

Vital Signs Town Hall Teleconference
Daily Pill Can Prevent HIV: Reaching People Who Could Benefit from PrEP
December 1, 2015
1:00 pm CT

Coordinator: Welcome and thank you for standing by. Your lines are in listen only mode until today's question and answer session. At that time, if you would like to queue up to ask a question, you may do so by pressing Star 1 on your phone.

Today's conference is being recorded, if you have any objection you may disconnect at this time. I would now like to turn the call over to Dr. Dan Baden. Sir you may begin.

Dan Baden: Thank you very much. Good afternoon everyone. I'm Dr. Dan Baden, the Senior Medical Adviser and CDC Office for State, Tribal, Local and Territorial support. I apologize for the delay getting going today. We had a lot of people who were stuck in queue and want to try and accommodate as many as possible.

I'm glad you could join us today. We'll be discussing the latest vital signs report about a daily pill that can prevent HIV. Before we get started, let's go over some housekeeping details. You can go online and download today's PowerPoint presentation so you can follow along with the presenters. The web address is www.cdc.gov/stltpublichealth, that's S-T-L-T, public health. Look on the far right side of the page for the vital signs teleconferences link or you can Google CDC vital signs town hall and click on the top link. That should get you there.

On the same web page, you can access bios for today's presenters and the audio recording and transcript should be there next week. There will time for

questions after today's presentations but you can get in queue at any time. Just press star 1 and say your name when prompted.

Back to our topic: Daily Pill Can Prevent HIV: Reaching People Who Could Benefit from PrEP. We're going to hear from three colleagues. First we'll hear from Dr. Dawn Smith, the Biomedical Intervention's Activity Lead in the Division of HIV of Aids Prevention at CDC's National Center for HIV, AIDS, Viral Hepatitis, STD and TB Prevention. She will talk about the findings in this month's vital signs report.

Then Dr. Howard Zucker will present. He's a Commissioner at the New York State Department of Health. He will discuss how New York State supported the use of prophylaxis against HIV and then hand the call over to Patrick Stonehouse, the Director of HIV prevention at the Chicago Department of Public Health. He will talk about Chicago's PrEP efforts.

Now, I'll turn the call over to Dr. Smith.

Dawn Smith: Good afternoon. Can you go to the second slide, please? PrEP is pre-exposure prophylaxis, which is a daily use of an anti-retroviral pill by people without infection, to help protect them against HIV infection, is one of several, highly effective prevention strategies that we have available to us.

One of the most potent is diagnosing who have HIV infection early and putting them on combination treatments to suppress virus and reduce their likelihood of transmitting HIV to others. Condom use has been a stalwart and for patients who can use condoms regularly, they are highly protective. For persons who injects drugs, reducing the sharing of injection equipment and implementation of drug treatment for these patients can significantly reduce the risk of HIV infection.

However there are many people who are still acquiring HIV infection and so there are two uses of antiretrovirals for negative people that have been shown to be highly effective at preventing their acquiring HIV. The first of those which we're discussing today is the daily use of antiretrovirals as pre-exposure prophylaxis. Clinical trials have shown that it reduces risk of acquiring HIV by more than 90% from sexual exposures and by more than 70% among injection drug users.

In addition, we have long used post-exposure prophylaxis, which is the use of antiretrovirals for a month following a significant exposure and at least in the case of healthcare workers, this was shown to be at least 80% effective.

Next slide. So as we were working to assist in the introduction of PrEP as a standard HIV prevention critical practice, the question kept coming up; so how many people are we trying to deliver PrEP to? And for that reason, we undertook the analysis that was reported in the vital signs to try to estimate the percentage in number of adults who have indications for PrEP in the United States.

These were based on the Public Health Service guidelines for the use of PrEP that were published in 2014. On the left, you can see for MSM, the set of criteria that we used - that we suggested in the guidelines that clinicians should use in trying to identify people who would benefit from PrEP.

On the right side of this slide, what we did was we looked for national representative databases in which we could assess the frequency of these different indications and on the right side, you can see what was available in the databases that either did or did not match the indication in the guidelines. For MSM, we were able to match the most important criteria.

Next slide. We did the same thing for heterosexually active adults, to try to estimate the number of men and women who had opposite sex partners, who had risk behaviors or partnerships that would indicate that PrEP might be of benefit to them. Next slide. And then for persons who inject drugs, we did the same thing. Focused on their injection behaviors.

