Financing and Delivery Mechanisms to Increase Pre-Exposure Prophylaxis (PrEP) Access in Populations at High-Risk of HIV Infection

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Executive Summary

HIV/AIDS infection remains a persistent and urgent public health problem in the United States. Though the use of antiretroviral (ARV) medicines has transformed HIV into a largely treatable chronic condition for individuals in care, the virus remain costly to treat, many infected individuals lack access to care, and even treated individuals face significant health disparities relative to uninfected individuals. While HIV infection levels in the United States have fallen since the 1980s, the rate of infection has been stagnant for over a decade in the overall population and is rising in several high-risk groups, demonstrating the need for strategic new approaches to HIV prevention.

One promising new HIV prevention strategy is the use of ARVs as pre-exposure prophylaxis (PrEP) among high-risk men who have sex with men (MSM). Several clinical and cost-effectiveness studies demonstrate that PrEP has the potential to reduce HIV infection rates for high-risk MSM in a cost-effective way. However, policymakers continue to face questions regarding how to improve drug adherence, offer services to the most high-risk individuals including African-American and Latino MSM and transgender women, and ensure that adequate financing mechanisms are in place to pay for the many biomedical and behavioral components of PrEP.

Policymakers seeking to increase PrEP access must further contend with the current political reality of constrained financial resources for public health assistance, including for state Medicaid programs and for HIV prevention programs that serve individuals at high-risk of HIV infection. Strategic opportunities for financing and delivery still exist, but numerous public and private sources will need to be mobilized for PrEP to reduce HIV infections in significant numbers.

Key financing and delivery opportunities include Gilead’s application for FDA approval of a prevention label for Truvada; National Institutes of Health (NIH) and Centers for Disease Control (CDC) funding for demonstration projects in San Francisco, Boston, and other U.S. cities; private and public health insurance coverage for PrEP; a Gilead-funded Patient
Assistance Program to help low-income patients pay for PrEP; and opening the PrEP drug market to non-Truvada PrEP formulations. Given that new clinical and cost evidence for PrEP is expected to arrive from a variety of studies and projects in the coming years, policymakers will need to adapt their implementation of PrEP accordingly.

**Policy Recommendations:**
The recommendations in this report are designed to help HIV policymakers and advocates like Project Inform improve PrEP access in a manner that is clinically effective, cost-appropriate, and politically feasible in line with existing research and evidence.

Consequently, this report recommends the following:
1. Support Gilead’s request for FDA approval of a prevention label for Truvada
2. Encourage the NIH and CDC to finance demonstration projects
3. Ensure public insurance coverage for PrEP through state Medicaid programs
4. Ensure private insurance coverage for PrEP
5. Advocate that Gilead develop a Patient Assistance Program (PAP) for PrEP
6. Encourage non-Truvada PrEP formulations and promote price breaks for Truvada
7. Promote PrEP in tandem with other combination approaches to HIV prevention
Introduction: The Problem

Antiretroviral pre-exposure prophylaxis (PrEP) represents a promising development in HIV prevention, with the potential for significant U.S. domestic and global public health applications. Recent clinical studies, including the multi-national iPrEX study financed by the National Institutes of Health (NIH) and the Bill and Melinda Gates Foundation, demonstrate that a daily oral dose of the combination antiretroviral medication FTC-TDF (marketed as Truvada by Gilead Sciences), when administered with follow-up HIV testing, safety screening, risk reduction counseling, and condom distribution, can reduce the rate of HIV infection among high-risk men who have sex with men (MSM) and transgender women. Several of these studies have found FTC-TDF to be well tolerated among this group, with few significant side effects and no evidence of drug-resistant virus among study participants who became infected with HIV after enrollment. Among all iPrEX study participants, those who received PrEP had a 44% reduction in HIV acquisition. Infection rates were even lower for study participants with regular medication adherence, with a 73% reduction in HIV acquisition for those with at least 90% adherence compared to participants receiving a placebo pill.¹

As promising as the iPrEX results are, policymakers must confront the key problem of how to finance and deliver PrEP in a real-world context of limited HIV prevention dollars and a large domestic and global population of at-risk individuals. Moreover, the recent closure of the FEM-PrEP clinical study, which was unable to prove the efficacy of PrEP in preventing HIV infection among high-risk heterosexual women in sub-Saharan Africa, points to a need to further refine which populations will most benefit from PrEP and how to effectively deliver the intervention to them.²

In addition to iPrEX, several recent clinical and health authority developments offer the potential to make PrEP more accessible, cost-effective, and targeted. In January 2011, the Centers for Disease Control and Prevention (CDC) released interim guidance that offers

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conditional support for medical practitioners to prescribe FTC-TDF “off-label” as PrEP to high-risk MSM. Follow-up conversations and meetings with major private insurers like Kaiser Permanente and Wellpoint reveal a willingness to reimburse PrEP in the limited circumstances described by the CDC’s interim guidance. Gilead Sciences moreover indicates a willingness to consider a Patient Assistance Program (PAP) to provide PrEP to certain low-income individuals. State Medicaid programs also appear willing to reimburse PrEP, though at least one state program has indicated a desire for FDA approval, more clinical studies, and further CDC guidance and/or U.S. Public Health Service (PHS) guidelines prior to approving specific reimbursement for PrEP.

State Medicaid reimbursement could be of particular importance, given that a key provision of federal health reform legislation mandates the expansion of state Medicaid programs in 2014 to provide coverage for all Americans up to 133% of the federal poverty line, which if enacted would dramatically increase the number of high-risk individuals with access to health care. Until 2014, community health centers could be a key provider of care to these individuals, though little evidence yet exists as to whether these centers will be willing to provide PrEP. According to the Congressional Budget Office (CBO), state Medicaid programs and other public health assistance programs could face pressure to reduce services if several central provisions of the current Republican House budget proposal are enacted.

