DISCUSSION AND RECOMMENDATIONS

Scaling Up Pre-Exposure Prophylaxis in California

FROM A THINK TANK HELD
November 14, 2014, Santa Monica, CA

Contents

Executive Summary

While there are bright spots of progress, new HIV diagnoses overall in the state of California remain troubling. In 2011, nearly 6,000 Californians were diagnosed with HIV and estimates for that year place the state first in new diagnoses in the country. As has been seen in many other locales, the epidemic has remained stagnant for some time, and new infections appear to be on the rise in some populations, particularly black men who have sex with men (MSM). And so bold action is needed to respond to this urgent need, and the use of antiretroviral (ARV) drugs in HIV-negative individuals to reduce HIV transmission may be key.

The use of ARVs for primary HIV prevention—called pre-exposure prophylaxis (PrEP)—was spurred by a study whose results were announced in the fall of 2010.

That study, called iPrEx, found that individuals taking the combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC)—marketed as Truvada—had a reduced risk of HIV infection of 44%. A later analysis of those with blood levels indicating regular use of the drug, found that efficacy could be 92% or greater. The results of iPrEx, which was conducted in men and transgender women who have sex with men, were followed not long after by results from the Partners PrEP study, which found that when HIV-negative heterosexual men and women took Truvada, their risk of acquiring HIV from a regular HIV-positive partner was reduced by 90% when adherence was high.

Unfortunately, PrEP roll out has been slow and uneven since the U.S. Food and Drug Administration (FDA) approved Truvada for use as PrEP (it was already approved to treat HIV in infected individuals). Researchers documented as recently as last year that PrEP knowledge among high risk MSM was surprisingly low, and another study found even lower PrEP awareness among clinicians. As well, social service and health care providers were inundated with stories of people seeking PrEP who were met with either confusion or hostility by health care providers and significant financial and health insurance barriers even when they obtained a prescription.

In order to address these barriers, the California HIV/AIDS Research Program of the University of California Office of the President, Project Inform, and the CARE center at the University of California, Los Angeles, sponsored a Think Tank, gathering nearly 60 stakeholders from around California on November 14, 2014 to discuss issues related to the uptake and roll-out of PrEP in the state.

The sponsors hoped to initiate a discussion around three interrelated issues regarding PrEP access and implementation: provider barriers, policy barriers and financing barriers. With such a large group, it was never intended that the meeting would result in a firm consensus on an advocacy and policy agenda to improve PrEP access in California. Rather, the goal of the meeting was to elaborate on barriers to the three areas of exploration, and to identify commonalities and areas of agreement among stakeholders on issues to explore further and on solutions to the barriers that were identified.

PROVIDER BARRIERS AND SOLUTIONS

Although some providers were early adopters when it came to PrEP, with some even prescribing Truvada off label before the FDA approved it for prevention, people seeking PrEP encountered numerous obstacles to finding a willing and knowledgeable provider. A closed Facebook group on PrEP with thousands of members documented hundreds of individuals across the United States who could not find a provider willing to offer PrEP services.

Sometimes the lack of willingness on the part of the provider was due to an unfamiliarity with prescribing an ARV, particularly for prevention purposes and the recommendation they gave to their patient was to seek out an infectious disease specialist. Unfortunately, too often the specialist was also unfamiliar with PrEP and did not feel comfortable engaging in the regular lab work, STI testing and treatment and counseling around sexual risks and adherence.

What's more, unlike HIV treatment, where there are relatively good directories of HIV specialists, there were not wide scale comprehensive PrEP provider directories at of the time of the Think Tank. Rather, word of mouth served as the primary conduit of information.

Also, because Truvada's maker, Gilead Sciences, has decided not to directly promote the drug for PrEP, traditional sources of provider education were essentially non-existent, leaving it up to the patient to bring recommendations from the Centers for Disease Control and Prevention (CDC) to a provider's attention.

On a practical level, providers were not only unfamiliar with providing PrEP, they were also often unfamiliar with providing ongoing sexual health care, including risk assessment and counseling. The lack of experience (and sometimes comfort) providing that kind of service came not only from scant training and mentorship, but also from being unaware of how to bill for those services and the mistaken impression that one could not be fairly compensated.

Finally, there remains a disagreement about the type of provider best suited to offer PrEP, with some favoring an infectious disease specialist and others favoring a primary care provider. There are good arguments on either side, though for PrEP to be implemented at a scale large enough to have a public health benefit it is likely that more rather than fewer providers will be needed. Some of the recommendations to address the issues raised above include:

PrEP Provider Barriers: Action Items/Follow-up

- Identify key issues from the Think Tank that would benefit from further study and exploration and look into having CHRP provide at least seed funding for this kind of work.
- Develop a statewide PrEP provider's list.
- Explore how to fund PrEP detailers/educations for providers that come out of the academic system.

POLICY BARRIERS AND SOLUTIONS

As stated, the HIV disease burden in California is formidable and the policy challenges and prescriptions are often quite complicated. The state has a mix of large urban areas with overlapping concentrated epidemics, and rural epidemics that are sometimes unique in their characteristics. Two counties receive direct funding from the CDC and set most of their HIV policies at the local level, while the rest of the state receives CDC funding through the State Office of AIDS (SOA) and while local priorities and decisions may be decisive, there is still much that state policy can affect.

PrEP has revealed stark differences in how various policy actors have adopted biomedical tools as a key component of HIV prevention efforts. San Francisco, which has a highly concentrated epidemic and substantial resources, has been quite aggressive in its adoption of PrEP and policies to support its implementation, while other counties with multiple HIV epidemic concentrations and often fewer resources, have found themselves challenged to develop and implement helpful policies.

As was stated earlier, we have a limited understanding of who offers PrEP, but we have an even more limited understanding of who is taking it. Estimates vary widely and few are backed up by good data. Because there are no systems in place to conduct PrEP surveillance, it is likely that knowing who is and isn't taking PrEP will remain a challenge.

Also, policy experts are still working out how to design and implement policies that respond to the challenges confronting both individuals seeking PrEP and those who would like to offer it, to speak nothing of increasing awareness and knowledge of the intervention. With limited public health dollars, and few models to document where and how PrEP may be cost effective on a population level, ideas that are feasible and easily implemented are critical. But public health policy makers should not focus so much on the short term that they lose sight of long-term goals and possibilities. Following are several policy action items that came out of the Think Tank.

Policy:
Action Items

- Conduct modeling based on current knowledge of PrEP efficacy and adherence and HIV incidence and prevalence in California. This will be used to determine a) how many individuals will need to receive PrEP to significantly lower incidence; and b) how much funding would be needed to treat those individuals.
- Institute a statewide plan for PrEP, with a provider's letter on PrEP from the SOA to clinicians once a PrEP plan is in place. This should outline how to conduct risk assessments and either prescribe PrEP or offer a warm referral to another provider for those found to be at risk for HIV infection.
- Examples of success of policy-based efforts include rapid HIV testing at delivery for pregnant women with communications to all emergency room providers and obstetricians. We should learn from rollout of these other interventions and policies—what worked and what didn't—and use them as models for PrEP implementation.
- Institute surveillance on PrEP use in conjunction (or at least harmonization) with the Centers for Disease Control and Prevention (CDC).

FUNDING BARRIERS AND SOLUTIONS

Truvada's hefty price tag—more than $1,000 per month retail—was a prominent talking point of those deeply opposed to PrEP and an issue of serious concern for those who championed the intervention. Even before Truvada was approved for PrEP, advocates were calling upon insurers to cover it and for Gilead to provide generous assistance to those with no insurance and co-payment support for the insured. Laboratory and medical visit costs, while not as expensive as the cost of the drug, were another perceived barrier to PrEP rollout.

Fears that state Medicaids would place undue restrictions on PrEP have thus far been unwarranted. While there were some hiccups initially, one of the Think Tank presenters commented that Medi-Cal, was probably the best coverage a person on PrEP could have.

Instead, it is people with incomes too high for Medicaid and who have poorer insurance or no insurance who have had the worst problems accessing PrEP. Some don't qualify for Gilead's medication assistance program (MAP) or must jump through multiple hoops to get it. Some get caught up in coverage denials by their insurance companies. While they might ultimately be approved by the Gilead MAP following a final denial from an insurance company, this still often leaves them with less than ideal coverage for lab costs.

Finally, there are those with poorer insurance plans, particularly bronze level plans purchased through Covered California, who have out-of-pocket costs that are thousands of dollars, placing PrEP beyond their means.

How states and counties should respond to these PrEP financing issues is still unclear, but discussions focused on financing as a part of, but somewhat separate from policy issues, led the participants to recommend further exploration and study. Some of the action items that came out of those discussions included:

PrEP Financing –Action Items

- Look at coverage of non-drug and non-medical costs. These include the use of PrEP care and social services navigators, assessments of where PrEP users are in the continuum of HIV prevention care and advocacy to expand the generosity of Gilead's support programs. These issues must be addressed to ensure successful implementation of PrEP.
- Explore the possibility to institute and fund some form of PrEP assistance program similar to that proposed in Illinois and New York.
- Identify and secure funding for capacity building.
- Secure funding to offer PrEP to individuals who are undocumented.

Introduction

California's rate of new HIV infections remains stubbornly high despite the adoption of well-studied public health interventions and significant resource investments. This is especially true among men who have sex with men (MSM), and to an even greater extent among young MSM of color. Transgender women and cisgender heterosexual women of color are also at higher risk than the general public. While standard HIV prevention tools have proved somewhat effective, additional tools and strategies are required if we are to hasten the end of the epidemic.

For example, non-occupational post-exposure prophylaxis (nPEP)—the provision of antiretrovirals (ARVs) for 30 days, commenced within 72 hours after a high-risk sexual exposure—is quite effective, but it requires someone to recognize their exposure as risky in the first place, to know about nPEP, and to seek timely and highly informed medical care. They must also be able to access the medication regardless of their ability to pay. This set of challenges has greatly impeded the widespread implementation of nPEP though it has been in existence for more than a decade.

A second, newer ARV strategy is PrEP, which requires that someone take medication on an ongoing basis—before, during and after sex or injection drug use. Where good adherence could be confirmed, results of randomized controlled trials have demonstrated that PrEP is highly effective, and this is true for penetrative anal and vaginal sex, and for injection drug use.

Currently Truvada is the only approved medication for PrEP. The FDA approved it in July 2012 after a thorough review of two studies, iPrEx (in men and transgender women who have sex with men) and Partners PrEP (in heterosexual men and women in serodiscordant relationships).

`Like nPEP was when it was first considered, PrEP has proved to be controversial. Some critics have called for caution before expanding PrEP statewide, citing safety, drug resistance and risk compensation concerns. PrEP, they speculate, might actually amplify behavioral risks, resulting in a new epidemic of STDs, HIV infection and drug resistance. PrEP defenders counter this, arguing that using ARVs prophylactically could mark a turning point in the epidemic among MSM, resulting in a welcome reprieve from the fear and stigma that have gripped them since the beginning of the epidemic and offer a more forgiving form of protection when they have already largely abandoned condoms anyway. The popular media, which derives much of its existence by amplifying controversy, has amplified this dichotomy.

The Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and the California HIV/AIDS Research Program (CHRP) have sought to employ research and clinical guidance to help consumers and providers make rational decisions about PrEP and to ensure safety and effectiveness. The NIH has funded or committed to fund several demonstration projects and CHRP has so far funded three in California, details about which are provided in a further section.

As the CDC's guidelines have become more widely disseminated and more consumers and providers have gained experience with PrEP and shared those experiences, the controversy has been significantly diminished and the conversa-

tion has increasingly moved from whether or not PrEP should be taken up at all, to how PrEP should be rolled out.

It is to guide the latter, that CHRP and Project Inform began discussing in late 2013 a meeting of a diverse set of stakeholders to bring clarity and coordination to PrEP implementation in the State of California and to begin laying the groundwork, perhaps, for a formal statewide PrEP plan. This discussion, which grew to include the University of California, Los Angeles (UCLA) resulted in the PrEP Think Tank, which was held November 14, 2014 at the Annenberg Community Beach House in Santa Monica, California. There were (TK) participants, a list of which is included at the end of the report.

Participants were presented with information outlining some of the key events that have taken place that have illustrated the key challenges with PrEP rollout. As with nPEP, effective PrEP is reliant upon consumers recognizing their own HIV infection risk, or upon knowledgeable providers—those willing to provide it, and who recognize that a shaming message of "just use a condom" is neither helpful or appropriate—who can conduct sexual histories, test for sexually transmitted diseases (STDs), and provide risk assessments. Moreover, a person must able to find affordable PrEP coverage that doesn't impose prohibitive financial burdens.

Implementation of the Affordable Care Act (ACA), and the expansion of Medi-Cal has brought about new opportunities for health care coverage for millions of Californians. This is significant for those who had enrolled in demonstration projects, but who were rolled off of the projects without an identified source for PrEP. We have found, however, that while Medi-Cal is generally covering PrEP quite well, high cost sharing through private insurance plans offered through Covered California present an insurmountable obstacle to obtaining PrEP.

Consumers interested in PrEP must also locate knowledgeable, willing and capable providers to obtain PrEP, or educate the providers they already have. This, as with ACA implementation, has proved challenging. What's more, public health administrations have done their best to respond to the changes in how medical care systems must provide HIV prevention services, a model that moves away from traditional community-based organizations (CBOs) as primary providers of prevention services.

There is ample evidence that these obstacles are already in play with PrEP, yet the response so far has been personified by a patchwork of programs often developing somewhat in isolation throughout the state and with varying levels of resources. This has led some to call for a PrEP "plan" to increase coordination and set goals for implementation

There is precedence for this, including the adoption of the ambitious National HIV/AIDS Strategy in 2010, after which cities and states began developing their own plans for greatly reducing the impact of the HIV epidemic in their jurisdictions.

PrEP implementation is developing quickly. In the months leading up to the Think Tank, Washington State announced that it was launching a drug assistance program to cover the drug costs of PrEP in the state. And New York State was in the process of establishing its own (TK) strategic plan, with an emphasis on PrEP, the details of which were made public after the Think Tank took place.

Prior to the Think Tank, organizers consulted with a broad group of advisors—including top-level state and key county public health admin-

istrators, providers, policy makers and consumer advocates—to outline a series of discussions that address California's specific PrEP expansion needs, and that would identify specific steps for improving statewide coordination, expanding funding, increasing uptake and access, and for developing policies that could fit into a larger California HIV plan.

The stakeholders invited to the Think Tank touched on every aspect of PrEP demand and access. They included not only potential and current PrEP users and PrEP providers, but also public health officials who govern and carry out HIV prevention policy, sexually transmitted infection providers and policy experts, representatives from nursing and social service groups, and non-profit social service providers and advocates. This greatly enriched the conversations that took place and ensured that multiple viewpoints and experience could be expressed.

From the Think Tank, it was always intended that the discussions taking place there would be captured and disseminated in the form of this report and continued through working groups and advisory councils convened by CHRP, the state and counties and other key groups.

This report is the culmination of the meeting. The agenda, as is the report, was broken into sections and included:

- Efficacy and effectiveness: An overview of the efficacy trials, and a review of effectiveness.
- Demonstration project takeaways: A report on the data collected from the first U.S. demonstration project, plus analysis from the investigators and study staff, with recommendations for transitioning participants interested in continuing PrEP post-study to health care providers.
- Marketing: Recommendations from a product-marketing expert on applying for-profit marketing strategies to introducing and building support for PrEP.
- The consumer perspective: A panel of PrEP users shared their perspectives and experiences.
- Provider education and access expansion.
- Policy and public health administration.
- Public and private funding of PrEP: How funding influences uptake and coverage.

The Think Tank discussions and recommendations are intended to spur additional conversations, and facilitate PrEP implementation effectively, comprehensively and expeditiously.

Placing PrEP in Context in the State of California

To introduce the meeting and its aspirations, Mario Pérez, MPH, the Director of the Office of AIDS Programs and Policy for the health department for the County of Los Angeles, and George Lemp, DrPH, MPH, the Director of CHRP shared their thoughts on the significance of the meeting and their hopes for the discussions that were to take place.

Pérez remarked that the timing of the Think Tank was quite fortuitous, that it comes at a time where there is significant and growing pressure from community advocates in Los Angeles County for PrEP. He shared his view, however, that we can't just lean on public health financing for PrEP, that we must be smart about going after multiple revenue streams, that we must think about scalability and timing and must also consider continued roll-out of the Affordable Care Act.

Pérez pointed out that data from the HIV Prevention Trials Network 061 study, which found that 6% of young black gay men in Los Angeles were becoming infected each year, screamed out for the need for PrEP roll out.

The time, Lemp and Pérez both said, is now. Previously, prevention has been rooted in community-based organizations (CBOs) and most typically AIDS service organizations (ASOs). PrEP, however, is pushing health education and prevention services into federally qualified health centers (FQHCs) sexually transmitted disease (STD) clinics and large public health care delivery systems. Even counseling and testing will require changes in service delivery models that increasingly depend on health care providers from a broad cross section of disciplines to ensure that a young woman or man doesn't get infected with HIV. Thus far, FQHCs and public hospitals have not had to significantly engage in prevention, other than emergency rooms offering PEP services. That will need to change.

Finally, Lemp commented that the context within which CHRP operates is a desire to translate what we know from clinical research into clinical care delivery, to uncover what we know and don't know about the role between public health and academia and the partnerships that can be developed.

PrEP: Data from Randomized Trials and the Real World

Since the first randomized controlled trial reported on efficacy in MSM and transgender women in November 2010, the drumbeat for PrEP has only grown stronger in each passing month. In the first pass at the data, researchers revealed that Truvada had reduced new HIV infections by 42% (a more complete review of the data increased this to 44%). Later analysis showed that high adherence led to a 92% or greater reduction in transmission. Results from heterosexual cisgender women and men in mixed status primary couples showed equivalent results.

Two subsequent clinical trials in cisgender women who were not in regular relationships with HIV-positive men failed to find a difference between those taking Truvada and those taking placebo. As very low adherence was revealed by drug blood level monitoring despite high self-reported adherence in both trials, and as lasting adherence overall was relatively low in iPrEx (particularly among South American participants who made up the bulk of the study participants) it became clear that near daily adherence was a hurdle that people would likely need help to get over.

Real world PrEP experience is still somewhat limited, but results from three studies have now been reported, and all have indicated that high adherence is possible, though not universal. Subsequent demonstration projects, including those funded by CHRP, are investigating several different adherence support strategies among a relatively diverse study population.

To more fully explore the data, and discuss what inferences may be drawn from it, the organizers asked Dr. Robert Grant, principal investigator of the iPrEx and iPrEx OLE study and Dr. Stephanie Cohen, principal investigator of The Demo Project, to share their experiences.

PrEP Efficacy, Safety and Important Trends

Robert Grant, MD, MPH, Professor at the Gladstone Institute of the University of California San Francisco and Medical Director of the San Francisco AIDS Foundation

At the opening of the conference Dr. Robert Grant provided an overview of the efficacy data for both PrEP and nPEP available thus far and how that data might influence the discussions to take place during the rest of the Think Tank.

The idea for PrEP to prevent HIV acquisition among HIV-negative individuals grew out of a confluence of two findings. First, the introduction of zidovudine (Retrovir) for the prevention of mother to child transmission proved to be quite efficacious and was the first proof of concept that the provision of an antiretroviral drug to the at-risk HIV-negative individual could block transmission of the virus.

Several years later, researchers began looking at the drug tenofovir DF for the prevention of sexual transmission in adults due both to its potency and its high barrier to the development of primary drug resistance. Subsequently, studies were conducted in macaque monkeys. Both vaginal and rectal challenges in macaques were undertaken starting in the early 1990s and the first paper by Tsai and colleagues was published in Science in 1995. These studies repeatedly showed high levels of protection against multiple exposures to HIV.

This early efficacy data in non-human primates led to the design and implementation of several randomized controlled trials of either TDF alone or TDF+FTC in humans. Grant presented a short summary of data from the iPrEx study in men and transgender women who have sex with men, essentially concluding that PrEP works very well, but is highly dependent upon at least moderate to high adherence.

Grant noted that in the iPrEx open label extension study dosing consistent with four or more pills per week resulted in zero new infections. Other issues to consider include TDF concentrations in tissue and the number of doses before sexual activity that might be necessary to allow for less than perfect adherence. Because TDF concentrations in the rectum accrue more quickly, seven daily doses should begin offering high levels of protection from receptive anal intercourse, said Grant. Because TDF concentrations are lower in vaginal tissue overall and take longer to accrue, he recommended that 20 daily doses be taken before a heterosexual woman would be protected from condomless vaginal sex.

Other clinical and behavioral issues related to PrEP include side effects and risk compensation. Data from randomized clinical trails exist and information of demonstration projects is beginning to be available.

With oral TDF+FTC, there has been no effect noted on liver enzymes, blood glucose levels, amylase or blood counts. There has been no effect on lipids or body fat, nor hepatitis B flares after stopping the drug. Nausea or abdominal cramping did occur, but in <10%, and there were minimal changes in kidney function and bone mineral density. Kidney function always reverted upon withdrawal of the drug and typically remained normal if the drug was resumed.

In terms of risk compensation, Grant called upon the group to think beyond simplistic binary definitions of risk. This is because use of PrEP often promotes increased awareness of actual risk of HIV infection. The pill can also act as a daily reminder of imminent risk and promotes risk mitigation strategies and social support. Users also report a welcome and profound sense of safety from PrEP and less fear and guilt. This leads to more positive thinking and often better choices.

Judgments about the potential for risk compensation also frequently get in the way of access, particularly from pernicious biases. Calabrese and colleagues reported in AIDS Behavior that clinicians assessed black MSM patients to be at greater likelihood of risk compensation than white patients even though most HIV behavior studies find that black MSM frequently report a baseline level for HIV risk that is lower than whites or Latinos. Moreover, Grant concluded that there are no "risky" people, merely people who move through risky periods.

Grant also briefly explored nPEP. He mentioned a paper by Roland and colleagues demonstrating both the feasibility and safety of nPEP in the Journal of Infectious Diseases in 2001 , but also a paper by Schechter and colleagues in the Journal of Acquired Immunodeficiency Syndrome in 2004 pointing to very low uptake of nPEP even when it was available . These findings, according to Grant, could point to challenges to the wider roll out of PrEP.

