a majority of the trials point to PrEP being a safe and effective HIV prevention intervention;
- a “pessimistic” one, in which studies uniformly point to a lack of safety and/or efficacy; and
- an “uncertain” one, in which studies do not produce clear results or in which study results are contradictory.

Recommendations are then made as to what actions should be taken now, prior to the availability of data from PrEP studies, so that organizations and communities will be prepared to meet the challenges of designing HIV prevention programs that take data from PrEP studies into account, regardless of their outcomes.

Current PrEP Clinical Trials

Clinical trials of PrEP are currently testing two products. Tenofovir disoproxil fumarate (TDF)—brand name Viread—is a nucleotide analogue reverse transcriptase inhibitor (NRTI) manufactured by Gilead and currently licensed to treat HIV infection in combination with other ARVs. TDF was selected as a candidate PrEP agent because it is a potent drug, can be dosed once daily, and has a generally favorable side effect profile. In 2006, however, data presented at the Conference on Retroviruses and Opportunistic Infections (CROI) showed that oral TDF delayed, but did not prevent, infection in rhesus macaques following repeated rectal exposure to SHIV (a hybrid simian-human immunodeficiency virus). Other data showed that six macaques were completely protected from weekly rectal exposures to SHIV when they were injected once daily with a combination of TDF and FTC (emtricitabine, another NRTI). A tablet formulation of these two drugs (brand name Truvada), also manufactured by Gilead and licensed to treat HIV infection, became a new focus of interest for PrEP research. To date, there have not been head-to-head comparisons of TDF and Truvada in nonhuman primates. Of the five current PrEP studies, two are using Truvada as the PrEP agent, including one that decided to switch to using Truvada after starting the study with TDF; the other three studies are testing TDF.

Trials are currently evaluating PrEP in heterosexual women (Botswana and West Africa); heterosexual men (Botswana); men who have sex with men (MSM) (Peru, Ecuador, and the United States); and injecting drug users (Thailand).

PrEP Clinical Trials

Study Location	Sponsor	Study Population	Primary Route of Exposure	Study Drug	Planned # of Participants	Target Completion Date
<i>Current Trials</i>						
Botswana	CDC	Heterosexual men & women	Vaginal/penile	Initially was TDF (n = 71), switched to Truvada (as of 1st quarter 2007)	1,200	2009
Peru/Ecuador	NIH	MSM	Penile/rectal	Truvada	1,400	2010
Thailand	CDC	IDUs	Parenteral	TDF	2,000	2008
United States (San Francisco, Atlanta, & Boston)	CDC	MSM	Penile/rectal	TDF	400	2009
West Africa (Cameroon, Ghana, & Nigeria)	FHI	Women	Vaginal	TDF	1,200 (936 enrolled)	2006
<i>Stopped Trials</i>						
Cambodia (trial stopped before enrolling)	NIH/FHI	Women	Vaginal	TDF	960	----
Malawi (trial stopped before enrolling)	FHI	Heterosexual men	Penile	TDF	400	----

Botswana

The CDC's PrEP trial in Botswana is a Phase II/III randomized, double-blind, placebo-controlled study enrolling both men and women in Gaborone and Francistown (Botswana's two largest cities). The trial initially used TDF as the PrEP agent. In March 2006, the study went on hiatus while a decision was made to switch from TDF to Truvada. At the time of hiatus, 71 persons had been enrolled in the TDF trial. In the first quarter of 2007, the study will restart using Truvada, and participants who were taking TDF will be switched to Truvada. Participants have a one-to-one chance of receiving study drug or placebo. Study endpoints are HIV seroconversion, adverse events, risk behaviors, adherence, and, in participants who seroconvert, altered viral load set point. As the HIV epidemic in Botswana is a generalized one in which young people are the primary risk group, the CDC's PrEP study is focused on 18-to-29-year olds. The main avenues of recruitment are VCT centers and STD and family planning clinics, but participants will also be recruited at non-healthcare venues, such as shopping malls and entertainment events. Radio, print, and TV ads are also used as recruitment tools and to educate the community. The study has 80% power to detect a 65% reduction in HIV, assuming an HIV incidence of 5%. The enrollment target is 1,200 participants, and study completion is expected in 2009.