More clinical evidence and studies will arrive in the coming years, offering the potential to address concerns about whether PrEP could increase ARV drug resistance and a rise in high-risk behavior, as well as whether PrEP is appropriate for non-MSM and transgender women groups. Multiple ongoing clinical studies in Thailand and sub-Saharan Africa are examining PrEP use for several additional groups at high-risk of HIV infection, including injection drug users, serodiscordant heterosexual couples, and heterosexual women. In addition, the NIH has indicated it will likely fund multi-year PrEP “demonstration projects”

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5 Personal communication with Coy Stout, Gilead Sciences. March 31, 2011.
6 Personal communication with Janet Zachary-Elkind, New York State Department of Health. April 5, 2011.
in Boston and San Francisco to further evaluate the use of PrEP. These demonstration projects offer the potential to evaluate a more “real-world” delivery of PrEP to high-risk individuals, including developing strategies to improve drug adherence, as well as to gather further cost data. Advocates are also encouraging the CDC to fund PrEP demonstration projects in additional cities, particularly several with large populations of African-American and Latino gay and bisexual men and transgender women, groups that are at particularly high risk of HIV infection.

This report’s methods include examining relevant literature published by medical and public health journals, examination of health reform legislation and public health authority guidelines, and conversations and interviews with HIV advocates and experts, CDC officials, Gilead representatives, and public and private health insurers. The report’s limitations primarily stem from the relatively new use of PrEP as an HIV prevention strategy. Consequently, the political and clinical landscape for PrEP financing and implementation is likely to change in significant ways in the coming years. At present, there is little evidence of significant community demand for PrEP, relatively few private and public insurers have yet considered whether to approve PrEP for reimbursement, and the budgets of many relevant public health assistance programs such as Medicaid are uncertain.

As a result of these factors, policymakers and advocates will be required to adapt their PrEP financing and delivery strategies as the policy climate evolves. In particular, there will be a need to assimilate extensive new clinical evidence on the use of PrEP in a variety of high-risk populations, anticipate and react to changes in the national political climate surrounding public health programs, and determine community acceptability and demand for PrEP among high-risk MSM.

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10 Personal communication with Dana Van Gorder, Project Inform. March 31, 2011.
The Policy Context: HIV Prevention Needs and the Promise of PrEP

<table>
<thead>
<tr>
<th>Key Facts on HIV Prevention Needs in the United States</th>
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<tr>
<td>⇒ Approximately 56,000 Americans are infected with HIV each year, and more than 1.1 million Americans are living with HIV.(^{11})</td>
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<td>⇒ The CDC estimates that 21% of Americans infected with HIV are undiagnosed, while another study estimates that one-third of people living with HIV are not in care.(^{12})</td>
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<tr>
<td>⇒ HIV/AIDS disproportionately impacts certain groups of Americans. These include gay and bisexual men (2% of the U.S. population but 53% of new infections); Black men and women (13% of the U.S. population but 46% of people living with HIV); Latinos and Latinas; and substance abusers of injection drugs.(^{13})</td>
</tr>
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<td>⇒ Gay and bisexual men are the only American group where the estimated number of new HIV infections is rising.(^{14}) Transgender women are at particularly high risk, with one recent study indicating that up 30% of transgender women in certain areas are HIV-infected.(^{15})</td>
</tr>
<tr>
<td>⇒ Several HIV cure research studies are in progress, notably involving gene therapy to prevent HIV from binding to CD4 cells. However, any potential cure remains years away from discovery and implementation.(^{16})</td>
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**The United States has significant HIV prevention needs**

In July 2010, the Obama administration released the first-ever National HIV/AIDS Strategy for the United States. The report documents an epidemic that presents a persistent and urgent challenge to national public health. According to the CDC, approximately 56,000 Americans become infected each year, and more than 1.1 million Americans are living with HIV. In addition, a significant percentage of people infected with HIV are undiagnosed – 21 percent according to a recent CDC report – and many who need treatment do not have access to it. Certain interventions have helped cut HIV infection rates from mid-1980s highs, including increased HIV testing, condom use, effective screening of the blood supply, screening and treating expectant mothers during pregnancy, minimizing infections from injection drug use, and advances in HIV treatment therapy. Still, new infections remain consistently above 50,000 per year, a rate that has changed little since the early-1990s. New infections moreover disproportionately impact certain groups of Americans. These groups include gay and bisexual men, who comprise approximately 2 percent of the U.S. population but account for 53 percent of new infections; Black men and women, who represent 13 percent of the population but account for 46 percent of people living with HIV; Latinos and Latinas, whose rate of infection is several times greater than that of Whites; and substance abusers of injection drugs and non-injection drugs such as methamphetamine. Within these groups, certain subgroups are more at risk than others. One recent study of five major cities for instance found that 28 percent of all Black gay and bisexual men were HIV-positive, compared to 18% of Hispanic/Latino MSM and 16% of white MSM.

Gay and bisexual men have and continue to comprise the largest numbers of new HIV infections in the United States. As the National HIV/AIDS Strategy emphatically states, “the United States cannot reduce the number of HIV infections nationally without better addressing HIV among gay and bisexual men.” Gay and bisexual men moreover are the only American group where the estimated number of new HIV infections is rising. Transgender

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women are similarly at high risk of HIV infection, with a recent CDC study finding that up to 30 percent of this group may be HIV-positive.20

The development of PrEP occurs as HIV infections continue to rise worldwide – 2.7 million new infections in 2008 according to the Joint United Nations Program on HIV/AIDS (UNAIDS) – and as possibilities for an HIV cure remain limited.21 Recently, researchers have been intrigued by the case of the so-called “Berlin patient,” an HIV-positive man treated in 2006 for leukemia with a bone marrow transplant from an HIV-resistant donor, and who has since been reportedly cured of HIV.22 But this type of transplant has limitations at the population level, involving both a high degree of mortality risk and a difficult-to-replicate donor match process. Other recent attempts to develop a cure, including several high-profile therapeutic vaccine clinical studies, have not yielded promising results.23 However, research to develop a cure is ongoing, particularly in the domain of gene therapy to knock out one of the primary receptors that HIV uses to bind to CD4 cells.24

20 Operario, 97.
24 Horn, “CCR5 Gene Therapy Shows HIV Treatment Potential.”
### Key Facts on Pre-Exposure Prophylaxis (PrEP) as HIV Prevention