In that regard, there is a long-known sociological and economic model known as the Theory of Innovation, whereby the acceptance and use of a new product or intervention may be predicted. The evidence for this theory being operational in PrEP uptake has been demonstrated by Liu and colleagues in 2013 in PLoS Medicine and by Jonathan Volk, MD, of Kaiser Permanente San Francisco at a public presentation in late 2014.

The theory posits that there are "early adopters" who are always looking for something new and are risk tolerant, followed by the "early majority", who look to the early adopters to filter out promising new innovations. People who are less risk tolerant fall into the categories of "late majority" and "laggards".

With PrEP we have predominantly seen its use in early adopters and by clinicians who are largely early adopters or very familiar with both TDF+FTC and knowledgeable about PrEP. There is evidence, as well, in the San Francisco Kaiser Permanente cohort, that we may be tapping into the early majority, as demand for PrEP has increased dramatically since early 2014 and anecdotally, providers are reporting that PrEP seekers are increasingly saying that their interest in the intervention was spurred by hearing about it from roommates and friends.

Grant next talked about factors that do and will affect dissemination of PrEP. These include both positive and negative aspects and sometimes both. Examples are:

- Good randomized controlled studies in both MSM and heterosexual men and women, but a lack of complete hard data on intermittent or event-based PrEP, and the data that do exist are limited to MSM. Grant called this "trialability."
- Another example Grant called "observability" included having some good online and social media resources for PrEP, but deficiencies include sex shaming of PrEP users, stigma for serodifferent heterosexual couples seeking to conceive and a lack of surveillance of PrEP. There is another problem with communications, which includes fear mongering about side effects, resistance and risk compensation.

- Something that has potential benefits, but challenges as well, include the movements for positive ownership of one's body, sexuality and health that are represented in both LGBT and feminist theory and activism. Unfortunately, there is often fragmentation both within and between these movements.
- Another problem exists with how PrEP is described, with the message that regimens must be strictly adhered to. This scares people.
- There are many doctors who are either leery of practicing sexual health or prescribing an antiretroviral and who are often judgmental about sex.
- There are advantages when notable opinion leaders come out as PrEP users, such as San Francisco city supervisor, Scott Weiner, but there are often gay bullies who engage in shaming.
- Two further issues related to PrEP. These include finding providers and specialty providers willing to provide PrEP and to be publicly identified as well, as well as challenging infrastructure, coverage and cost issues with people who have private health insurance. This is particularly true for people who bought less expensive plans issued under the Affordable Care Act or who have minimal coverage from employer-based plans.

Real World PrEP: Insights from the First PrEP Demonstration Project

Stephanie Cohen, MD, MPH, Medical Director, San Francisco City Clinic

The first demonstration project concluding in the United States (The Demo Project) enrolled 557 men and transgender women who have sex with men in San Francisco, Miami and Washington DC. The study began in September 2012, just after Truvada was approved by the FDA and concluded in January of 2014. The principal investigators, including Cohen, have presented some of the data from this project and she highlighted those findings at the Think Tank.

The study was open-label TDF+FTC. At recruitment, prospective participants filled out a behavioral questionnaire, and underwent HIV, hepatitis B and STD screening, among other lab tests and medical screening.

Reasons the participants gave for joining the demonstration project, Cohen said, included wanting to protect oneself, having a partner who was HIV positive and to make sex without condoms safer. Word of mouth drove recruitment and a person's level of risk at the baseline risk assessment was a significant predictor of enrollment.

Those who declined to participate gave a variety of reasons, but the most common reasons were not having enough time, concern about side effects, not perceiving being at risk and wanting more time to think about it.

Cohen reported that PrEP adherence was assessed by tests of drug blood levels and hair samples. Overall, 71 percent of participants had Truvada levels consistent with taking at least four doses per week, which previous analysis has determined offers an exceptionally high degree of protection from HIV infection.

There are questions about PrEP, however, that were unanswered before the demonstration project commenced and that the project helped answer. First, what was the best protocol to transition an nPEP client to a PrEP client? Of importance was how to confirm HIV status during the transition period and whether there should be a gap between nPEP completion and the initiation of PrEP. Cohen reported that there was an additional risk to instituting the gap and that the demonstration project got rid of it.

Another question was what type of counseling was ideal and by whom and how often. The demonstration project combined risk reduction with motivational interviewing performed by trained counselors.

Lastly, there remains a question of what to do with serodiscordant couples, particularly when the HIV-positive partner has achieved sustained viral suppression. Should PrEP be recommended in these situations, she asked? Clearly, further analysis and discussion are needed.

If the demonstration project Cohen described were the first study to look at real world use of PrEP (e.g. when provided according to a schedule and with the resources of a typical clinical care setting), she was also curious what "real" real world usage would look like once the demonstration project ended.

In all, 91% of participants expressed an interest in continuing PrEP after the study ended. At the San Francisco site a total of 42% ever took

PrEP following completion and 37% were currently taking it. Uptake at the Miami and Washington D.C. sites was much lower. Lack of, or incompleteness of health insurance was the number one reason that those who wanted PrEP could not access it.

Important next steps, said Cohen, included affordability and insurance issues as well as access to PrEP-friendly health care and supportive services.

At the time of the Think Tank, Gilead had recently expanded their medication assistance program (MAP) to those without health insurance who made below 500% of the Federal Poverty Level, or roughly $58,000 per year for a single individual. Those making more than that are not eligible for the medication assistance program. Gilead also increased the benefit of its co-pay program that covers the first $300 per month of insurance copayments, but which does not cover deductibles. This means that those with high deductibles, especially those who chose bronze level plans through Covered California, would be on the hook for very high out-of-pocket costs until the deductible was satisfied, thus putting PrEP out of reach for those individuals.

According to Cohen, for those eligible for Medical, PrEP is covered and there are no preauthorization processes in place. Employer-based insurance and insurance through Covered California also generally covers PrEP, though prior authorization and high copayments may be in place.

No less important is the issue of provider knowledge and experience providing PrEP and other sexual health care services. To that end, the Bay Area Perinatal AIDS Center (BayPAC) has put together a San Francisco Bay Area provider list that it makes available online.

Cohen also noted that there is a smartphone app called "PrEPmate" to help with adherence, and that offers online tools and answers questions via text. PrEP services available at the time of the Think Tank in San Francisco included Kaiser Permanente, the San Francisco City Clinic, San Francisco General Hospital's Ward 86, the San Francisco AIDS Foundation and BayPAC.

One participant asked Cohen what the goal of the counseling was in the demonstration project. She commented that the goals included a focus on adherence, status awareness, condom use and substance use. It could be, added another participant, that the role of counseling with PrEP studies and practice might be different than what has been offered with other forms of HIV prevention in MSM. His hunch was that the role of counseling might be more helpful in PrEP, because it is wanted. Robert Grant commented that the relationship between counselor and participant in iPrEx strengthened over time and resulted in a different kind of counseling experience.

Cohen fielded another question on the role of the PrEP navigator at City Clinic. She replied that they first conduct an assessment of risk and interest, followed by an assessment of coverage for those who are otherwise good candidates for PrEP. The navigator also provides education on health insurance and offers how-to guides on obtaining coverage. Amplifying on this, one participant commented that community educators could provide some of these same services outside of City Clinic and that we ought to be educating them.

CHRP demonstration projects: History and where they are

In 2012, CHRP funded three collaborative projects to test and evaluate innovative approaches of two interventions intended to improve health outcomes and curb the HIV epidemic in California. Multidisciplinary teams of investigators were tasked with engaging populations most adversely affected by HIV to provide testing and linkage to care plus antiretroviral treatment for those who were found to be HIV-positive (referred to as "TLC+"), while at-risk individuals who were HIV-negative would be offered PrEP in addition to prevention counseling and medical monitoring.

Those three projects included a project in Los Angeles County called PrEP and TLC for HIV Prevention (PATH), another project taking place in San Diego, Long Beach and Los Angeles, called Active Linkage, Engagement and Retention to Reduce HIV (ALERT) and a project at the East Bay AIDS Center in Oakland called Connecting Resources for Urban Sexual Health (CRUSH).

Representatives from each project were asked to provide a brief overview and any current progress from each project as it concerns PrEP. Progress on the TLC+ portion of the projects was not presented.

PATH

***Raphael Landovitz**, MD, M.Sc., Associate Professor of Medicine, University of California Los Angeles*

The overarching goal of the proposed LA County PrEP and TLC+ for HIV Prevention (PATH) program is to implement a coordinated response to the local HIV/AIDS epidemic through a set of innovative, evidence-based interventions across the continuum of HIV prevention and care, targeting individuals and communities at highest risk of and affected by HIV in Los Angeles County (LAC). The PATH Consortium is led by the Division of HIV and STD Programs at the LAC Department of Public Health, and Consortium partners are the University of California, Los Angeles, the Los Angeles Gay and Lesbian Center (LAGLC), the OASIS Clinic/Charles Drew University, and AIDS Project Los Angeles.

The LAC PATH PrEP program aims to enroll 375 high risk men who have sex with men (MSM) and male to female transgender individuals of diverse racial/ethnic backgrounds, who are delivered a customized prevention package (CPP) that may include PrEP, in addition to risk reduction counseling, sexually transmitted infection (STI) screening and treatment, substance use and mental health screening and referral. Participants are seen at one of two sites, and there is both an nPEP cohort and a PrEP cohort.

Self-reported adherence is recorded, but adherence is validated by real-time drug levels at each visit. Thus far, Landovitz reported that he and his colleagues had found two subsets: people who do fine with daily adherence; and those who need extra support, using drug levels as a guide.

For all of those in the study, the investigators are using a model known as Integrated Next-Step Counseling, developed by Rivet Amico. Those initially found to not have enough drug levels in the blood are offered extra support, called Level 1. This is Targeted Integrated Nest-Sept counseling. For those with persistent undetected drug levels, there is a Level 2 intervention that includes an additional 6 sessions of support.

Landovitz also reported that there is a Calcium and Vitamin D sub-group study. This will inform bone density loss using markers of bone turnover.

ALERT

David Moore, PhD, Associate Professor of Psychiatry, University of California San Diego

This demonstration project is a collaboration of three HIV testing sites (San Diego HIV, STD, and Hepatitis Branch, The City of Long Beach Department of Health and Human Services and LAC-USC Emergency Department) with three CCTG primary care clinics (UCSD Owen Clinic, Harbor-UCLA Medical Center and LAC-USC Rand Schrader Clinic). There are three Aims, two dealing with HIV care linkage and retention and a third with PrEP adherence.

Moore reported that the study has randomized 379 MSM and transgender women to one of the two arms (e.g. iText or standard of care). This is a 48-week trial and the goal is to have at least 15% of the study participants be African American. The study is still attempting to enroll this demographic. So far, the baseline STD prevalence is quite high. Moore also explained that based on a preliminary look at the baseline data there are differences in PrEP eligibility. For instance, should there be different strategies for those in serodiscordant monogamous relationships versus those with multiple partners?

So far adherence to the iText messages is very high. Eighty percent have responded to the texts. Retention is also high, with 94% remaining in the study through 24 weeks.