Peru/Ecuador

The "Andean PrEP study" in Peru and Ecuador is a collaborative research project of the Gladstone Institute and UCSF (San Francisco, U.S.), Impacta (Lima, Peru), Asociacion Civil Selva Amazónica (Iquitos, Peru), and Fundación Ecuatoriana Equidad (Guayaquil, Ecuador). The study plans to enroll 1,400 high-risk MSM, who will be randomized one-to-one to receive Truvada or placebo. Participants will be followed on study drug for 72 weeks, and will be monitored for HIV infection, adverse effects, risk behavior, and STIs. A subgroup of 200 participants will be monitored for fat composition and bone mineral density. If there are seroconversions in the study, drug resistance and immune responses will be examined. Hepatitis B infection is not an exclusion criterion for this study. As both agents in Truvada (TDF/emtricitabine) have activity against HBV, there may be a benefit for participants with hepatitis B. However, there may also be an increased risk of hepatitis flares when the drug is stopped. The target date for study completion is the 1st quarter of 2010. The current study is powered to detect evidence of 60% efficacy with 86% power, assuming 4% incidence. As such, this is a "proof of concept" trial. The investigators and sponsors are exploring the possibility that the study size could be increased by adding sites in order to estimate efficacy with greater confidence.

Thailand

The CDC's PrEP study in Thailand began enrolling in June 2005. As with the study in Botswana, the Thai trial is a Phase II/III randomized, double-blind, placebo-controlled safety and efficacy trial with 1:1 drug/placebo randomization. Study endpoints are HIV seroconversion, adverse events, risk behaviors, adherence, and altered viral load set point in seroconverters. Unlike in Botswana, the Thai study will continue to use TDF rather than switching to Truvada. The Thai study aims to enroll 2,000 HIV-negative injecting drug users, aged 20-60 years (~88% male, 12% female). The study has 87% power to detect a 67% reduction in HIV, assuming an HIV incidence of 3%. The study is expected to finish in 2008.

United States (San Francisco, Atlanta, & Boston)

This CDC-sponsored trial is the only major PrEP study currently being done in the United States. It is being conducted by the San Francisco Department of Public Health (SFDPH), AIDS Research Consortium of Atlanta (ARCA), and at a newly added third site in Boston, the Fenway Community Health

Center. It is primarily a safety study that seeks to enroll 400 MSM aged 18-60, who are randomized to receive TDF or placebo. It is a diverse cohort, with >25% being men of color. All participants receive risk-reduction counseling, condoms, and linkages to services. The study will look at tolerability and clinical adverse events; will perform laboratory assessments (including CBC, chemistries, liver function tests, lipid assays, and renal function tests); HIV antibody tests; and STI testing. The San Francisco site will also perform baseline and annual DEXA scans to assess body composition. HIV testing is performed quarterly (and interim) using rapid HIV assays, and PCR is used if there are symptoms of acute retroviral syndrome. For participants who seroconvert, the following will occur at seroconversion and at 1, 3, 6, 9, and 12 months—linkages with medical and psychosocial care, inventory of clinical symptoms, CD4+ T-cell count and viral load measurement, genotypic and phenotypic testing (baseline, some on follow up), and specimen storage. A behavioral assessment will examine sexual risk behaviors by partner serostatus, recreational drug use, depression, motivations for study participation, and perceptions of TDF efficacy. Study completion is expected in 2009.

The San Francisco site is also conducting a survey looking at prevalence of current PrEP use in the community, and factors associated with its use. It is a population-based survey of 400 MSM in the San Francisco Bay Area, and also a survey of MSM attending circuit parties. Survey questions will capture data on demographics, venues, social gatherings, meeting sex partners, substance use, sexual behaviors, harm reduction strategies, serosorting, knowledge and use of postexposure prophylaxis (PEP), and knowledge and use of PrEP. The survey will be useful in characterizing what is happening in the MSM community now, before results of the larger PrEP studies are available.