So now I'm going to go through a little bit about how the analysis were actually done in a stepwise fashion. Next slide. So for MSM, we started with a National Health and Nutrition Examination Survey (NHANES) and we assessed the number of men in that survey who were ages 18 to 59, and the subset of those who had reported having sex with a man in the last 12 months. We then looked at their HIV status of those men and we selected those men who were HIV negative, had had a test and were negative in the previous 12 months. And further subsetted it those who reported sex with at least two men, in the last 12 months.

We then applied the behavioral criteria and the STD criteria that were available in this data set. So whether they had any condomless sex with another man, whether they had gonorrhea or chlamydia in the previous year. And of that group of men who met the behavioral and STD criteria, we then weighted them using NHANES recommended methods to yield a national estimate.

Next slide. For heterosexually active adults, we needed to use two databases. We used the NHANES database to identify men and women, aged 18 to 59, and removed through those who were - the men who were eligible as MSM. Again, we selected for those who were not known to be HIV positive. We then went to the National Survey of Family Growth sample, which included men and women ages 18 to 44 and we chose those who had sex with an

opposite sex partner in the last 12 months. Specifically those who had two or more opposite sex partners. And then we looked at the behavioral indicators in the guidelines.

So we selected those who had an HIV positive partner or who had condomless sex in the prior four weeks – that was the way the question was asked in the survey – and also, in addition to having condomless sex, they had sex with a person who injected drugs in the last 12 months or if they were women, they had condomless sex in the last four weeks and sex with a bisexual male.

We then applied those behavioral proportions to the population estimate from the NHANES data and again, weighted it to obtain a national estimate. Next slide. For injection drug users, we used a national survey - a household survey of drug use. They had participants who were at least 18 years of age and we selected those who were injected in the past 12 months using a needle that had first been used by someone else and again, weighted it to yield a national estimate.

Next slide. So these methods gave use estimated numbers of persons in each of these risk categories. So for MSM, age 18 to 59, we estimate 492,000 men who would have indications for PrEP. For persons who inject drugs, we estimated 115,000 and for heterosexually active adults, about 624,000. These together added to about 1.2 million.

But we then also wanted to look at of the men in the analysis who had sex with men age 18 to 59, what proportion had indications for PrEP. It was approximately 1 in 4, and for IDU, it was approximately 1 in 5 and for heterosexually active adults, it was approximately 1 in 200, who had indications for PrEP.

Next slide. So our conclusions were ones that consistent with the definitions in the guidelines. The proportion in number of HIV negative adults who were estimated to have indications for PrEP are as previously stated, with a total estimate of approximately 1.2 million adults in the United States with substantial risk for acquiring HIV infection.

Next slide. Reducing the number of new infections in the United States, which has been hovering around 40,000 per year -- diagnosed infections -- can be accelerated by increasing the number of persons who are diagnosed with HIV infection, receive treatment and achieve viral suppression but also including a higher number of persons at substantial risk for HIV infection who are offered and use PrEP. And a continuing and expanding the use of other prevention strategies including the use of clean needles, condoms, etcetera.

Next slide. So healthcare providers are being asked to test patients for HIV as a regular part of medical care, to discuss HIV risks and continued use of prevention methods including condom use with sexually active or drug injecting patients. And then when they identify patients for whom PrEP may be indicated, to perform the recommended test and prescribe PrEP to those patients consistent with the recommendations of the clinical practice guidelines.

For patients on PrEP, we want all clinicians to counsel patients on how to take it daily—PrEP did not work well when it wasn't taken regularly—and help patients apply for insurance or programs to help pay for PrEP. The guidelines call for scheduling appointments every three months to repeat HIV testing before giving prescription refills and to reassess adherence to medication and risk reduction practices.

Next slide. State and local health departments and community based organizations can help to raise awareness about PrEP use. Many of the people for whom PrEP is indicated have never heard of it. Also they can be helpful to train healthcare providers, we know that information about PrEP has been growing among healthcare providers but still a third of providers have never heard of it.

Develop policies and procedures at the health department level that will increase access to PrEP and monitor its use among those who are the highest risk for acquiring HIV infection. And last we asked health departments and CDOs to educate people about risky sexual and drug use behaviors and ways to reduce their risk, including PrEP, but not exclusively PrEP.

And for those who are interested in using PrEP, give them information about how to access it. Next slide. Thank you and I would now like to turn it over to Dr. Zucker.

Howard Zucker: Thank you. Thank you very much. Good afternoon, I'm Doctor Howard Zucker, I'm the Commissioner of Health for New York State and it's my pleasure to discuss the AIDS Institute's efforts to increase the use of Truvada as pre-exposure prophylaxis or PrEP in New York State.