CRUSH

Jeffrey Burack, MD, Attending Physician, EAST Bay AIDS Center

The CRUSH Project aims to evaluating the effectiveness of a tailored package of HIV care, treatment and prevention interventions to address the sexual health care needs of young (aged 18-29) gay and bisexual men who have sex with men, persons who are transgender (male-to-female and female-to-male) who have sex with men, and the sexual partners of HIV-infected individuals. The project's goal is to demonstrate the feasibility and effectiveness of integrating and implementing comprehensive sexual health services within an existing youth clinic to support HIV prevention and care engagement.

Active enrollment in CRUSH began on February 10, 2014. As of March 16, 2015, CRUSH has enrolled a total of 208 participants. To date, over 550 HIV point-of-care rapid tests have been conducted. Participant demographics include: 29% African-American/Black, 31% Hispanic/Latino, 18% White, and 22% other races/ethnicities. Average age of participants is 25. Most (94%) participants identify as male, 2% as female, and 2% each as a transwoman or transman. CRUSH is maintaining extremely high retention rates as well: nearly 90% of all participants who have enrolled still participate in study activities, with very little loss to follow up (8 discontinued early / withdrew consent, 12 have been lost to follow up). The addition of a CRUSH retention coordinator, who supports and navigates participants through study visits, and provides appointment reminder notices, has been essential to the success of retention in the study thus far. Since enrollment commenced, CRUSH staff have recruited 59 positive young MSM into the study. Of these, 89% have been retained. Of the 208 participants enrolled into CRUSH, as of March 16, 2015, 91 are actively taking PrEP, and 115 overall have accessed PrEP over time. Additionally, 36 participants have chosen to participate in sexual health services only, without seeking PrEP-of these, nearly half (n=14) started on PrEP and have discontinued, but continue to see a CRUSH provider for all routine STI care and treatment.

How to implement PrEP: Facilitating and Creating Demand

As was explained in the first presentation by Grant, new innovations in medicine and other fields go through a predictable continuum with early adopters being the first to take them up. It has been no different with PrEP. While some have complained that PrEP uptake has been slow, it is difficult to measure this as there is no meaningful surveillance of PrEP use in the United States. There has certainly been public controversy about PrEP and those who would use or prescribe it, however, and thus some measurable trepidation among both prospective patients and the health care providers they approach to prescribe it.

Two important determinants of PrEP uptake are demand and supply. Or, more specifically, what are people at risk of HIV infection asking for, and how ready are providers, health care systems and government administrators to provide it?

To address these questions, the organizers invited three stakeholders to offer their take on the issues related to PrEP demand and to be available for wider discussion with the Think Tank participants.

Two PrEP users first shared their experiences with deciding whether PrEP was right for them, the reasons that led them to try the intervention and how they were able to access it. Both were L.A. residents and Latino: one a gay male and the other a transgender female. Neither is representative of everyone seeking PrEP. Both had a relatively easy time finding a provider willing to prescribe Truvada, and both had insurance coverage for the drug.

Plenty of individuals who have sought advice and shared their stories on the popular Facebook page PrEP:Facts have recounted significant difficulties finding a willing provider and once issued a prescription, securing coverage to pay for it. Also unusual was their willingness to "come out" publicly as PrEP users, speaking to the high levels of stigma about PrEP and the risk factors that require it which still remain in place.

Nevertheless, both offered insights into the motivations of PrEP users and some of the ways that PrEP might ideally be offered.

The third presenter focused on marketing and creating the demand for PrEP, which many feel remains low given its promise. In order to provide a fresh perspective, the organizers asked a professional marketer to detail the methods and thinking that go into branding and marketing a retail product; in this case Barbie dolls.

At its heart, successful marketing efforts are based on a detailed and sophisticated understanding of consumers, combined with messages that speak to their wants, needs and aspirations.

With PrEP, this is complicated and challenging. Budgets for market research are miniscule and insights must be gleaned from the small amounts of qualitative research and anecdote gathering that are possible. As well, there are multiple populations of PrEP users with varying quantity and quality of data to support the use of Truvada for primary prevention. These users have different risk factors, challenges to recognizing and acting on HIV risks, medical and sexual care access and social circumstances. Last, , funding to conduct marketing and outreach is relatively small, has only recently been focused on PrEP and is still finding its footing.

Even with the need to prioritize a limited amount of funding, however, there are solutions. One is to maximize the venues and publications most likely to reach the target audience. Another is to get current PrEP users to speak on behalf of it. And finally, to generate simple but catchy messages that communicate the most information in the least time.

PREP DEMAND: USERS SPEAK

Prior to FDA approval, and in the first year following approval, PrEP users largely kept a low public profile with just a few notable exceptions. At that time, there was great controversy with critics and advocates taking firm stances and media sources often stoking the controversy. Some PrEP critics had significant financial resources and their public campaigns against PrEP helped keep the controversy going.

Aside from public debates about the existing data and worries about how PrEP would play out in the real world, there were public and private excoriations of those who might need PrEP or be inclined to use it. This had real world consequences for people at risk for HIV, providers who wanted to or did offer the therapy as well as for potential policy makers and funders.

The organizers of the Think Tank reached out to two PrEP users whose voices have often been absent from discussions about PrEP, gay men of color and transgender women. Ernesto Provencio and Prue Mendiola were glad to share their stories.

Ernesto Provencio:

Provencio, a 35 year-old gay man initiated PrEP as part of the PATH study in 2013. At the time, he had recently ended a long-term monogamous relationship. During that relationship, he had become used to sex without condoms and realized that going back to condoms would be a challenge. He also began seeing an HIV-positive man after the breakup and he wanted to remain negative.

Provencio says he'd heard about PrEP and started looking into clinical trials, in large part because he wanted to do something to help his community.

He found that being a more informed consumer ultimately helped him transition from the clinical trial to standard medical care. He said, "In my case I was fortunate, because my doctor also knew a lot about PrEP. The situation was a lot easier for me."

In contrast, he reported that he had encountered a lot of individuals trying to access PrEP who kept getting referred from one provider or project to another. He also cited the great amount of misinformation about PrEP that was out there. It made it hard for people to decide what would be right for them. He says he was particularly frustrated with the AIDS Healthcare Foundations campaigns against PrEP, because he felt they misrepresented what the consensus of the scientific community was saying about its effectiveness and safety. He felt this led people to be confused about the intervention.

When asked by the audience whether he'd had discussions with friends about PrEP, he said yes. Though he hadn't gone out of his way to disclose to everyone that he was on PrEP, he said some people knew. Provencio said that at first people mainly asked him about side effects, and he was able to tell them both what the data showed and what his own experience had been. Ultimately, they began asking if he knew a provider who would be open to prescribing PrEP. Because finding a knowledgeable and willing provider isn't necessarily easy, Provencio says he tells friends that we have to educate some of our own providers. If you have a provider you trust, he tells them, give them the CDC work sheet. He also mentioned that Project Inform has a PDF to help people with their doctors.

The audience also asked him what he thought about the studies finding that intermittent adherence could be highly effective. Did that information make him tempted to take the drug less frequently? He said that when he started with the study he "freaked out" about forgotten pills. Now, knowing that PrEP is forgiving, it has eased his mind. He does miss doses occasionally, but is still highly adherent.

Prue Mendiola:

Mendiola, a 27year-old transgender female, has been working with transgender women through the Transgender Service Provider Network (TSPN) since (TK). She is recently divorced and well insured with a good relationship with her doctor. She told her provider that she wanted to start PrEP and her doctor said, "Okay," immediately and had no judgments. Though she hadn't yet started PrEP at the time of the Think Tank, she indicated that she would be soon after.

At this point, Provencio and Mendiola fielded questions from the other participants.

QUESTION: "Are either of you aware of the shaming that has taken place, with people called, "Truvada Whores"?

RESPONSE: Mendiola indicated that yes, there is certainly stigma. She finds this is often not so much about the drugs, but about transgender and MSM sex and intimacy.

QUESTION: "Are the voices in the transgender community coming through?

RESPONSE: Mendiola said she holds a series of meetings called "Trans-Forum," which seek to educate the community on PrEP. Some are saying that PrEP is not effective for transgender women, but she reported, feels that the community overall is ready to embrace it. She recommends education and increased access.

QUESTION: "How do we get more transgender women into PrEP studies?

RESPONSE: Mendiola cited negative feedback from the women served by her organization, because all of the studies lumped MSM and transgender women together. While the studies claimed that there was not high demand for PrEP among transgender women, she felt that this was due to the way the studies were designed and described in recruitment and screening.

QUESTION: "What is the level of risk to post-operative vaginal tissue in transgender women? Does Truvada reduce the risk to this tissue?

RESPONSE: Mendiola explained that until very recently it was incredibly expensive and difficult to access surgery of this type and so many transgender women had not had it. For this reason, a lot more research is needed.

QUESTION: "If your partner was HIV-positive and on antiretrovirals with a suppressed viral load would this affect your decision to be on PrEP?"

RESPONSE: Mendiola said that she would stay on PrEP. Though she knows the data, she feels that the risk remains, however small. Provencio said that he also would continue PrEP for the peace of mind and because he participates in consensual non-monogamy with his partners.

QUESTION: "What do you think is the best way to get education to communities at risk?

RESPONSE: Mendiola says that although she takes an active role in this she still blames herself for the lack of PrEP education among transgender women. She said that TSPN plans monthly forums and wants to do more education.

PREP DEMAND: MARKETING TO USERS

How to market PrEP to prospective users, providers and policy makers

Nitya Madhavan, Senior Director of global marketing for Barbie at Mattel

Madhavan opened with the caveat that she is not at all an expert on PrEP or public health, but was glad and honored to have been invited to share her experience with building a market for a new product and understanding the needs and wants of what in her line of work are called customers.

Her first piece of advice was for those who wished to create a demand for PrEP to develop in-depth profiles of the people they would like to know about and consider PrEP. To do so, Madhavan explained, means identifying the following information and asking the following questions:

- Demographics, which can indicate how your market is getting their information
- Psychographics (psychological criteria, e.g. attitudes, aspirations, etc.)
- Likes? Dislikes?
- What is their problem or need, and what is the benefit to finding them a solution?
- What is their greatest hesitation in trying the product?

She also said to consider your communication message. What are you trying to say to your consumer? How do you reach them? She recommended finding ways to answer the following questions:

- Where do they hang out?
- What do they watch? TV? Movies?
- What do they read? How do they read? Online? Offline?
- What do they search for online? Knowing this is critical in understanding how your consumer finds you via search terms.

It can be helpful to create consumer profile models that detail your primary consumer(s). These can serve as a guide by which to construct your marketing messages. Choose a name for each profile and get specific: lifestyle, activities and likes. Define each profile clearly. Draw distinctions between each one. Identify a variety of potential consumers.

A participant asked Madhavan how she'd respond if her profiling budget were cut in half, to which she replied that she'd use word of mouth: talk to the community, and describe the community in your profile. Madhavan suggested focus groups, individual interviews and surveys as methods of identifying helpful details. She added, "Throw a dart." Use that as a starting point and refine your profile as you go; form a community advisory board with a cross section of community to make sure you're still on the right path.

When asked how she'd seek out people at the opposite end of the spectrum from Mattel (e.g. people with no money), she advised approaching consumers in a space that they are most comfortable. Those who might benefit from PrEP might be less engaged in media, she explained, and less engaged in health services. Guerrilla marketing and social media might be more effective to reach these people. (Another participant suggested that dating sites and apps might be effective avenues for outreach.)