West Africa (Cameroon, Ghana, & Nigeria)

The Family Health International (FHI)-sponsored PrEP study in West Africa planned to enroll 1,200 women in 3 countries (400 each from Cameroon, Ghana, and Nigeria). In Ghana, the entire trial was successfully completed. For a variety of reasons, data collection in Nigeria and Cameroon was stopped prematurely after enrolling 136 and 400 participants, respectively. The study was a two-arm, placebo-controlled, double-blind randomized trial, in which the primary endpoint was to evaluate the safety (adverse effects and liver/kidney function tests) and preliminary effectiveness (HIV seroconversion) of oral TDF in preventing HIV acquisition. The study also assessed adherence, potential disinhibition related to PrEP availability, and TDF resistance. A formative research protocol using qualitative methods (participant observation, focus groups, and in-depth interviews) also sought to measure responses to both the PrEP study and potential product availability among a broad array of community stakeholders and trial participants pre-, during, and post-trial.

Clinical data from the West Africa study were presented at the XVI International AIDS Conference held in Toronto in August 2006. Of the 936 HIV-negative women enrolled (half randomized to take TDF, half randomized to placebo), eight seroconversions occurred—two in the TDF group and six in the placebo group. These results were not statistically significant. TDF was shown to be safe, however, with no significant differences emerging between treatment groups in clinical or laboratory outcomes. Adherence to the daily regimen was estimated at approximately 70%. No evidence of self-reported risk compensation (disinhibition) occurred in study participants.

Social science data from the West Africa study were presented at both the Bangkok (2004) and Toronto (2006) International AIDS Conferences. Key findings from these investigations included (1) identification of study-related preventive health care such as STI testing and treatment, condom provision and HIV counseling as important motivators for consistent study participation; (2) the need for better integration of scientific research concepts with cultural values, such as participants' religious faith, to improve informed consent comprehension; and (3) the value of social analysis before, during, and after trial implementation for monitoring and addressing emergent challenges.

Planning for Possible Implementation of PrEP

Once the current PrEP studies are completed and data become available, there will be a need to rapidly and equitably scale up prevention programs in the United States that provide PrEP (in the case of unequivocally safe and effective study outcomes), and/or develop communications strategies that address PrEP and its role in the larger context of HIV prevention options (regardless of study outcomes). A recurring theme at the May 2006 PrEP think tank meeting was that planning for PrEP implementation must begin now, well before study data become available. Without ample time to engage communities and plan for the various possible outcomes of current PrEP studies, researchers, program planners, clinicians, and policymakers will find themselves unable to rapidly respond to demands for programs and services that take PrEP research data into account. An important opportunity will have been missed.

A complicating factor in planning for PrEP is that the data from the current studies will not become available at the same time. Rather, as shown in the table of PrEP trials in the previous section, data from these studies are due anywhere from mid-to-late 2006 to early 2010. Data from an early study may be contradicted by data from later studies, yet communities and other stakeholders may not be willing to wait until all studies are completed to take action.

At the May 2006 think tank, three scenarios were analyzed—an optimistic one (in which all or a majority of the PrEP studies point in an efficacious direction); a pessimistic one (in which studies uniformly fail to show that PrEP is safe or effective); and a more complex “uncertain” scenario in which the evidence does not point strongly in either direction, either due to conflicting data from different studies, or from studies not providing clear outcomes.

Regardless of scenario, planning for and implementing prevention programs that incorporate the findings of PrEP studies will require significant organizing and work. The scenarios in which data from studies all point in the same direction (either optimistic or pessimistic) are likely to be relatively straightforward to address, in that there will be a fairly clear mandate as to what should be done (although *how* to implement programs, pay for them, etc may still be complex). A scenario in which PrEP data do not converge on a common conclusion, however, will be much more complicated to address.

While an “uncertain” scenario may be the most difficult to address, it is probably also the most likely to occur. It is quite possible that the situation with PrEP will be similar to that for postexposure prophylaxis (PEP), in which a lack of definitive evidence for efficacy has left significant questions unanswered about how best to use it. For example, while the protection conferred by PrEP may be different for vaginal vs. penile exposures, the study in Botswana (in which half the participants are male and half female) may not be sufficiently powered to detect these differences. An uncertain scenario will require an extraordinary degree of nuanced communication about what is known and not known, both directly to affected communities and through the media.