- According to several studies, PrEP can reduce HIV infection rates for certain high-risk groups, such as gay and bisexual men and transgendered women.\(^\text{25}\)

- The iPrEX study of 2,499 men who have sex with men (MSM) and transgender women found that the use of a one-pill-a-day dose of Truvada, when combined with HIV risk reduction counseling and condom use, resulted in a 44% reduction in the numbers of individuals infected with HIV.\(^\text{26}\)

- The iPrEX results demonstrated that higher drug adherence promoted efficacy in protection against HIV infection. Participants who took Truvada on 90% or more of days experienced 73% fewer HIV infections than those receiving a placebo.\(^\text{27}\)

- Numerous ongoing clinical studies are examining the effect of PrEP use on HIV infection rates among other high-risk groups, such as injection drug users in Thailand and serodiscordant heterosexual couples and heterosexual women in parts of sub-Saharan Africa.\(^\text{28}\)

### PrEP has the potential to improve HIV prevention in the United States

In the absence of a cure, the National HIV/AIDS Strategy focuses on several biomedical and behavioral approaches scientifically proven to reduce HIV transmission at the population level.

\(^{26}\) Grant, 2587.  
\(^{27}\) Grant, 2594.  
\(^{28}\) AVAC, “Ongoing PrEP Trials.”
level. These are: abstinence from sex or drug use, HIV testing, condom availability, access to sterile needles and syringes, and HIV treatment for HIV-positive individuals. The Strategy further highlights two approaches that could be of particular relevance to gay and bisexual men and other populations at high-risk of HIV infection. Testing and Linkage to Care Plus, or TLC+ (referred to in alternative forms as “test and treat” or “test and link to care”), is a framework for integrating HIV testing, care and treatment, social services and prevention activities into a comprehensive initiative to reduce HIV infection rates in certain high-risk communities. A current National Institutes of Health study of TLC+ is underway in Washington D.C. and the Bronx, two urban areas with persistently high rates of HIV infection. A second promising approach highlighted by the Strategy is pre-exposure prophylaxis, or PrEP. Both TLC+ and PrEP stress a combination approach to HIV prevention, with biomedical and behavioral interventions included. This signifies that neither approach is meant to replace traditional prevention efforts focused on condom use, HIV testing, risk counseling, but rather to supplement them with expanded use of ARVs and a coordination of biomedical and behavioral prevention efforts.

**Definition of Pre-Exposure Prophylaxis (PrEP)**

Pre-exposure prophylaxis in the context of HIV infection signifies the use of antiretroviral medicines by HIV-negative individuals at high-risk of infection. For HIV-positive individuals, antiretroviral therapy has been shown to dramatically reduce HIV levels in the body, promote restoration of immune health, reduce the risk of AIDS-related health complications, and reduce the transmission of the virus to uninfected partners. While an HIV diagnosis in the 1980s signified the likelihood of rapid reduction in immune health and near-term mortality by AIDS-related complications, the use of powerful antiretroviral medicines since the mid-1990s has extended the life of many HIV-positive individuals to near-normal levels. In addition, several recent studies indicate that expansion of HIV treatment can lead to a reduction in “community viral load,” the estimated average viral load of all HIV-positive persons in a community, and therefore a reduction in new HIV infections.

30 University of California San Francisco, Center for AIDS Prevention Studies (CAPS). “Can HIV testing plus linking HIV+ people to care and treatment reduce HIV transmission?,” Fact Sheet 69 (2010).
32 Underhill, 210-211.
34 University of California San Francisco, CAPS.
Antiretroviral prophylaxis has previously been used with great success to decrease mother-to-child HIV transmission.\textsuperscript{35} Another existing use is post-exposure prophylaxis (PEP), which is recommended after suspected exposure to HIV-infected fluids and which must be started within 72 hours to be effective.\textsuperscript{36} While studies have shown its effectiveness in limited cases particularly among medical workers and among “serodiscordant” couples where one partner is HIV-positive, its use has been restricted by the need to start therapy so soon after exposure. Other common, effective uses of chemoprophylaxis include the use of anti-malarial drugs to inhibit malaria infection.

Initial studies of PrEP have yielded significant promise. Research on mice and nonhuman primates demonstrated that the antiretroviral medicines tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) when used in combination in a single tablet (FTC-TDF) have few side effects and high levels of efficacy in combating HIV replication.\textsuperscript{37} An additional study of daily oral TDF use among African women indicated few side effects, and another of tenofovir 1% vaginal gel showed a 39\% reduction in HIV infection among those women receiving the gel in the study.\textsuperscript{38} In both studies, high treatment adherence was correlated with a high degree of protection against HIV infection.

The largest and most extensive study to evaluate PrEP use for high-risk MSM is the Preexposure Prophylaxis Initiative (iPrEx), funded by the National Institutes of Health and the Bill and Melinda Gates Foundation.\textsuperscript{39} The study was conducted between July 2007 and May 2010, and its results were released in late-fall 2010. This study involved the random assigning of 2499 HIV-negative men and transgender women who have sex with men to either receive an oral combination pill of the two antiretroviral drugs FTC-TDF, or a placebo once daily. The median study participation period was 1.2 years with a maximum of 2.8 years, and study participants were recruited from sites in Peru, Ecuador, South Africa, Brazil, Thailand, and the United States. According to the iPrEx researchers, men and transgender women who have sex with men were selected given that they are “disproportionately affected by the global epidemic” of HIV/AIDS. One recent CDC study in the United States for instance found that up to 19\% of MSM in American urban areas were infected with HIV.\textsuperscript{40}

\textsuperscript{35} Buchbinder, S72.
\textsuperscript{36} Buchbinder, S73.
\textsuperscript{37} Grant, 2588.
\textsuperscript{39} Grant, 2587-2599.
\textsuperscript{40} Centers for Disease Control, “HIV among Gay, Bisexual and Other Men Who Have Sex with Men.”
The iPrEX study’s main findings were that oral FTC-TDF “provided protection against the acquisition of HIV infection.”\textsuperscript{41} 100 of the participants became infected during study follow-up (36 in the FTC-TDF group and 64 in the placebo group), pointing to a 44% reduction in HIV incidence for participants who received FTC-TDF. Few side effects were reported in the treatment group, and there was little evidence of drug resistance among participants who tested HIV-positive after receiving FTC-TDF. The study moreover found that high-risk behavior, specifically receptive anal intercourse without a condom, decreased among all study participants after enrollment.