Madhavan explained the distinction between "casual" and "power" users: Power users already understand your product; casual users are those you still need to convince.

Another participant asked Madhavan for guidance on staying nimble, and for amending a message as new information emerges, taking into account the slow review process for PrEP, and judgments based on incomplete information. Madhavan advised changing the way the message is communicated, but not necessarily the message itself. Change how you speak to people, and where you approach them, she said. She also suggested buying search terms as a technique for redirecting the conversation.

How do you make PrEP sexy? Madhavan answered this with questions of her own. How far do you want to push it? Do you want to add more controversy to your message? Humor? People tune out, she said, if you push the "educational" perspective too hard.

One participant asked Madhavan how she would go about countering an opposing company or voice. She pointed to Goldieblox, a toy company that markets building blocks to girls, as an example. Goldieblox, she said, went after the Barbie brand with a controversial "pink shaming" message. Rather than having Mattel go head-to-head with Goldieblox, they let others speak on their behalf. In the case of marketing PrEP, she suggested partnering with community leaders who have a broad network, and who can fight that fight on your behalf.

Madhavan said that it's worth spending a lot of time to identify influencers and networks. Find as many as you can, she said, and form teams. Turn to celebrities or other notable figures who can tweet, blog and grant interviews. Recruit influencers from key communities. Find people with access, and who know how to talk to their own communities. For example, ask a Latino to reach out to the Latino community.

In discussing strategies to counter corporate resistance to controversy (e.g. no condoms), Madhavan suggested making an emotional appeal. She compared PrEP controversies to those surrounding birth control. Make noise, she said. People will listen, and then new clients will drive the demand, whether or not corporate support was there in the beginning.

There are two competing challenges in providing PrEP, said one participant: the capacity for distributing PrEP via the healthcare system, and building public demand for PrEP. How to do both? Madhavan said that ideally money could be applied to both, but if that's not possible she suggested picking one to emphasize while maintaining at least a minimal level of support for the other. When resources allow, bolster the other, she said.

Competing PrEP marketing messages between communities is challenging, said a participant, pointing out that the message, "Unprotected sex got safer!" appeals to one group, but alienates another. To this, Madhavan said, contradictory messages regarding condoms makes for confusing advertising. Instead, market toward the lowest common denominator so they can absorb your message in 30 seconds. Get clearer on the message.

With respect to directing a message, one participant said, PrEP will be consumer-driven, so it's best to focus on consumers versus doctors, as opposed to doctor-driven drugs.

PrEP Supply: Special Topic Panels

The next segment of the Think Tank included presentations and discussion on three topics: access to PrEP; policy issues related to PrEP provision and uptake; and funding issues that would enhance PrEP awareness, training and access. Panelists were drawn from leaders in each subject area. The panelists gave opening remarks, which were followed by questions or comments from other Think Tank participants and answers provided by the panelists.

A central goal of the Think Tank was the development of action items and other types of recommendations that could be used to increase and improve culturally competent PrEP provision in the state of California.

To that end, each of the three sections included introductory remarks by the section moderator and the panelists to frame the issue, followed by broader discussion among the participants to build on this for the development of the action items and recommendations.

The action items are listed at the beginning of each section, followed by notes of each discussion.

PREP ACCESS: THE PROVIDER'S VIEW

PANELISTS:

***Robert Bolan**, MD, Medical Director, LA Lesbian Gay Bisexual Transgender Center*

***Robert Grant**, MD, MPH, Professor at the Gladstone Institute of the University of California San Francisco, Medical Director, San Francisco AIDS Foundation*

MODERATOR:

***Raphael Landovitz**, MD, M.Sc., Associate Professor of Medicine, University of California Los Angeles*

As Robert Grant stated in his PrEP overview at the beginning of the day, new medical interventions are taken up in a relatively standard way, with early adopters and laggards. With most medical innovations, however, there is often a marketing and education push to increase awareness and knowledge of these new interventions and to help providers feel comfortable with them. PrEP, however, has been an exception to this, as to date there has been relatively little marketing to and education of providers.

This, along with a multitude of factors, including unfamiliarity and discomfort around providing sexual health services, unfamiliarity with the use of antiretroviral drugs, and disagreements about which providers should offer PrEP, have led to an apparently slow uptake of Truvada for primary HIV prevention.

Because Truvada's maker, Gilead, has explicitly decided not to actively market Truvada for prevention, it is incumbent on others to do this work. Medical societies have yet to do this and none have expressed a willingness to take up this work. The AIDS Education and Training Centers have begun to incorporate PrEP as an option for education and a national warm line is available. Still, for PrEP to have a population level impact, much more will be needed to reach even minimal thresholds of coverage and the state and its counties will have to play a major role.

Following is a list of recommendations to begin addressing barriers to provider awareness and education, followed by a recap of the discussion that led to their identification.

PrEP Provider Barriers: Action Items/Follow-up

- Develop working groups that flow out of the Think Tank and the observations and action items.
- From these working groups, identify key issues that would benefit from further study and exploration and look into having CHRP provide at least seed funding for this kind of work.
- Develop a statewide PrEP provider's list.
- Explore how to fund PrEP detailers/educations for providers that come out of the academic system.
- Develop an adequate (or at least minimally adequate) surveillance system for PrEP.
- Get more funds for marketing, especially funds beyond that offered from Gilead.
- Get consumer and provider feedback and see if we can get a pro-bono marketing campaign to get the message out.

Introduction, Raphael Landovitz:

Landovitz opened by explaining that there are two sides to the supply-side coin: one is a discussion on provider knowledge and education and a complementary but separate discussion on financing of PrEP. He assured the participants that the finance side would be handled in another section.

He next shared a concern that PrEP could end up promulgating and exacerbating the disparities that already exist in public health and sexual health care. He shared a story, which he said he was sure was just one example that others could add to, about a patient being shamed by his doctor.

In this case, Landovitz heard about a patient who had seen one of Landovitz's colleagues and had had a bad experience. The provider, who was an HIV specialist and who Landovitz said should know better, had told this patient that he "didn't need PrEP, he just needed to use condoms and stop being so promiscuous."

In this case, the patient was persistent, and turned to a well-known Facebook page run by Damon Jacobs called "PrEP Facts". He and asked if others had experienced a similar form of shaming. Many came to his support. Landovitz said this is a classic example of why we must educate providers in PrEP delivery and to insist that it is not appropriate to moralize.

Robert Bolan:

Bolan began his remarks by reporting that in the previous couple of weeks before the Think Tank he had been thinking that Primary Care Providers (PCPs) could be among the best to offer PrEP. As he reconsidered all that is required of PrEP beyond the lab tests, sexual and adherence counseling and prescribing, however, he said he'd changed his mind. Specifically, he noted that while there needs to be easier access to TDF+FTC through providers, there also need to be navigators who can help with insurance and pharmaceutical access programs. There need to be mid-level providers who can educate and counsel clients on adherence. This led Bolan to a recommendation of a hub and spoke model, with the hub being patient education and financial/insurance advisement and the spokes being the medical providers to whom clients are referred.

Bolan also commented that he is less concerned with what some have expressed as a major concern: that being a potentially dramatic increase

in the rate of STDs other than HIV among PrEP users. For one thing, he explained, because STD testing will be conducted frequently and continuously, there will most certainly be a numeric increase in STD diagnoses regardless of whether actual transmission has increased. Also, because people are tested frequently they can be treated promptly, thus potentially decreasing the rate of ongoing transmission of STDs to others.

Robert Grant:

Grant began his remarks by saying that he believes all types of practitioners should be able to provide PrEP, provided that they have proper training, knowledge and skills. Moreover, he believes that provider education should that mimic what the pharmaceutical industry employs: frequent visits to clinicians to educate them about products and strategies and to alert them to updates to product efficacy and safety. In this case, however, detailers would not come from the manufacturer, but instead from accredited academic institutions. He noted that one such program for PrEP is in existence.

Beyond simple knowledge of the clinical data, however, is the issue of knowledge about standards of care in regards to HIV, STD, HBV and kidney function testing. Also important is how to treat HIV-negative people who are at risk for HIV infection and in need of prevention services, both how to serve them and how to bill for those services. He commented that while providers may be resistant to new treatments and technologies when educated as part of a group, one-on-one training and mentorship could be effective. In particular, he recommended a small set of messages (ideally three, but less than seven) for each encounter.

One way to maximize provider time would be to limit visits with the provider to 10 or 15 minutes, while a separate service worker could spend an additional 30 minutes on counseling. This could help facilitate a patient's thoughts on and experiences with adherence and address any fears.

Lastly, Grant noted that primary care providers should be particularly interested in offering PrEP, because of the potential to bring young healthy people into their practices. It is a good business decision, he said.

Access Discussion:

COMMENT/QUESTION: Where are the priorities for targeting information and education to providers? How might this vary by provider type, practice type and location? What are the biggest barriers?

RESPONSE: Physicians are often resistant. Most have not been properly trained during their residency in conducting a sexual history. We need to be giving lectures in medical school and starting that education process now. Also, it's overwhelming when a practitioner only has 30 minutes for a complete physical. This supports Bolan's model of hub and spoke.

RESPONSE: Billing codes for sexual health counseling actually pay really well, contrary to common wisdom. Physicians who are worried about time or overwhelmed can bill it as a "sexual health" service code. There is a list of billing codes on Project Inform's website.

RESPONSE: Family planning clinics can be a great source for PrEP. Planned Parenthood has said they are interested in providing PrEP, but haven't figured out yet how to do it. Target providers that are comfortable with sexual health already. On a related note, STD clinics are moving toward becoming sexual health clinics, and PrEP is a tool to spur this on to greater acceptance. Healthy individuals seeking PrEP care are also getting other health care, such as blood tests. One counter to this argument, however, is that it can be challenging to interest individuals who aren't interested in reproductive health services to go to a placed like Planned

Parenthood. Likewise, many sexual health care providers don't conduct rectal and pharyngeal STD tests.

COMMENT/QUESTION: How do we decide who is low, medium, and high risk, and establish consistency in who to provide for?

RESPONSE: The trials so far were conducted in individuals at fairly high risk for HIV acquisition. More data is needed for those at lower risk. We must also be careful about how we are defining risk behavior, especially as it concerns background incidence and prevalence in a given community.

COMMENT/QUESTION: The CDC guidelines are very broad – most college students qualify.

RESPONSE: Some college students who would be deemed lower risk by some actually have very high levels of risk. Risk is often mischaracterized. During the PROUD study in the United Kingdom, MSM were randomized to immediate or deferred PrEP initiation. The monitoring board closed the deferred arm early due to a significant difference in HIV acquisition between the two arms, suggesting that the actual incidence of HIV must have been two to four times higher than anticipated.

COMMENT/QUESTION: I agree that the CDC's PrEP guidelines are too broad. There is a gap between the CDC guidelines and the studies. There needs to be a guideline for specific risk groups, and their different epidemiology.

RESPONSE: The State Office of AIDS (SOA) is interested in looking at its role in HIV prevention

RESPONSE: Many women at risk don't see themselves as at risk. We need to develop specific questions to help women find their risk.