For each of the three scenarios considered—“optimistic”, “pessimistic”, and “uncertain”—an analysis was performed to determine what steps would need to be taken in the United States with regard to research priorities, prevention programming, funding, community relations/communication, and media relations, should that scenario come to pass. A detailed examination of each of these scenarios follows.

“Optimistic” Scenario

An issue that emerged at the May 2006 think tank was the recognition that there needed to be some consensus as to how “good” and/or consistent the PrEP research data would need to be in order to argue for widespread implementation. This underscores the need for either a PrEP-specific or more broad HIV prevention leadership group to take responsibility for coordinating and analyzing PrEP study data as it emerges, and working with communities, government, and the media to ensure that messages about PrEP are disseminated as quickly and accurately as possible.

Research Priorities

Even if current PrEP studies show the strategy to be safe and clearly and consistently efficacious, there will still be the need to conduct further research.

Phase IV/postmarketing studies will be important in continuing to monitor for adverse effects (including impaired renal function), as well as in tracking development of resistance, evaluating quality of life, alternate modes of delivery, and alternate dosing schedules (including use by people with short-term risk scenarios).

Additional research may help to elucidate the minimum dose necessary to confer protection, as well as the consequences of intermittent dosing.

There will be the need to determine the optimum frequency of HIV testing in people using PrEP, conduct active surveillance of PrEP failures, and examine how PrEP may be used by women wishing to conceive.

Prevention Programming

A consensus to implement PrEP based on positive research outcomes will bring significant challenges for those in charge of prevention programming, whether in government, health care institutions, or CBOs. The agents currently being studied for PrEP are prescription drugs. Most prevention providers, however, are not licensed to prescribe drugs. It will be important to ascertain what alternate methods of PrEP delivery may be possible. There may be precedents to consider from the substance-use treatment milieu, in which medications can be made available outside of traditional clinical channels. Prevention providers, clinicians, and representatives from regulatory agencies (ie, FDA) will need to get together to discuss what options are feasible and how they can work.

There will also need to be discussions about how potential PrEP users would be screened for pre-existing HIV infection, receive ongoing monitoring for HIV infection and adverse effects, and be screened for hepatitis B virus (HBV). As TDF has activity against HBV and may cause hepatitis flares upon drug discontinuation, those taking PrEP would need to be screened and monitored for HBV. Even if PrEP is shown to be highly effective, delivery of PrEP would ideally be integrated into a comprehensive package of prevention services, including adherence counseling, risk-reduction counseling, and mental health services, and how this will work will need to be determined. It will be important to identify existing local services that work well, as these may be the best avenues for providing PrEP.

Additionally, prevention providers will need to find ways to identify and target individuals in high-risk phases of life (such as young MSM moving to cities or people starting commercial sex work), as well as potentially hard to reach “hidden” populations such as non-gay identified MSM. Prevention providers would also need to engage with the criminal justice system to establish ways that PrEP can be made accessible in correctional facilities.

There are likely to be liability concerns for drug companies and institutions providing ARVs for use as

PrEP. It will be useful to explore whether product registration or some other mechanism may provide some form of indemnification against product liability. Exploration of packaging options—such as considering separate branding and packaging for an ARV used as HIV treatment versus PrEP, may help to reduce stigma associated with the approach.

Funding

Perhaps the biggest implementation challenge if PrEP proves to be safe and effective will be determining who will pay for it. The more effective PrEP is shown to be, the stronger the policy arguments will be for implementing it as part of a comprehensive HIV prevention approach. It will be necessary, however, to ensure that sufficient resources are in place to provide access to those that need it, and that any barriers are identified and proactively addressed. It is not clear what funding sources would be used to ensure access, however. Insurers may not opt to cover the costs for the off-label use of antiretrovirals used for HIV prevention (and drug companies may not pursue labeling changes with the FDA to adjust the indications to include HIV prevention, due to liability concerns and other issues). Public programs such as Medi-Cal in California are already strained, and the AIDS Drug Assistance Program (ADAP) is currently designed to provide medications only to those with an HIV diagnosis. It has been suggested that additional cost-effectiveness analyses would be useful in furthering discussions on paying for PrEP. Ultimately, government, clinicians, HIV program planners, affected communities, health care organizations, and third-party payers will need to come together to address the issue of how PrEP programs should best be funded.