**PrEP requires biomedical and behavioral interventions to be effective**

Of particular importance to the iPrEX study was the inclusion of behavioral interventions to complement the biomedical use of FTC-TDF drugs. All study participants received regular HIV testing, risk-reduction counseling, condoms, and management of sexually transmitted infections. Researchers have noted that a combination approach of biomedical and behavioral interventions has proven effective for other major health issues. These include coronary heart disease, for which there was a 50% reduction in U.S. mortality between 1980 and 2000, due to both a reduction in risk factors such as smoking and biomedical interventions including pharmacologic therapies.\textsuperscript{42} In addition, iPrEX study participants receiving FTC-TDF were tested for signs of side effects, including decrease in renal function, and participants who tested HIV-positive while in the study were tracked for evidence of HIV resistance to FTC-TDF. These interventions reflect concerns that PrEP could accelerate antiretroviral drug resistance and lead to long-term, adverse health side effects, issues that have emerged with extended ARV use in HIV-positive populations.

**Drug adherence remains a concern for PrEP implementation**

The iPrEX study found a significant incidence of participants with irregular adherence to medication, with a concurrent effect on rate of HIV infection. Participants who took the drug on 50% or more days as measured by pill count, bottle count, and self reporting experienced 50.2% fewer HIV infections. By contrast, those who took the drug on 90% or more of days had 73% fewer HIV infections.\textsuperscript{43} Other studies of pre-exposure prophylaxis, such as of West African women using tenofovir gel, have similarly indicated problems with drug adherence and subsequent drops in protection against HIV infection. Likewise, drug

\textsuperscript{41} Grant, 2587.
\textsuperscript{42} Buchbinder, S76.
\textsuperscript{43} Grant, 2594.
adherence remains a concern in the context of HIV-positive individuals taking daily antiretroviral medicines. Not only does irregular PrEP drug adherence decrease protection against HIV infection, but patients who become infected with HIV while on treatment risk developing ARV drug resistance, thereby compromising their HIV treatment possibilities.

The CDC provides interim guidance on PrEP for MSM

One indication of the influence of the iPrEX study is the decision by the CDC in January 2011 to issue interim guidance to health providers on prescribing Truvada “off-label” as PrEP to MSM. The guidance offers qualified support for providers to prescribe PrEP if it is targeted to high-risk MSM, is delivered in combination with prevention services such as access to condoms and risk-reduction counseling, and includes regular HIV testing and monitoring of drug side effects, adherence, and potential increases in patient risk behavior. The guidance also notes several PrEP-related concerns, including that ARVs besides Truvada could be prescribed as PrEP, that intermittent dosing may produce lower rates of protection, and that PrEP will be delivered without regular HIV screening, condom access and risk-reduction counseling, and monitoring of drug resistance and side effects. The CDC furthermore promised to update its guidance in the coming months with official Public Health Service (PHS) guidelines on the use of PrEP for high-risk MSM in combination with other prevention approaches.

Health reform presents opportunities and challenges for PrEP coverage

In principle, the Patient Protection and Affordable Care Act of 2010 (ACA) has the potential to significantly impact the HIV prevention needs of Americans. As indicated by the National HIV/AIDS Strategy, many Americans at high risk for HIV infection either lack health insurance or are not regularly seeing a health provider. One study for instance has estimated that a majority (62%) of HIV-infected individuals receiving care are unemployed, and nearly half (45%) have annual incomes less than $10,000. Reliable numbers for uninfected individuals at high-risk of HIV infection are comparatively limited, but we can

46 Kates, S256.
presume that there is likely a high correlation between poverty and being at high-risk for HIV infection, thereby increasing the effect of ACA on this population.

ACA requires most U.S. citizens and legal residents to have health coverage and helps individuals up to 400% of the federal poverty level (FPL) by expanding Medicaid to 133% of FPL and providing premium tax credits for coverage through new Health Insurance Exchanges for those between 133-400% FPL. When the new coverage goes fully into effect in 2014, an estimated 17.1 million uninsured adults with family income at or below 133% FPL will become eligible for Medicaid, with many more between 133-400% FPL supported with subsidies to purchase health coverage through state health exchanges.\textsuperscript{47} This dramatic expansion of health coverage for low-income Americans consequently has the potential to impact many populations at high-risk for HIV infection.

One key element of the health reform law with potential implications for HIV prevention is the requirement that most newly-eligible adult Medicaid beneficiaries receive coverage of “essential health benefits.” These essential health benefits also apply to the new Exchange plans and to the individual and small group insurance markets. ACA stipulates that essential health benefits include “preventive and wellness services” and “prescription drugs” among other categories of service.\textsuperscript{48} In the coming year, the Secretary of Health and Human Services (HHS) will provide more details on which preventive services will qualify as essential health benefits. In making its determinations, HHS has commissioned the U.S. Labor Department and the Institute of Medicine (IOM) to review the scope of coverage in a variety of existing employee health plans.\textsuperscript{49} However, it also appears that HHS will be influenced by political concerns regarding the cost of health reform, which could limit required coverage to a set of relatively low-cost, non-controversial procedures or the agency’s recommendations could lack specificity in terms of required coverage.