COMMENT/QUESTION: One of the largest potential benefits of PrEP is connecting at-risk people to regular health care, so we should look for someone to promote MSM of color into the program. We'll need different points of access for various communities, i.e., there will be people who will go to LGBT centers, and others who won't. We should create ways to refer people of different communities for intake or ongoing management.

COMMENT/QUESTION: There are concentric circles of risk with the highest in the center. We've been providing it and marketing it to middle-risk individuals: how do we get to the really high-risk people who are not seeking care?

RESPONSE: Sometimes STDs can be your friend from a public health standpoint (aside from asymptomatic STDs). Good partner service and notification is one way to bring them in.

COMMENT/QUESTION: How about a tear-off sheet to bring to your doctor, a sort of "how-to."

RESPONSE: Should we at the county level provide a checklist, giving steps for how to traverse system?

RESPONSE: CDC handouts do a great job of this. There are materials to bring to your doctor, pamphlets about PrEP, etc.

RESPONSE: We hear that even that is too complex.

COMMENT/QUESTION: University of California campuses are going to be providing PrEP with a $25 copay. They aren't sure how to roll it out yet. However, this will fall on practitioners who aren't trained to talk about sexual health. UCs have given talks to younger practitioners, and they are interested. Going forward it would be good to integrate that into training. We'll keep seeing practitioners who judge and deny, but that hopefully the instances of that will go down.

COMMENT/QUESTION: I feel that there are really important sections of our community that we're missing by not taking it out of the health care setting. Particularly MSM of color and women at risk, they are not in health care settings day-to-day. They are at the grocery store. We need to figure out how to reach out to them in those settings.

COMMENT/QUESTION: I want to go back to a question of scale. Hub and spoke is good, but PCPs are a very different concept. Which groups should we prioritize? As we think about how to mobilize a service, we can't ignore issues of scale. Who gets served first? We need a medium term option and an immediate option. There are different levels of capacities with different providers.

RESPONSE: The STDs clinics, student health centers and HIV centers are going to be the furthest along with providing PrEP. I would just not want to walk out with us saying that PCPs can't provide sexual health care. We are in the middle of a burgeoning syphilis epidemic. We have to get PCPs engaged in sexual health to get on top of the syphilis. PCPs' clients are sexually active and they should be treating them. Response: We are having PCPs provide PrEP in the bay area. Not all men seek care there, but we have providers who are generalists who provide sexual health care and are early adopters. We have guidelines for them, and it's enough for the providers to get going.

PREP PROVIDER BARRIERS: OTHER CONSIDERATIONS

- A statewide provider's list would be very helpful in and of itself, but it could also serve as a backbone for surveillance and information to identify the volume of services provided. The list should be curated, put in one form for research and another for consumers.
- Explore following Pennsylvania's lead in putting together an academic detailing program.
- Should PCPs offer PrEP and follow individuals on PrEP without oversight and guidance from infectious disease specialists? Some feel that it should be possible with proper training. For instance, some of the most knowledgeable and successful HIV providers are not infectious disease specialists. Others feel either that infectious disease specialists should be the only ones offering PrEP or that they should always play at least an advisory role, because of the danger that PrEP will be offered by PCPs who aren't knowledgeable or prepared to offer the intervention.
- You can do a spoke and hub model that is different than the one proposed by Bolan, whereby an infectious disease specialist does the initial intake and oversight, but PCPs take responsibility for ongoing care. You can also do clinical modeling and detailing to PCPs to provide the full course of care. Both should be considered, explored and modeled.
- Family planning clinics could be an ideal target—Planned Parenthood is apparently interested in figuring out how to provide PrEP, but doesn't yet know how. There are draft protocols from other institutions that could be repurposed for sexual and reproductive health clinics.
- One of the problems with many sources of care is the lack of resources for tracking new STDs, particularly rectal and pharyngeal testing. Clinics and labs in San Francisco do testing of multiple anatomical sites in one visit, but most in California do not.

- There is a question of how to deal with risk designations when trying to assess whom PrEP is right for and this is particularly true for cisgender women.
- There is the question of how to reach those at highest risk. Based on STD rates at baseline and over time, it seems that a majority who are self-selecting or referred for PrEP are truly high risk. So far, however, these appear to be a relatively highly resourced and motivated group of individuals. How to go beyond that is a critical question.
- Should there be California State guidance on PrEP, particularly one that includes very simple tools and a rational guide to assessing risk.
- Should PrEP risk assessments and referrals be conducted, at least in part, from non-traditional locations, such as the Department of Motor Vehicles or pharmacies at large big box stores such as Wal-Mart? This has worked well for HIV testing and other diseases.
- Given trends in provider availability and the added strain from the expansion in health care under the Affordable Care Act there are questions about how much provider access can be expanded to meet a higher demand. Thus, what are the resource constraints, especially among PCPs and what is realistic?
- How much can be task-shifted to mid-level providers, such as nurses and trained risk assessors and outreach workers?
- PrEP 2.0 (in the form of more flexible dosing strategies) and 3.0 (in the form of other drugs) are not too far in the distant future. Learning from current rollout of PrEP and future planning for these realities is important.

POLICY – POLITICAL, LEGAL AND ADMINISTRATIVE SOLUTIONS TO PREP DEMAND AND DELIVERY

PANELISTS:
***Karen Mark**, MD, MPH, Interim Chief, Office of AIDS, California Department of Public Health*
***Sonali Kulkarni**, MD, MPH, Medical Director, Division of HIV and STD Programs, Los Angeles County Department of Public Health*
***Patrick Loose**, Chief, HIV, STD and Hepatitis Branch of Public Health Services at County of San Diego*
***Nicholas Moss**, MD, MPH, Director of the HIV/STD Unit, Alameda County Public Health Department*

MODERATOR:
***Terry Smith**, MPA, Associate Director of Education, AIDS Project Los Angeles*

The urgency for public policies that facilitate PrEP uptake and provision are made starkly clear by the fact that roughly 10 percent of all new HIV diagnoses in the United States occur in the state of California. And as the most populous state in the nation, the diversity of the epidemic in California as well as the fact that two of its counties receive direct funding from the CDC, makes it difficult for state policies to meet the needs of every jurisdiction.

Nevertheless, the panelists offered perspectives from the State Office of AIDS and three counties with diverse circumstances and epidemics. Overall, discussions following the panel presentation focused on state-based solutions to the barriers that have hindered PrEP roll out rather than on city or county policies—though the panelists did address local challenges.

The SOA has already initiated several measures, including the development of a statewide PrEP provider guide (currently focused on Ryan White clinics), updated PrEP information on the SOA website, and consideration of at least some elements of a PrEP guidance from the state.

A fundamental question that has yet to be fully addressed, however, is the desirability and utility of a statewide HIV plan that incorporates PrEP, following the recent model of New York State.

This same issue came up in the financing section as a possible focus for funding asks going forward, but a statewide plan, akin to the National HIV/AIDS Strategy, could help focus efforts and with proper metrics hold administrators and policy makers accountable for the trajectory of the epidemic and both care and prevention continuums at a statewide level.

Following are recommended action items and a more in depth look at the presentations and discussion.

POLICY: ACTION ITEMS

- Identify and advocate for PrEP policy asks that are discreet from budgetary asks.
- Conduct modeling based on current knowledge of PrEP efficacy and adherence and HIV incidence and prevalence in California. This will be used to determine a) how many individuals will need to receive PrEP to significantly lower incidence; and b) how much funding would be needed to treat those individuals.
- Institute a statewide plan for PrEP, with a provider's letter on PrEP from the SOA to clinicians once a PrEP plan is in place. This should outline how to conduct risk assessments and either prescribe PrEP or offer a warm referral to another provider for those found to be at risk for HIV infection.
- Examples of success of policy-based efforts include rapid HIV testing at delivery for pregnant women with communications to all emergency room providers and obstetricians. We should learn from rollout of these other interventions and policies—what worked and what didn't—and use them as models for PrEP implementation.
- Institute surveillance on PrEP use in conjunction (or at least harmonization) with the Centers for Disease Control and Prevention (CDC).

Introduction, Terry Smith:

Smith introduced the discussion about policy by commenting on community perspectives he had heard at PrEP forums, which he said were well attended. He said he was hit the hardest by how scared people were about sex. We think that people don't care about HIV any more, but they do. PrEP is the first opportunity to experience intimacy again in a way that some felt condoms diminished. Also important, he said was that young black MSM have heard PrEP was only for high-risk people. Although the community has been heavily impacted, young black MSM don't see themselves as being at high risk. It's necessary, he said, to change the language for PrEP to become wide-scale. The community has to demand it.

"We are tired," Smith said, "of how HIV has impacted the community, and we want to do something."

He added that we need to have hard conversations about what we're willing to give up (portions of HIV budget), and how to translate that to our community. Closing, he said we all need to improve access to PrEP while also challenging people to stay HIV negative and responsible for their status.

Karen Mark:

Mark began her presentation by citing some sobering statistics. There are 5,000 new cases of HIV diagnosed each year in the state of California. That translates to 14 every day. "We must step back," she said, "and say that this is unacceptable, that we need to better. PrEP is a relatively new but promising tool, and it is important to think about how we will use it."

We must also remember, she added, that PrEP is not entirely new. Since the early 1990s we have treated pregnant women and newborns and have virtually eliminated mother-to-child transmission in California. Similarly, there are commonalities with the introduction of the birth control pill in the late 1950s and early 1960s.

There was initially a lot of controversy and differing opinions and initial limitations on access to the pill, Mark reminded the participants. We didn't accept that then, however, and instead educated women on their options and gave them the information they needed to make choices. That's how one does the best job in preventing unwanted pregnancies. "We don't tell young women, 'I'm only going to give you condoms,' though we do tell them that the pill doesn't protect against HIV," she said.

"The same should be true for PrEP," she said "Inform people about all of their options and empower them to make good choices. PrEP is here to stay. It is FDA approved for oral daily use, and intermittent and injectible forms are coming. We will have other options and need to think about HIV prevention in a whole new way."

The ACA has also changed public health, Mark said. For every dollar spent on health care only 3 cents is spent on public health. Everything else is absorbed in the medical system and PrEP is a medical intervention. We need to encourage the medical system to take on the costs of PrEP and to alleviate the burden on the public health system wherever possible.

Next, Mark said she wanted to give an overview for how HIV prevention funding and programs at the state level comes to be. The state, she said, receives CDC dollars that are administered by the Office of AIDS. This funds activities throughout the state excepting San Francisco and Los Angeles, both of which are directly funded. The state funding is focused on helping the rest of California. There is a small general fund, but that is focused on testing, outreach and access to care. There is no other funding.

With what exists, however, Mark said that the Office of AIDS is interested in helping counties look at how to help with PrEP. The Office is monitoring PrEP implementation, the demonstration projects, and the progress at Kaiser Permanente. The Office is also working closely with the STD control branch, recognizing that STD clinics are great places to encounter high-risk individuals.

The STD prevention branch of the state can make site visits to health centers that are in various phases of implementing PrEP. HIV test counselors, she said, should be educating clients about PrEP.

Mark reported that the Office of AIDS had sent a survey to 44 STD clinics enquiring about whether they were prescribing PrEP. About half have responded so far and most of those were Ryan White-funded clinics. Thirteen were willing to be a part of a statewide provider directory. The Office plans to start with Ryan White clinics, but expand later.