Community & Media Relations

Regardless of the outcome of PrEP studies, nuanced communication with communities and the media will be necessary to accurately represent what is known and not known and to counter misinformation about PrEP that is likely to arise. If studies show PrEP to be a safe and highly effective HIV prevention strategy, the most important message to communities and the media may be one of moderation—in order to avoid disinhibition that may result from overenthusiasm toward the approach (and which could offset its benefits), and to ensure that PrEP is seen as part of a broader package of prevention and not as a “quick fix”.

“Pessimistic” Scenario

A pessimistic scenario—one in which studies consistently fail to show safety and/or efficacy of current PrEP approaches—does not necessarily mean the concept has failed or should be discarded. In the field of HIV microbicides, there have been as many as 9 disappointing studies, yet researchers have used the unsuccessful studies to inform their research agenda, and there is currently a strong HIV microbicides research program and considerable enthusiasm regarding the approach.

Research Priorities

Negative study outcomes would point to the need for additional research to determine what did not work, and how to achieve a better outcome. Unsuccessful studies could result from several factors, including insufficient adherence, development of resistance, poor tolerability, study conduct, safety, not meeting study endpoints, insufficient study power, and/or problems related to study design.

A think tank comprised of PrEP researchers and other key stakeholders would be instrumental in reviewing study outcomes, considering why primate data is different, and strategizing for moving forward the next generation of studies.

Prevention Programming

Although prevention programmers would not need to figure out ways to implement widespread PrEP service programs in light of consistently negative research findings, there would still be the need to

ensure that constituent communities understand what the negative findings mean, do not succumb to pessimism about other emerging HIV prevention research strategies, and have access to the range of alternative HIV prevention services available.

Funding

Funding discussions given negative research outcomes would take on a different meaning than they would if findings were positive. Whereas positive findings would create the need to fund service programs, negative findings would focus attention on the continued need to support ongoing research on the PrEP concept. This will require a sustained process of educating the funding community about the status of PrEP research. Briefing materials, similar to those created by the AIDS Vaccine Advocacy Coalition (AVAC) on the status of HIV vaccine research, may be useful in this regard.

Community & Media Relations

Messaging to communities and the media will need to be as clear as possible and provide straightforward messages about what is known and not known. It will be especially important to craft messages that do not allow negative PrEP findings to create a downward spiral in which people become pessimistic about other HIV prevention research strategies. Trying to explain the complexities of generally negative research findings to communities and the media can be complicated; this was the experience of disseminating results from Project Explore, a large behavioral HIV prevention study in MSM which did not generally show efficacy, but provided a number of interesting and important research findings.

“Uncertain” Scenario

An uncertain scenario—one in which studies either do not show a clear positive or negative finding, or the results of some studies conflict with the results of others—is perhaps the most likely outcome of the current crop of PrEP clinical trials. It would also be a complex scenario to address in that clear mandates on what to do may be in short supply, and messages related to PrEP and HIV prevention in general may become quite complicated. We believe that it is important to get ready for this scenario.

Research Priorities

Researchers will need to account for any disparities in safety and/or efficacy among PrEP trials—there may be biological, pharmaceutical (eg, different drugs used) behavioral, cultural, or other reasons. Mixed data may point to the need for additional research to resolve these disparities and address unanswered questions.

As with postexposure prophylaxis, there may be some limits as to what clinical trials can tell us, and stakeholders must be prepared to address whether and how to implement PrEP programs based on incomplete or conflicting data.

It would be important to ensure that funding for PrEP research not be stopped, but advocacy may be needed to move this research agenda forward, to ensure that we are not overlooking a potentially effective HIV prevention opportunity.

Prevention Programming

Given a lack of clear consensus on PrEP’s safety and/or efficacy, program planners may be in the difficult position of deciding to what extent they should incorporate PrEP into their suite of prevention services. In this regard, consensus guideline development will be critically important, as such guidance can be particularly useful in situations where data are mixed or conflicting. An expert committee comprised of PrEP researchers, clinicians, prevention providers, affected communities, and govern-

ment will need to issue recommendations covering all aspects of PrEP use, including patient selection, screening, dosage, monitoring, and evaluation. Although such guidelines will also be necessary should data show PrEP to be effective, they will be especially desirable for agencies and clinicians should the PrEP data be less conclusive.