One agency that stands to influence which preventive services are considered essential health benefits is the U.S. Preventive Services Task Force (USPSTF). The USPSTF claims to take an “evidence-based approach” to evaluating the effectiveness of preventive services, and assigns recommendations on an A-D and I rating scale for specific services, with an “A” or “B” rating signifying a recommendation in favor of a given service, a “C” rating signifying

\textsuperscript{47} Kaiser Family Foundation, “Expanding Coverage to Adults through Medicaid Under Health Reform.”
no recommendation, a “D” rating signifying a recommendation against a service, and an “I” rating signifying insufficient evidence to evaluate a service.\textsuperscript{50} In assigning its ratings for a particular service, the USPSTF consults relevant clinical literature, weighs the balance of health benefits and harms, and considers total economic costs, among other factors. The USPSTF has recently been empowered by several provisions in ACA, including a requirement that all private health insurance plans provide coverage for preventive services that receive a USPSTF “A” or “B” rating, and that state Medicaid programs receive small financial incentives for covering these services.\textsuperscript{51}

A review of USPSTF-recommended preventive services, however, reveals a deliberate approach based in examination of extensive clinical studies that is unlikely to favor a relatively new chemoprevention service like PrEP. Of the current 45 recommended preventive services for adults, only two are related to chemoprevention services – the use of aspirin to prevent cardiovascular disease (CVD) among older individuals, and the discussion of chemoprevention with women at high risk of breast cancer and low risk for adverse effects of chemoprevention.\textsuperscript{52} In contrast to PrEP, both the use of aspirin to prevent CVD and tamoxifen to prevent breast cancer have undergone extensive clinical and cost-effectiveness studies, and are approved by the FDA for these indications.\textsuperscript{53} The USPSTF moreover has been reluctant to approve the CDC-recommended HIV prevention strategy of routine screening for the general population, which could indicate further difficulties for a PrEP recommendation, even for an intervention targeted initially to high-risk MSM.\textsuperscript{54}

The USPSTF regularly solicits advice regarding which preventive services to include in its annual reviews. Given evidence of the Task Force’s conservative approach to assigning recommendations, it is quite likely that PrEP would currently receive a rating of “C,” “D,” or “I,” which could prove damaging to other attempts to expand PrEP coverage in the coming years. A more prudent approach would be to wait several years before submitting PrEP for USPSTF review, at which point the Task Force will presumably consider such evidence as further PrEP clinical and cost-effectiveness studies, and FDA approval and PHS guidelines.


\textsuperscript{54} Personal communication with Andrea Weddle. Executive Director, HIV Medicine Association (HIVMA). 2/2/2011.
Cost-Effectiveness of PrEP as an HIV Prevention Tool

<table>
<thead>
<tr>
<th>Study</th>
<th>Population targeted</th>
<th>QALY*</th>
<th>Cost-Effectiveness improves if:</th>
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</thead>
</table>
| Paltiel et al.   | MSM with mean age of 34 and HIV incidence rate of 1.6%       | $298,000  | ⇒ PrEP efficacy increases to 90%  
⇒ A younger population with mean age of 20 is targeted  
⇒ PrEP cost is reduced by 50% |
| (2009)           |                                                              |           |                                                                                                |
| Desai et al.     | 25% of all high-risk MSM in New York City                    | $31,970   | ⇒ PrEP efficacy increases to 95%  
⇒ PrEP cost is reduced by 50% |
| (2008)           |                                                              |           |                                                                                                |

*QALY here is expressed as US dollars per quality-adjusted life-year gained. A higher QALY reflects a more costly intervention relative to quality and quantity of life years gained.

PrEP Cost-Effectiveness in the United States: Targeting the Most High-Risk

While iPrEX and other clinical studies demonstrate the potential efficacy of PrEP to reduce HIV infection, these studies pay comparatively less attention to PrEP’s cost-effectiveness. Given the high cost of HIV medicines, does PrEP’s ability to reduce new HIV infections make economic sense? Several recent studies find a moderate level of PrEP cost-effectiveness relative to other behavioral and biomedical HIV prevention approaches, with significantly
more attractive cost estimates if PrEP is targeted to the most high-risk individuals, efficacy is increased due to high drug adherence, and/or price reductions occur for FTC-TDF.\textsuperscript{55}

Policymakers gathered at a February 2011 CDC symposium convened prior to the Conference on Retroviruses and Opportunistic Infections (CROI) expressed their desire to see cost analysis built into PrEP demonstration projects and studies in the coming period, which could influence the willingness of public and private insurance programs to cover PrEP.\textsuperscript{56} In particular, policymakers want more information on how much it will cost to design a comprehensive program that targets high-risk individuals who would most benefit from PrEP. Though cost-effectiveness studies tend to rely on theoretical assessments of costs and benefits that do not necessarily match “real-world” settings, they can still be useful for understanding the tradeoffs in designing an effective, targeted PrEP program.

One cost-effectiveness study of PrEP by Paltiel cautions that PrEP is “unlikely to confer sufficient benefits to justify the current costs of tenofovir-emtricitabine,” but that “price reductions and/or increases in efficacy could make PrEP a cost-effective option in younger populations or populations at higher risk of infection.”\textsuperscript{57} The study assumes the annual cost of PrEP per person would be $8700 (based on the current treatment price of FTC-TDF), PrEP would be delivered to a large group of MSM with a mean annual HIV infection incidence of 1.6% and with a mean age of 34. The study also makes several conservative assumptions about the PrEP target population, including that every targeted individual would normally receive annual HIV testing, even though reports suggest that most HIV-positive people do not receive their diagnosis until several years after infection.\textsuperscript{58}

The baseline results for the Paltiel study are that the use of PrEP yielded an incremental cost-effectiveness ratio (ICER) of $298,000 per QALY gained. This figure compares relatively poorly with other HIV prevention approaches and with preventive health services such as colorectal screening and home dialysis.\textsuperscript{59} However, the study finds significant improvements in cost-effectiveness if PrEP efficacy is increased from 50% to 90% through adherence support ($107,000 per QALY), PrEP is targeted to a more high-risk population with HIV incidence of 3.1% ($150,000 per QALY), PrEP is targeted to a younger population with a mean age of 20 (QALY of $189,000), or PrEP cost is reduced by 50%


\textsuperscript{56} AVAC, “PrEP at CROI – A review of some of the discussions and key data presented.”

\textsuperscript{57} Paltiel, 806.

\textsuperscript{58} Paltiel, 807.