Mark said that her office has also heard from others about the need for and utility of California state guidelines and that is something she said her office would like to develop. The CDC guidelines, she said, are great, but that for a PCP who only has a few minutes with a provider even the checklist is a challenge. She said she thinks there is utility to a very short checklist telling providers what they really need to know, for instance, such as testing them carefully for HIV and STDs at baseline and every 3 months, offering no refills beyond that period, and other important details. The Office is working on something like that and urged the participants to send her their own versions.

Mark said that her office is looking into reimbursement and access issues. So far Medi-cal has among the best access to PrEP in California

as a system, but she realizes that there have been challenges here and there. The office is looking to put together information to cover that issue, will provide a workshop in the spring of 2015 about PrEP and is working on a PrEP website.

Sonali Kulkarni:

Kulkarni began her remarks by telling a representative story about the challenges involved with PrEP in some people at high risk for HIV infection. In her case, she spoke about a 22-year-old Latino male she had seen. Kulkarni diagnosed him with gonorrhea, but at an earlier time point he had been diagnosed with syphilis. He initially said he only had sex with omen, but ultimately admitted to sex with men and he had a very high risk for HIV.

Though he was a good candidate for PrEP, and though she carefully explained how it could help him, the young man declined to use it. This was a real case and she said she simply hit a brick wall. He just didn't want to talk about it. Kulkarni asked, "How do we culturally tailor PrEP for this kind of consumer?"

People are not coming in for PrEP, she said, but they are coming in for other things. Many do not disclose that they are MSM. She thinks we need a strategy not only for people who need it and want it, but also people who don't.

Next, Kulkarni talked about the challenges of provider training in Los Angeles County. It is a very large jurisdiction. With the current resource allocation, this doesn't allow for training and support of all PCPs. Given this; the health department will be operating from strategic measures. These build off of the knowledge that HIV disease is concentrated in certain communities and this provides geographic access points.

The county is relying on providers who are not funded by public health dollars. Rather, that money would be used to help cultivate centers of excellence, like the LA GLBT Center. That said, we also need to be sure that other clinics can do this as there are many who wouldn't want to come into the Center and there are other settings for high-risk individuals, she explained.

A fundamental question, said Kulkarni, is whether to drive demand or capacity. She recommended that we do both, but offer different combinations in different parts of the county. In some areas with lots of demand there should be a focus on capacity, but in other areas with both low capacity and demand, such as South LA, there should be a focus on increasing demand.

The county does have experience ramping up biomedical HIV prevention, said Kulkarni. For the last four or five years LA has had an nPEP program in place to provide it to anyone regardless of insurance at LA GLBT Center and the Oasis Clinic. This service has not been advertised, but there has been successful word of mouth dissemination.

Since the County was already funding this project, she said that many expected it to do something similar for PrEP. She said they would like to, but there are significant financial differences. For nPEP, the county only needs to cover 28 days of medication, rather than ongoing coverage, as is the case with PrEP. They are talking about leveraging other sources of funding, such as private medical insurance and Gilead's MAP. The question, she says, is what is the public health role for those who fall through the gaps, such as people who don't meet the criteria for the MAP or have a co-pay higher than what Gilead will cover. The county doesn't yet have these calculations, but wants to figure it out.

Even for nPEP, however, the county has had to be very creative and use sources outside of CDC and STD funding or funding from Ryan White, none of which cover nPEP. The department is having lots of conversations with community partners, such as STD clinics, health educa-

tion counselors, and providers. Kulkarni said that there is an LA county newsletter to all providers for prevention and they are writing a piece on PrEP.

Patrick Loose:

Loose began by commenting on the sweeping changes since the implementation of the ACA and San Diego county has felt this acutely in STD testing and treatment funding. The county is no longer the payer for primary care. Instead, funding was devoted to helping people transition to private insurance and expanded Medicaid.

There were also negative changes that were forced on the county. He said that it wasn't like the county had additional funding for other things now that they weren't paying for primary health care. Instead, they just lost funds and there was heavy pressure from a fiscally tight funding administration to constrain costs even though the health department was still responsible for the costs of covering health care for indigent patients who were not being covered by expansion of health care through the ACA. That said, the county does not provide direct health care. Instead, it contracts those services out to others.

Loose commented that San Diego is a "purple" area with both conservative and liberal values. The biggest question was how to package PrEP such that it would be palatable to both constituencies. The county felt that it was best to promote it as recommendations by the CDC or FDA. In San Diego, however, the LGBT community is strongly organized, he said, and this helps.

The health department is trying to figure out how to implement performance measures for PrEP provision to high-risk individuals. Questions, Loose said, were should they measure referrals, uptakes or some other metric? That will have to be negotiated with providers. The county is also trying to figure out how to ensure that individuals are referred as necessary.

Ultimately, he said, the county must be transparent with stakeholders and they need to have conversations with STD clinics about how to screen for risk and refer individuals for PrEP.

There is a certain frustration tolerance, he said, among those seeking PrEP. How much work are they willing to do to get it? There are obstacles to finding willing providers. Medi-cal is supposed to have the fewest roadblocks but Loose stated that he is aware of people encountering problems. Hopefully, he said, that will be temporary.

Of importance, he said, was to deal with problems of equity. It's important to not always focus on downstream problems, but to create structures now that prevent downstream problems later.

Nicholas Moss:

Moss opened by describing the county that he serves. Alameda County is mid-sized, and diverse, both racially and economically. It has 200 new cases of HIV diagnosed per year, mostly among MSM and disproportionally among African Americans. Roughly 5% to 10% are among women.

Alameda County's approach to PrEP is constrained by having a very small team and there are no funds for an STD clinic in the county. They have helped the CRUSH project and the East Bay AETC. Moss said that the department's ongoing role is to educate about PrEP and other STD prevention and control issues and to innovate and integrate, including PrEP education referrals and making providers aware of the intervention.

One potential improvement that he described as necessary is the incorporation of HIV partner and care linkage services into STD investigator work to increase access to people who might benefit from PrEP. The goal, he said, is to look at PrEP use in recently diagnosed individuals and to continue to identify the risk populations in order to continue to ensure broad access and to generate buy-in from stakeholders.

PREP POLICY: OTHER CONSIDERATIONS

- Policy is often mixed with finance. There are demands for regulation, sometimes with no money, creating tigers with no teeth. There is no larger body to compel social justice and health equity. We need to figure out how to make community health managers, etc., aid us, and not let Insurance companies dictate.
- What numbers of people will need to be on PrEP to significantly reduce HIV diagnoses? Set it as a goal. Example: The pressure put on New York Governor Cuomo to advocate for HIV+ reduction – can California do something similar – endorsement and commitment regarding PrEP from the state?
- There's the issue of data. We don't have enough data. We need more surveillance. Gilead just updated their numbers and presented them at the HIV conference in Glasgow. There were 3253 unique starts and 42% were women. This was nationwide in the United States But Gilead's data is not that great. Not all pharmacies were in the report and it doesn't capture Medicaid.

FINANCING PREP

PANELISTS:
***Courtney Mulhern-Pearson**, Director of State and Local Affairs, San Francisco AIDS Foundation*
***Anne Donnelly**, Director of Health Care Policy, Project Inform*
***David Kilburn**, Executive Director, AIDS Support Network*

MODERATOR:
***David Evans**, Director of Research Advocacy, Project Inform*

Paying for PrEP, regardless of who is paying, is a daunting challenge. Not only is Truvada very expensive (in excess of $1,000 per month at the pharmacy), but regular doctor visits and lab costs add additional expenses to the equation. Also, while PrEP is likely to be cost effective for a single individual, predicting cost effectiveness for a population at high risk of HIV infection has been challenging. It has also proved challenging to manage out-of-pocket costs for individuals, particularly those who have inferior private insurance or those whose incomes place them beyond the reach of medication assistance programs.

In order to realize the promise of PrEP, however, it will be necessary to tackle the issue of cost and financing head on and to be creative about solutions. As Pérez explained in his introduction, the public health care system will be unable to fully absorb the cost of PrEP, even if there are eventually long term savings.

Moreover, since models of the number needed to treat to reduce new HIV infections in a population are few and have had mixed methods and results, it is difficult to calculate true cost effectiveness. As well, existing cost effectiveness studies have typically utilized the lower bound of efficacy from clinical trials, as the assumption was that real world adherence and effectiveness would be at the low end of that seen in randomized clinical

trials with incentives to remain in care and programs to support adherence and behavior change.

It is possible, however, to make recommendations now in hopes of better information in the future. Action items to propel discussion and the finding of solutions follow.

PrEP Financing: Action Items

- Address drug and provider coverage gaps, particularly for a growing class of individuals who are underinsured. The gaps not only include high cost sharing for HIV medications, but limited access to skilled and willing providers. Also, many providers don't know how to bill properly and so erroneously conclude that they can't afford to offer PrEP to patients. These issues must be addressed.
- Look at coverage of non-drug and non-medical costs. These include the use of PrEP care and social services navigators, assessments of where PrEP users are in the continuum of HIV prevention care and advocacy to expand the generosity of Gilead's support programs. These issues must be addressed to ensure successful implementation of PrEP.
- Explore the possibility to institute and fund some form of PrEP assistance program similar to that in Illinois and New York.
- Convene a call with advocates and county officials in less populous counties to talk about PrEP implementation.
- Identify and secure funding for capacity building.
- Secure funding to offer PrEP to individuals who are undocumented.

PREP FINANCING NOTES

David Evans:

Evans provided a simple introduction for Courtney Mulhern-Pearson and David Kilburne, saying that they represented two very different approaches to PrEP. This is, quite overwhelmingly, a situation of vastly different resources. Mulhern oversees state and local advocacy for one of the nation's largest HIV organizations, the San Francisco AIDS Foundation, in one of the country's top HIV prevalence cities. San Francisco has relatively generous funding directly from the CDC and the city budget.

On the other end of the spectrum, Kilburne is the Executive Director of a HIV and Hepatitis C organization that tries to do HIV care and prevention in a county that receives just over $200,000 per year.

The organizers felt that it would be helpful to have such diverse perspectives represented, both for the purposes of the Think Tank discussions as well as for those who read the proceedings.

Courtney Mulhern-Pearson:

Mulhern began her talk by saying that she was not at the Think Tank to answer the unresolved questions regarding the financing of PrEP, but rather to spur conversation and dialogue about this issue among the highly qualified and diverse participants in the room.

She started by commenting that there continue to be significant coverage gaps and that she has had phone calls from a lot of people who want PrEP, but can't afford it. There are, she said a number of reasons why.

The first, obviously, is the cost of the drugs and how expensive they are. As Mark said earlier, Medi-Cal probably has the best coverage, and Mulhern half-joked that she would love to have everyone who needs PrEP on Medi-Cal. People in private insurance, including those with employer

plans or plans purchased through Covered California, can have significant issues with prior authorization and costs. They often have high drug and medical deductibles and high up-front costs to spend down those deductibles.

Mulhern recounted that Grant had send her a patient who he wanted her help and who had a cost-sharing problem. In his plan, once he met the deductible, he still had a monthly co-pay of $493 per month. Even taking away the first $300 that Gilead covers with its own co-payment program it left the man with an unaffordable $200 per month on his own. That, said Mulhern, is just the drug cost issue.