Funding

Funding needs in light of unclear or conflicting study results may be complicated, in that there may be both a demand to fund PrEP programs to some degree, as well as to fund additional research. The lack of compelling data may make both of these particularly challenging, however. It will be necessary to engage prevention funders, both public and private, to come to consensus regarding the cost-benefit of funding for PrEP for high-risk uninfected individuals.

Community & Media Relations

The process of communicating complex messages about unclear or conflicting PrEP study data will need to be handled delicately—there will be confusion, and messaging should be designed to minimize confusion and emphasize what is known. Engaging communities and media representatives now, prior to the release of study data, will build trust and will allow for ongoing communications that may avoid communities feeling that they have been set up for disappointment. The development and dissemination of consensus guidelines may also be useful in helping to develop messages for communities, as it will provide some clarity on whether and how PrEP should be used—in which populations, what situations, etc.

Disparities

Many of the populations most in need of effective HIV prevention strategies in the U.S.—racial, ethnic, and sexual minorities; the economically disadvantaged; youth; substance users—are those who may be least likely to be able to access PrEP, should it prove to be safe and effective. Programs to roll out PrEP would likely face massive challenges in reaching the populations most in need of this intervention.

The accessibility and quality of HIV care has been shown to vary by ethnicity, socioeconomic status, gender, and insurance status. The HIV Cost and Services Utilization Study (HCSUS), a nationally representative sample of HIV patients and providers of HIV care in the United States, began in 1996, around the time that protease inhibitors began to revolutionize the treatment of HIV. Data from HCSUS showed that ARVs diffused less rapidly to disadvantaged groups—HIV-infected African Americans, Latinos, and those of lower socioeconomic status were less likely than others to receive antiretrovirals following the advent of “highly active” therapies in the late 1990s. It was also shown that there was a large unmet need for services—benefits counseling, mental health care, housing, alcohol and drug treatment services, etc.—and that the need was greater among the uninsured and those of lower income. Prior to the advent of protease inhibitor-based therapies, similar disparities were also the case for distribution of zidovudine (AZT).

As significant disparities exist with regard to the accessibility of ARVs and related care services for HIV-infected people in the United States, it can be expected that, without adequate planning and specific intervention, racial and ethnic minorities and those of lower socioeconomic status at risk for HIV will be the least likely to have access to PrEP. To overcome these challenges, researchers, public health officials, and community advocates need to start working together now to figure out ways to dialogue with communities, prepare them for the time that PrEP data become available, and develop strategies for ensuring access to PrEP and related HIV prevention services. Testing specific outreach strategies may be instrumental in finding effective ways to engage communities and begin to build workable models of delivery for PrEP.

Recommendations for What to Do Now

There is no need to wait for the results of clinical trials to begin work on addressing many key PrEP issues. In fact, it will be too late to adequately research, plan for, and effectively implement strategies for integrating PrEP into the HIV prevention framework, unless this work is started well before study results are released.

The following recommendations summarize some of the most salient points raised at the May 2006 PrEP think tank meeting held at UCLA, and highlight important opportunities for taking action now to advance PrEP research, plan for future PrEP implementation and programming, engage communities and the media, and assume leadership for moving the PrEP and larger HIV prevention agenda forward.

Research Priorities

There are currently five trials evaluating the safety and/or efficacy of either TDF or Truvada for PrEP, in addition to several community and clinician surveys looking at current knowledge of and attitudes toward PrEP and use of PrEP. Additional research may be needed, however, to evaluate PrEP as an HIV prevention strategy, to assess current attitudes and degree of use in at-risk communities, and to establish optimal mechanisms for rolling out PrEP if it proves to be effective. Communities need to be engaged in the research process now, prior to the availability of efficacy data from other large studies.