\textsuperscript{59} Paltiel, 811.
($114,000 per QALY). The study’s authors moreover acknowledge that PrEP cost is significantly reduced when HIV testing is not considered routine in the target population (QALY of $109,000).\textsuperscript{60} If several of these changes occur in PrEP cost and delivery or regarding HIV testing assumptions, the study concludes that PrEP may be “cost-effective by current U.S. standards.”\textsuperscript{61}

An additional study by Desai confirms promising cost-effectiveness for PrEP if targeted to a high-risk population of MSM. The study used HIV/AIDS surveillance data to simulate the HIV epidemic and the effect of a 5-year PrEP program on high-risk MSM in New York City. “High-risk MSM” are here defined as “those who in the past 6 months reported unprotected sex with an HIV-infected person, unprotected sex in exchange for money or drugs, anonymous sex, five or more sexual or needle-sharing partners, or were diagnosed with a sexually transmitted infection.”\textsuperscript{62} The study envisions a PrEP program targeted to 25% of high-risk MSM in the city, with a predicted reduction in HIV infections of 8.7% over 5 years assuming PrEP efficacy of 50% and program adherence of 50%.\textsuperscript{63}

Unlike the Paltiel study, Desai estimates that more than half of prevented infections would occur not among those who directly receive PrEP, but from those men who would indirectly benefit due to an overall reduction in HIV incidence in the community. The study determined a cost of $31,970 per QALY, a number that would be deemed favorable under most cost-effectiveness estimates of preventive health services in the United States. This figure reflects a 5-year combined cost for drug and support services of $58,700 per person, weighted against an HIV-related lifetime treatment cost of $343,130 and 6.95 QALYs saved.\textsuperscript{64}

The Desai study makes several public health claims in its assumption that 25% of high-risk MSM in a major city could be enrolled in a PrEP program. To achieve this goal, the study’s authors claim these individuals could be reached for enrollment “through local HIV prevention programs and through venues and publications whose primary audience is MSM.”\textsuperscript{65} This assumption reflects the current reality that specialized clinics and physicians sensitive to gay men’s health issues will be the initial providers of PrEP.\textsuperscript{66} Moreover, the

\textsuperscript{60} Paltiel, 810.
\textsuperscript{61} Paltiel, 813.
\textsuperscript{62} Desai, 1831.
\textsuperscript{63} Desai, 1834-1835.
\textsuperscript{64} Desai, 1831.
\textsuperscript{65} Desai, 1831.
The Pretorius study has several important applications for PrEP in the U.S. These include the contention that PrEP is deemed more cost-effective with higher efficacy and a more targeted intervention to high-risk individuals, particularly in more sexually active populations and very high-risk groups like commercial sex workers and MSM with multiple partners. Also, as in South Africa, the cost of PrEP in the U.S. is far lower than a lifetime of ART, making PrEP a more attractive cost option if HIV infection – and consequent ART treatment – can be avoided. Furthermore, the Pretorius study notes that HIV prevention

67 Desai, 1835.
69 Pretorius, 1.
70 Pretorius, 9.
funding is either leveling off or falling in many countries, which places pressure upon PrEP programs to be cost-effective within a package of HIV prevention strategies.71

Recommendations

The following recommendations outline a set of pathways for PrEP to be financed and delivered in a manner that maximizes clinical efficacy, addresses cost concerns, and accounts for political feasibility in a climate of constrained HIV prevention dollars. Advocates may choose to prioritize certain pathways as further clinical and cost data on PrEP arrives in the coming period.

Support Gilead’s request for FDA approval of a prevention label for Truvada

Recent conversations with Gilead officials indicate the company’s willingness to pursue FDA approval for Truvada to be prescribed for HIV prevention.72 Gilead however does not plan to package Truvada in a separate formulation and pricing structure for prevention purposes. Rather, the company intends to include with Truvada a package of instructions that outlines the drug’s FDA-approved uses for treatment and prevention purposes.

Though some advocates may be disappointed by Gilead’s decision to not implement a dual-pricing structure, with lower prices for Truvada as PrEP, this decision has several policy advantages. These advantages include the ability of PrEP to benefit from existing public and private insurer reimbursement approval for Truvada prescribed for treatment purposes. In the short-run, health providers may be able to prescribe Truvada “off-label” for prevention purposes, and insurers will approve reimbursement just as they would for Truvada for treatment purposes. In the long-run, Truvada marketed for both prevention and treatment purposes decreases the likelihood that PrEP will be viewed as a “lifestyle drug,” and therefore be deemed ineligible for reimbursement.

71 Pretorius, 9.
72 Personal communication with Coy Stout, Gilead Sciences. May 31, 2011.
An additional policy consideration in favor of keeping the same package and price for Truvada are the ethical and practical objections to setting a higher price for HIV-infected individuals to receive treatment than for HIV-negative individuals to receive prevention services. Given current funding shortfalls for public assistance programs for HIV medications, such as ADAP, it would be untenable to set a lower price for the same drug to be used by HIV-negative individuals. Also, a dual-pricing structure would be difficult to enforce given the significant financial incentive for patients to request that their doctors prescribe the lower-priced version of Truvada.

**Encourage the NIH and CDC to finance demonstration projects**

In recent weeks, the NIH has indicated that it is likely to finance the majority of costs for “demonstration projects” for PrEP to be held in the two U.S. iPrEX study sites, San Francisco and Boston. In addition, Gilead will provide Truvada to be used by project participants. The demonstration projects will attempt to evaluate the efficacy of PrEP outside the clinical study context, with participants receiving PrEP drugs and services through HIV testing and STI clinics rather than through a research study site as with iPrEX. Clinical questions to be addressed will be similar to those of the iPrEX study, including the ability of daily Truvada to reduce HIV infections among high-risk MSM, and any issues surrounding drug tolerability, development of drug-resistant HIV, and changes in risk behavior due to use of PrEP.

The demonstration projects will also ideally address implementation issues such as adherence support and targeting of PrEP to the most high-risk individuals, as well as cost and community acceptability concerns. These issues could prove particularly valuable in determining public and private health coverage for PrEP and a potential long-term recommendation by the USPSTF. Demonstration projects are likely to begin in the coming year and are set to continue for several years. If their results are promising, they could also help galvanize enthusiasm in the HIV advocacy community to support a more expansive PrEP roll-out in high-needs communities.