There are other barriers, she said, with the costs that surround the medication. Lab costs are a barrier. She had a call from a man in Arizona on Medicare. His Part D drug plan covered TDF+FTC at a reasonable cost, but his lab costs were being denied and he is now faced with covering all of them on his own. It is possible, Mulhern said, that this may require only a policy review and may be a case of the policies not catching up with the guidelines, but it is still concerning.

She went on to explain that individuals with Bronze plans in the marketplace exchanges will still have medical deductibles to meet even once they have spent down their drug deductibles. If the person's provider is following the model used by Kaiser Permanente, this would mean lab costs and doctor visits each month for the first six months of PrEP care.

Mulhern next explained that Donnelly was ill and couldn't be present for the Think Tank, but did provide some remarks that she wanted Mulhern to share.

Donnelly wrote that when we think about PrEP coverage we should consider it as a whole. The drugs, labs, doctor visits and counseling are a critical part, but we should also view it within the continuum of HIV prevention and treatment and move beyond the silos of those two sometimes opposing systems to one of integration.

She then wrote that there need to be both short- and long-term strategies. The low hanging fruit, she commented, was the insured population who have good coverage, but she also explained that even those with private insurance need benefits counseling and probably navigation to better plans that fill in the gaps with existing coverage.

In the shorter-term, she wrote, we must think of PrEP as just one part, that while it requires us to emphasize risk to HIV-negative individuals we must also be looking to systems integration to gain efficiencies.

Longer-term strategies, she wrote, need to be considered as well, because she seem them as vital to determining what are viable long-term ways to cover PrEP and ensuring that those who need it can afford it.

Mulhern then expanded on this by saying that while most advocates were pleased to see Gilead's MAP and co-pay program expand coverage, there are still gaps to fill. We risk, she said, having situations where only those who are well off can access PrEP and that's not what we want.

She mentioned that there is a great need for broader education about the co-pay program to providers and patients so that all who qualify for it can take advantage of it. This means funding good navigators and assisters for both HIV-positive and HIV-negative individuals. We need people who can help people choose good plans for their needs. We also need to make sure that those navigators and assisters are aware of the broad range of programs and formulary issues.

On the longer-term agenda, Mulhern said, is the possibility of doing a statewide plan for California on HIV and that this should include PrEP. She mentioned that talks are happening now to bring that forward, but predicted that this would be an uphill battle.

Mulhern also reported that she and others are working with the policy research advisory committee of CHRP to estimate the needs and costs of an ADAP-like program for PrEP, or what some are referring to as a PrEP-DAP.

This is in the very early stages, she said, with researchers at UCSF looking at questions about the numbers of people who would need to be on PrEP to bend the curve in the epidemic and what the costs could look like. Washington State has such a program and estimates the cost of the drugs in one year is $8,000 per person. (New York announced its own hybrid model in January 2015).

Even if the state is willing to look at funding such a program, the overall cost could be impossibly high. Back of the envelope calculations, Mulhern said, is that up to 80,000 people would need to be treated with PrEP. The group hopes, she says, to have something soon to begin to educate legislators and to move forward more in the next budget cycle.

Mulhern then ended her remarks by introducing Kilburne and describing how he and his colleagues in San Luis Obispo County have the unenviable task of figuring out what to do about PrEP when they have no HIV prevention funding at all and no funding for HIV testing.

David Kilburne:

Kilburne opened by explaining that his organization has been around for nearly 30 years. The county had subcontracted HIV services to the organization, but after the state funding cuts in 2009, the county decided that it could no longer fiscally administer the grants and so his organization took them over. He also commented that there are lots of counties like his in California.

The organization is talking about how to roll out a PrEP program and people are very excited about this. There has been a marked uptick in new infections in 18 to 27 year old MSM in the county in recently years. The community wants PrEP, said Kilburne.

Currently there is only one half-time provider who treats 90 percent of the HIV-positive clients. They also treat transgender individuals in the county. The provider would like to offer PrEP as well, but this means longer wait times before appointments for the HIV-positive clients. Kilburne and his colleagues are advocating for another half-time provider.

To put this in perspective, he said, his organization serves 220 HIV-positive clients and 450 with hepatitis C with an SOA-funded budget of just $220,000 per year. They are doing this on a shoestring.

"I really see the importance of the smaller counties to integrate services, "Kilburne said. In his county the same people who enroll clients in Covered California also enroll for ADAP and help with other kinds of benefits counseling. "We just have to do things differently in a small community with limited resources," he added.

Kilburne said he was honored to be at the Think Tank with the vast resources of knowledge and experience among the participants and felt that there was much that could be learned from one another. He said that hopefully there will be more statewide meetings that will benefit rural communities. People often call them low incidence communities, he said, but he contradicted that by calling them low resourced, because without high rates of testing one can't know the true incidence.

Kilburne advocated for under-resourced communities to gather together, he said to share best practices and translate the research into the field. In San Luis Obispo, he commended, they have verified that they can get health care payers to cover PrEP, but lack the resources to educate providers and the community.

FINANCE DISCUSSION

COMMENT/QUESTION: Would the SOA be willing to pull together resource groups from underfunded counties in the state?

MARK: It's unclear who would be doing that. Would it be CHRP or someone else? I don' t know who would be in charge, but yes to participating.

COMMENT/QUESTION: Policy research centers are going to take a closer look at PrEP and cost. The older assessment estimated $500 mill to implement PrEP. Maybe 80% might get covered somehow. We need a better handle on cost.

RESPONSE: Perhaps we need creative thinking to take away structural costs. A Prius and not a Cadillac, a scaled down program. Explore ways to reduce cost.

COMMENT/QUESTION: We have an undocumented immigrant population, which are 10% of those at risk, especially a problem in counties that don't have access to medical care.

COMMENT/QUESTION: Someone on Medicare isn't always going to take lab tests. How important are lab tests? Can we take them away – how important is it for accessing PrEP?

COMMENT/QUESTION: Can we leverage funding from other programs: Packaging services at a PrEP visit? Or is that robbing Peter to pay Paul?

COMMENT/QUESTION: We may be looking at savings on Ryan White side: savings in delivery of healthcare and purchasing of drugs. It's an opportunity to revisit a broader HIV agenda. Can all these resources be re-envisioned to contain and control HIV? We have time to work with and our funding streams; less in care, more in prevention, with the dollars we have.

RESPONSE: California only has about 900-1,000 people enrolled in the Office of AIDS Health Insurance Premium Payment (OA-HIPP); yet we still have a great need of Ryan White dollars in HIV care. Lots of HIV care not covered by traditional insurance products.

COMMENT/QUESTION: How do we open up resources to be used in at-risk populations? We need to be rethinking domestic HIV resources, with PrEP as part of mix of eligible resources and equal access to PrEP. Department of Healthcare Services (DHCS) needs to be involved. We should maximize public and private plan resources.

RESPONSE: DHCS has been a good partner so far on PrEP.

COMMENT/QUESTION: Will we get more bang for our buck with easier and cheaper to treat people on PrEP versus waiting for them to become infected?

RESPONSE: It's hard to know to whom you make that argument. The system or company paying for PrEP is often not the system or company paying for HIV care later on. If the system were less broken, the argument would be more compelling. Now we are dealing with a more insured population.

COMMENT/QUESTION: What's the role of the Office of Patient Advocate?

RESPONSE: I don't know what we're trying to get them to do. Hopefully additional research will point out gaps.

COMMENT/QUESTION: Do people not know that their insurance is covering PrEP and HIV tests?

RESPONSE: No they don't. We've never had success doing routine HIV tests. There has been minimal uptake in providers offering it. A lot of it is having benefits counselors teach people how to choose and use their plans.

COMMENT/QUESTION: I hear two different themes. One says that we have finite resources,

so what are we going to give up? This contrasts with the other theme, which is to go after more resources.

RESPONSE: We need to pursue both of them. We need system fixes but we also have to deal with practical issues.

COMMENT/QUESTION: How do we deal with the insurance plan issue? How can we use advocacy to change things like a 20% or more cost-of-drug co-pay?

RESPONSE: Project Inform and others are trying to help with that. We need more advocates.

RESPONSE: The hope is that the insurance buyer's guide for plans in the state marketplace put out by Project Inform and several members of the HIV alliance members will make that more clear (the guide was published and may be found at *www.projectinform.org/coveredca*). People are going to Covered California counselors who don't have information on HIV/PrEP plans. There is advocacy around tiering issues in insurance as a whole, not just HIV.

COMMENT/QUESTION: We need a research model of Bronze plan coverage for PrEP to see how it would affect uptake, as a way to convince insurance plans to change and help to shift money toward prevention (e.g. require Covered California plans to offer TDF+FTC as a non-specialty medication for PrEP and HIV, so that people can afford insurance through a Bronze plan and get PrEP.

RESPONSE: That may be true, but equity issues still exist, especially among the privately insured and uninsured.

RESPONSE: Focusing on PrEP could have unintended consequences. We need to broaden coalitions, not make them smaller. With the ACA we're having more success than in the past.

PREP FINANCING: RECOMMENDATIONS:

- There are important challenges that must be overcome to increase financing gaps. These include: a lack of models of cost per patient per year and how many individuals might need this kind of assistance; lack of a clear vision for what this kind of program would look like (e.g. would it cover the cost of drugs and medical tests and services or only one or the other?); Lack of clarity on the ability and capacity of the SOA to work with advocates to make the case these kinds of funds in the state budget; and a historical lack of political support in the state to fund HIV prevention or other types of public health interventions.
- There is a need for a streamlined finance model for PrEP provision: What are the minimum obligatory laboratory tests? Explore the potential to leverage other funding (e.g. any potential savings from Ryan White in coming years.)
- There needs to be more leadership from the Department of Health Care Services, the Insurance Commission and payers of last resort.
- There is the need to develop a scalable model for PrEP provision. What are the immediate needs and possibilities? What would be needed in the medium term for expansion and with more funding, and what are long-term goals?
- There is a need to leverage more resources from health insurance companies and to reverse an overall trend to reduce services, restrict provider access and raise out-of-pocket costs.

Information about the conveners:

CHRP

Since its founding in 1983 by California State Legislature, the California HIV/AIDS Research Program (CHRP) has supported excellent, timely, and innovative research that is attentive to the needs of California, accelerating progress towards prevention, care and treatment for HIV/AIDS. During this time over $250M has been awarded for over 2,000 research projects.

CHRP provides start-up funds for the development of cutting edge research in California, providing critical leverage to bring in federal and private dollars to the state. A 2006 survey of California investigators found that more than five dollars in federal and other grant support was generated for every dollar invested by CHRP in California-based research.

PROJECT INFORM

Project Inform fights the HIV and hepatitis C epidemics by assuring the development of effective treatments and a cure; supporting individuals to make informed choices about their health; advocating for quality, affordable health care; and promoting medical strategies that prevent new infections.

UCLA CARE CENTER

The UCLA Center for Clinical AIDS Research and Education (CARE) provides state-of-the-art medical care and conducts clinical trials for people living with HIV and AIDS. Their highly trained, nationally recognized physicians are leaders in the field of HIV Medicine, Infectious Diseases, Oncology and other areas relevant to the health of our patients. The CARE Center's research team is committed to conducting a broad program of ethical and high quality clinical, behavioral and prevention research to promote the health of people living with or at risk for acquiring HIV and other infectious diseases.

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