Recommendation: Advocate for Additional Research, Including Alternative Trial Designs

Additional well-designed and adequately powered efficacy studies may be needed to definitively answer important questions about the safety and efficacy of different approaches to HIV PrEP. While Phase III randomized controlled trials are considered the gold standard and, in the best cases, can provide a high level of clarity with regard to research outcomes, such trials may also be limited in their ability to address important questions about PrEP efficacy. Insufficient HIV incidence, required sample sizes, lack of adequate resources, and problems with trial implementation may all limit the feasibility of large randomized trials. It will be important to consider alternative clinical trial designs and develop creative approaches that allow for the degree of subtle, refined comparisons that may be necessary to address important questions about PrEP safety, efficacy, and implementation. There is also the need to start planning now for meta-analyses of PrEP studies.

Recommendation: Focus on Current Patterns of Use

Studies evaluating PrEP are moving forward; however, there is little understanding of whether people in at-risk communities are aware of PrEP, or to what degree they may be using it already. There is an urgent need to develop the research capacity to evaluate what is currently happening in communities with regard to the level of awareness of PrEP, attitudes towards PrEP, and levels and patterns of use—including “casual dosing” and intermittent use. Qualitative methods may be useful in examining issues of PrEP acceptability in communities, and in assessing community interest and potential barriers to rollout.

Recommendation: Begin Conducting Operational Research

If PrEP studies show the intervention to have an acceptable degree of safety and efficacy, there will be the need to quickly roll out PrEP programs based on solid evidence of how they should be implemented. Operational research that examines the best way to roll out PrEP programs in various communities and based on various levels of certainty of PrEP research data will prevent needless delay and confusion once PrEP data are released. The need for operational research is especially acute for incarcerated populations, gay youth, non-gay identified MSM, and other hard-to-reach or vulnerable populations.

Prevention Programming

HIV prevention programs—whether at the government level, at clinics, or through CBOs, need to consider now how they will respond once PrEP research data become available.

Recommendation: Work on Bridging Medical and Non-Medical HIV Prevention

If PrEP is deemed suitably effective for implementation, there will be immediate tensions about how to provide it to those at risk. TDF and Truvada are prescription drugs, and most prevention providers are not currently licensed to prescribe them. Those most at risk are often those without insurance or good access to health care. Mechanisms will need to be created that address how people at risk will be identified, screened for PrEP eligibility (ie, tested for HIV and hepatitis B), provided with access to PrEP, and monitored—both clinically (for side effects, laboratory markers, etc) and behaviorally (adherence, ongoing prevention counseling, etc).

Prevention and treatment advocates may have different approaches toward providing information to their constituents, and these may cause confusion about PrEP, both now and in the future when more data become available. While a physician, adhering to “do no harm”, may advise that a patient “don’t try this at home” until more is known, a treatment advocate may instead provide information about what is known and not known, and encourage clients to make their own informed decisions. A prevention provider may say something else entirely. Treatment advocates may be good at helping a client evaluate the pros and cons of PrEP from a medical perspective, but may not be well versed enough in behavioral prevention to understand what the bigger-picture prevention needs of the client might be. A prevention provider may have similar limitations.

The interest generated by PrEP may create an important opportunity to provide more comprehensive prevention management that takes clients’ clinical and psychosocial needs into account. For example, since those at risk for HIV are typically also at risk for hepatitis B and C, it would be desirable to incorporate vaccination for HBV and counseling & testing for HCV into PrEP programs, in addition to behavioral approaches such as individualized risk reduction and adherence counseling.

Bridging medical and non-medical HIV prevention will require a commitment among government, clinicians, treatment and prevention CBOs, regulatory agencies, third-party payers, communities, and other stakeholders to hold meetings and begin working together now to come up with solutions to these complex issues.

Community & Media Relations

Whatever the outcome of PrEP studies, nuanced communication with communities and the media will be required to accurately describe the study results and to counter any misinformation. In the meantime, there is also a critical need to provide accurate information about PrEP, to dispel inaccurate or sensationalist representations, and to prepare communities to think about PrEP and the larger context of HIV prevention.