**Ensure public health insurance coverage for PrEP through state Medicaid programs**

Given the correlation between high poverty rates and high risk of HIV infection documented in the National HIV/AIDS Strategy, public health coverage programs such as Medicaid – particularly in its expanded form starting in 2014 – will be crucial to assuring

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73 Personal communication with Dana Van Gorder, Project Inform. April 2011.
PrEP reimbursement for those individuals most in need. Medicaid however is currently under extraordinary political pressure at both the federal and state levels, with threats of widespread spending cuts being made in many programs, particularly if the federal government adopts a Medicaid state block grant program as proposed in the current Republican House budget proposal. As a result, PrEP is unlikely to be high on the radar of Medicaid policymakers in the near-term. Initially, this could mean that health providers will submit drug reimbursement requests for Truvada – which is currently covered by all state Medicaid programs for HIV treatment – without identifying a prevention indication. However, in the long-term this approach could be complicated by program requests for proof of a positive HIV test in order to approve Truvada reimbursement, or it could trigger a denial of coverage due to Truvada constituting substandard therapy when used alone for treatment.

Communication with state health officials in New York, which has one of the most expansive Medicaid programs, also indicate that FDA approval and PHS guidelines would be important for providing official support for PrEP coverage. One useful policy option could be for the Centers for Medicare & Medicaid Services (CMS) to issue a letter asking state Medicaid programs to cover PrEP, perhaps citing the promising iPrEX results and the interim CDC guidelines for PrEP. However, this option appears unlikely in the near-term given CMS’ current focus on assuring the Medicaid expansion mandated by health reform legislation. It appears instead that PrEP coverage will be determined instead on an individual state level, reflecting the need for a state-by-state advocacy strategy to ensure coverage.

If significant gaps in coverage remain after the projected Medicaid expansion, advocates may consider seeking federal funding for a PrEP program modeled along the lines of the AIDS Drug Assistance Program (ADAP), which provides HIV drugs to low-income HIV-positive individuals. However, this option appears unrealistic in the near-term given the current budget shortfalls and political pressures being placed upon public health insurance programs at the federal and state level, including for state ADAP programs, which had nearly 8,000 individuals on waiting lists in 11 states in April 2011.

Ensure private health insurance coverage for PrEP

74 Congressional Budget Office, “Long-Term Analysis of a Budget Proposal by Chairman Ryan.”
75 Personal communication with Janet Zachary-Elkind, New York State Department of Health. April 5, 2011.
Recent conversations with major private insurers such as Kaiser Permanente and Wellpoint and large employers such as Levi, Strauss & Co. indicate a willingness to provide reimbursement coverage for PrEP prescribed “off-label” to high-risk MSM. According to a Wellpoint representative, the insurer is currently leaving the matter to the discretion of individual health providers and will not question whether Truvada is being prescribed for prevention or treatment purposes. Wellpoint, Kaiser, and Aetna all appear willing to follow the guidance of the CDC’s interim guidelines for PrEP, authorizing its off-label use in limited circumstances where a patient is deemed at particularly high-risk for HIV infection. PrEP-related services, such as follow-up HIV testing and blood test monitoring for drug effects on renal function, would also be eligible for coverage. Continued reimbursement of PrEP does however appear to be contingent upon FDA approval. If the FDA were to specifically rule against approving Truvada for prevention purposes, insurers like Wellpoint currently willing to prescribe PrEP “off-label” would likely limit their coverage due to liability concerns.

Comparatively less evidence is available on PrEP coverage for other major insurers operating across the United States. It appears likely that PrEP is not yet even on the radar of most private insurers, given its relatively low use and that separate billing codes have not yet been created for prescribing Truvada for prevention rather than treatment. In the short-term, this may mean that prescriptions are authorized for coverage with little attention paid to whether Truvada is being used for treatment or prevention purposes. Official private insurer coverage, however, could be important in the long-term given ACA stipulations regarding “benchmark” or “benchmark-equivalent” coverage in newly expanded state Medicaid programs and Exchange plans in the coming years. In effect, many states will be required under certain circumstances to “benchmark” the services provided in their new Medicaid programs to services provided by major private insurers operating in their state. If major private insurers are willing to offer coverage for PrEP, there may be a health reform mandate for the Medicaid program in certain states to cover PrEP as well.

Advocate that Gilead develop a Patient Assistance Program for PrEP

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78 Personal communication with the office of Dr. Samuel Nussbaum, Wellpoint. March 30, 2011.
79 Personal communication with the office of Dr. Samuel Nussbaum, Wellpoint. March 30, 2011.
Gilead has recently indicated a willingness to consider including Truvada as PrEP in a Patient Assistance Program (PAP). PAPs offer free HIV drugs to people with low-incomes who do not have other access to medicines through programs like Medicaid or AIDS Drug Assistance Programs (ADAPs). Gilead’s current PAP for Truvada covers people up to 500% of FPL. Gilead has not yet determined whether PrEP would be included in the existing Truvada program, or whether a separate PAP would be created. In either case, PAP coverage for PrEP offers the potential to cover low-income individuals who either lack insurance, or their insurance program is unwilling to provide PrEP coverage.

This approach is, however, not without its policy concerns. Enrollment in existing PAPs for instance is limited by lack of health provider and patient awareness of their existence. PAPs also tend to require verification of income, usually in the form of pay stubs, which can create bureaucratic hurdles for low-income individuals to register in these programs. Meanwhile, Gilead may be reluctant to offer an expansive PAP for PrEP if health insurers that serve low-income individuals, such as the “expanded” Medicaid programs and new Exchange plans, prove unwilling to offer PrEP coverage.

**Encourage non-Truvada PrEP formulations and promote price breaks for Truvada**

Truvada has been the antiretroviral drug of choice for PrEP studies due to its demonstrated efficacy, tolerability, and relatively low tendency to lead to drug resistance. However, there are significant policy risks in creating a one-product monopoly in the PrEP antiretroviral market. Gilead’s patent for Truvada will continue until 2021, limiting the ability of competing drug manufacturers to produce generic versions of FTC-TDF in the United States. Several clinical studies are examining the efficacy of TDF alone (brand-name Viread) to serve as a PrEP substitute. Gilead however also holds the patent on Viread, and the drug is only marginally less expensive than Truvada. Given these realities, certain researchers are considering the potential of antiretrovirals such as lamivudine (3TC) and maraviroc to be used as PrEP. If these drugs demonstrate clinical efficacy, the expansion in the PrEP market could lead to price breaks for public programs like Medicaid that pay for HIV medicines.

**Promote PrEP in tandem with other combination approaches to HIV prevention**

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81 Personal communication with Coy Stout, Gilead Sciences. March 31, 2011.
Ensuring financing for PrEP through public and private health programs is an essential step in increasing access for the most high-risk individuals. However, PrEP will only truly have a significant impact on HIV prevention if delivery mechanisms are created to supply PrEP to high-risk individuals in a comprehensive and compassionate manner. At present, many health providers have difficulty in providing HIV prevention services to patients due to the stigma surrounding topics such as sexual health and drug use and the stigma of a positive HIV status. Moreover, many health providers themselves lack the skills and sensitivity to identify high-risk patients and ensure that these patients receive adequate HIV prevention services.

One approach for improving PrEP delivery and building health provider competency would be to collaborate with existing programs that attempt to increase HIV and STI testing and offer universal access to treatment. These programs include the “test and linkage to care,” or TLC+ programs underway in high-incidence parts of Washington, DC and the Bronx.85 Ongoing research from South Africa demonstrates that a universal access to treatment program in combination with PrEP is likely to have a more significant prevention impact than either program alone.86 iPrEX principal research Bob Grant has moreover discussed how a well-designed PrEP program could help reduce the stigma of HIV testing and treatment by offering an additional motivation for high-risk individuals to get tested.87

**Conclusion**

As demonstrated in this report, considerable energy and collaboration will be required to ensure that PrEP is sufficiently financed and delivered to the populations that are at highest-risk of HIV infection. Current clinical studies are most extensive for high-risk MSM, but follow-up studies are in progress for other high-risk populations like serodiscordant heterosexual couples and injection drug users. In order to maximize the HIV prevention potential of PrEP, effective financing will need to include public and private health insurance coverage and patient assistance programs, as well as incorporate cost and clinical efficacy data from pending demonstration projects. PrEP service provision can furthermore be targeted to high-risk individuals through integration into existing HIV prevention models, including “test and linkage to care” programs in high-incidence communities.

86 Pretorius, 9.
87 AVAC, “PrEP at CROI – A review of some of the discussions and key data presented.”
Given the current scarcity of HIV prevention dollars and difficulty in reaching high-risk individuals, these financing and delivery mechanisms will not be “quick-fix” solutions to increasing PrEP access. The policy climate surrounding public health assistance and HIV prevention programs is likely to evolve considerably in the coming period. Challenges like the recent closure of the FEM-PrEP trial will undoubtedly continue to affect the choices available to policymakers. Conversely, new opportunities will likely emerge from demonstration projects and from the implementation of nationwide health reform. As such, the recommendations presented should be seen as a starting point – based in the most current clinical and cost evidence – for increasing access to PrEP among high-risk populations in the United States.

### Appendix A:
A Sample of Ongoing Pre-Exposure Prophylaxis (PrEP) Trials (February 2011)

<table>
<thead>
<tr>
<th>Trial; Trial Phase</th>
<th>Location</th>
<th>Sponsor</th>
<th>Population (mode of exposure)</th>
<th>Intervention arm(s)</th>
<th>Status/ Results Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phases III, IIb (safety and effectiveness)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bangkok Tenofovir Study, Phase II/III, safety and effectiveness</td>
<td>Thailand</td>
<td>CDC</td>
<td>2,400 injecting drug users</td>
<td>Daily oral TDF</td>
<td>Fully enrolled/ Q1 2012</td>
</tr>
<tr>
<td>Partners PrEP Phase III, safety and effectiveness</td>
<td>Kenya, Uganda</td>
<td>BMGF</td>
<td>4,700 serodiscordant heterosexual couples</td>
<td>Daily oral TDF; daily oral TDF/FTC</td>
<td>Fully enrolled/Q1 2013</td>
</tr>
<tr>
<td>VOICE (MTN 003) Phase IIb, safety and effectiveness</td>
<td>South Africa, Uganda, Zimbabwe</td>
<td>MTN, NIH</td>
<td>5,000 heterosexual women (vaginal)</td>
<td>Daily oral TDF; daily oral TDF/FTC; daily topical 1% tenofovir gel</td>
<td>Enrolled Q1/2013</td>
</tr>
<tr>
<td><strong>Phases I, II (safety, adherence, acceptability, feasibility)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>TDF2 (CDC 4940) Phase II, safety and adherence</td>
<td>Botswana</td>
<td>CDC</td>
<td>1,200 heterosexual men and women (penile and vaginal)</td>
<td>Daily oral TDF/FTC; switched from TDF Q1 2007</td>
<td>Fully enrolled/ Q2 2011</td>
</tr>
<tr>
<td>IAVI E001 &amp; E002 Phase 1/11, safety, acceptability, adherence</td>
<td>Kenya, Uganda</td>
<td>IAVI</td>
<td>150 serodiscordant couples and men and women (vaginal and penile/rectal)</td>
<td>Daily oral TDF/FTC; intermittent oral TDF/FTC (twice weekly + coital dosing)</td>
<td>Completed / Q3 2011</td>
</tr>
<tr>
<td>PrEP Using TMC278LA</td>
<td>United Kingdom</td>
<td>St. Stephens AIDS Trust</td>
<td>100 men and women (vaginal and penile/rectal)</td>
<td>TMC278LA injected intramuscularly</td>
<td>Enrolling / 2011</td>
</tr>
</tbody>
</table>

ATN- Adolescent Trial Network; BMGF- Bill & Melinda Gates Foundation; CDC-US Centers for Disease Control and Prevention; DAIDS-Division of Acquired Immunodeficiency Syndrome; FHI-Family Health International;
Financing and Delivery Mechanisms to Increase PrEP Access

Source: AVAC (See http://www.avac.org for a more detailed listing of all ongoing PrEP trials)

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