Recommendation: Develop Simple, Clear Messages About PrEP

Although the safety and efficacy of TDF or Truvada for HIV PrEP has not yet been determined, it is important to develop messages about PrEP that are as simple and clear as possible. Fact sheets for providers, community members, and the media should be developed that outline what PrEP is and is not, what is currently known and not known, and what the current status of PrEP research is. Such materials would be helpful in countering inaccurate perceptions and managing expectations, and would help to lay a foundation of accurate information that will be important once research data

become available and interest in the intervention increases. It will be necessary to carefully differentiate pre-exposure prophylaxis (PrEP) from postexposure prophylaxis (PEP), as the terminology, acronyms, and concepts are similar enough to cause significant confusion. Messages will ultimately need to be “staged”, in that information will need to be updated as results from the various PrEP studies become available.

Recommendation: Engage the Media Now on PrEP Issues

The cultivation of media relationships is an ongoing process and is something that should begin now to ensure that media are invested in PrEP and can represent the issues accurately, both now and once data become available. To this end, it may be prudent to target science writers, who are experienced in reporting on complex health and technology issues. Given that the media loves a good story, it may be wise to highlight positive conflict with regard to PrEP. Conflict is not necessarily a bad thing—it points out the tensions in situations and can be helpful in that it is essentially what makes things newsworthy. It would be useful to convene a PrEP media relations working group to do press releases, maintain a Web site, and distribute materials to media and public relations outlets.

Recommendation: Foster Prevention Advocacy in At-Risk Communities

When communities have a solid understanding of HIV prevention options, feel empowered to engage with researchers and policymakers, and have established communication channels within communities, the potential benefits of PrEP are more likely to be realized (and the potential risks lessened). Researchers, HIV prevention and treatment advocates, and community advocates and organizers can help to facilitate this by helping to disseminate accurate information about PrEP and PrEP research to communities, encouraging communities and researchers to engage one another in active dialogue, and work at boosting research literacy in communities and strengthening community networks. This will be especially important in racial and ethnic minority communities and those of lower socioeconomic status. The better communities are at understanding, articulating, and advocating for their prevention needs, the more likely it is that the results of current PrEP studies will be able to be effectively integrated into comprehensive prevention programs that address those needs.

Moving the PrEP Research and Advocacy Agenda Forward

Recommendation: Convene PrEP Leadership Group

A PrEP leadership group could play an instrumental role in moving the research agenda forward, engaging in PrEP and HIV prevention advocacy, and planning communications strategy. A leadership group should be comprised of PrEP and other HIV prevention researchers, community members, clinicians, funders, government and industry representatives, treatment and prevention advocates, and other stakeholders. Such a group would help to ensure a coordinated research effort, minimize duplication of effort, and serve as a central point of communication on PrEP issues.

The best scenario may be one in which a PrEP committee is part of larger HIV prevention leadership group. This would maximize the ability to assess the potential impact of PrEP on other emerging prevention research strategies (ie, vaccines, microbicides, male circumcision), and to plan and coordinate research and advocacy for the full spectrum of behavioral and biomedical HIV prevention strategies. Such a leadership group would help to ensure that the most promising research avenues are explored, that effective strategies are implemented as quickly and equitably as possible, and that the maximum benefit can be obtained from HIV prevention strategies.

Suggested Reading

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PrEP Think Tank Meeting

The UCLA Program in Global Health held a PrEP think tank meeting May 11-12, 2006 at the UCLA campus in Los Angeles. The think tank, “Policy and Practice Implications of HIV Pre-Exposure Prophylaxis (PrEP) in the United States”, brought together approximately 60 leading PrEP researchers, community advocates, clinicians, industry representatives, foundation funders, and representatives from California and Federal government. The two-day meeting focused on reviewing the current status of PrEP clinical trials and considering the policy implications of various research outcomes for U.S. settings. The presenters at the meeting were Robert M. Grant, MD, MPH; Lynn Paxton, MD, MPH; Susan Buchbinder, MD; Ward Cates, MD; Michelle Roland, MD; and Martin Shapiro, MD, MPH. Breakout groups were formed to discuss policy implications of the optimistic, pessimistic, and uncertain PrEP scenarios. Although the think tank meeting was instrumental in framing much of the discussion and many of the recommendations presented in this monograph, the views it expresses and conclusions it makes are those of the UCLA Program in Global Health, and are not necessarily those of any individual or agency represented at the meeting.

PrEP Think Tank Meeting: Participant List

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