The AIDS Institute is the section of New York State Department of Health that's concerned with HIV, AIDs, STDs, viral hepatitis and LGBT and drug user health. And I'll be sharing updated figures on the use of Truvada as PrEP among Medicaid recipients between 2012 and 2015.

Next slide please. Certain key events enable the state to emphasize the importance of PrEP. In 2009, the AIDS institute formed a work group to review established and potential biomedical HIV prevention strategies such as

PrEP and post-exposure prophylaxis or PeP. The institute posted their guidance in 2014 after the CDC issued guidance documents for the use of PrEP in at risk populations, as well as the FDA's approval of Truvada in 2012.

These events as well as studies show the efficacy of PrEP provide the impetus for the AIDS institute to develop its PrEP strategic plan. And in 2014, the institute posted its guidance for the use of PrEP to prevent transmission of HIV. That same year at the U.S. Public Health Service issued its clinical practice guidelines. And in June 2014, Governor Andrew Cuomo created a task force to develop and implement strategies to end AIDS as an epidemic in the state of New York.

Next slide please. The PrEP strategic plan is a dynamic document. It includes activities that may stand alone or be developed in response to elements that have already been implemented. As part of that, the department issued guidance to both clinicians and non-clinicians based on the science of PrEP.

But we still need to do some policy related groundwork. We've created a PrEP assistance program modeled after the AIDS drug assistance program which helps the uninsured and the under insured pay for the medical laboratory services associated with PrEP, though not the drug itself. In addition, the AIDS institute worked with our Medicaid program to secure coverage of PrEP and PrEP related services.

On the next slide, you'll see that we also need the support of our stakeholders to help promote PrEP. We need to build an infrastructure that enhance the access and availability of PrEP, and we need increased access to PrEP and post-exposure prophylaxis—key components of the governor's ending the epidemic initiative.

Next slide. The AIDS Institute also took some other steps. For instance, we conducted pilot projects at several clinical sites, including local STD clinics, to better understand the context where PrEP was being offered, and based on our findings, we are issuing a 3 million dollar request for applications before the end of the year to implement lessons learned. For instance, these funds will enable us to support patient navigators to increase access to PrEP, and they will help us integrate PrEP and PrEP-related services within the general primary care. And these funds will help support these strategies through 2020.

Next slide. The state health department and the New York City Department of Health and Mental Hygiene continue to collaborate on many aspects of the strategic plan. Both agencies have posted PrEP and post-exposure prophylaxis-related information on their websites. The information includes directories of clinics as well as practices that are offering PrEP. And also the state health department AIDS Institute adapted a PrEP tool kit from the city health department for use in counties outside of New York City.

Slide 7, next slide. There are three major components to our initiative to end the AIDS as an epidemic in New York State. Enhance the access to an availability of PrEP to high risk populations is one of them. We also want to identify people with HIV who are undiagnosed and link them to healthcare. And we want to keep people with HIV in healthcare and treat them with anti-HIV therapy to maximize viral suppression. The information about the initiative can be obtained through the links that are shown here on the slide.

Next slide. As you can see, there has been a substantial increase in the number of Medicaid recipients filling prescriptions for Truvada as PrEP. The number of prescriptions rose from 259 in 2013 to 1330 by June 2015. And more recent data show that additional 357 recipients billing at least one prescription for PrEP between July 1 and September 30th, 2015.

Next slide. Between July 2012 and September 2015, our analysis shows that 2065 Medicaid recipients billed at least one prescription for PrEP, and most were enrolled in the Medicaid managed tier plan. Most are men residing in New York City under the age of 50—you'll see it on the slide there with the demographic data—and most, as far as we can tell, were white.

Next slide. Similar analysis shows that 3,026 recipients have filled prescriptions for post-exposure prophylaxis or PrEP during that same time period. Most fit the same profile as PrEP. But unlike PrEP, most people filling prescriptions for post-exposure prophylaxis are female and again, you'll see that on that slide.

Next slide. No doubt the use of PrEP is on the rise. Among Medicaid recipients its uses has gone up more than fivefold since 2012. This demonstrates that efforts to increase access in usage by both the state and city health departments are working and together we are building both patient and provider awareness and working towards a shared goal in ending the epidemic.

Next slide. I'd like to thank the CDC for the opportunity to participate today. I'd like to thank the audience. We will glad to answer questions after the next presentation. And now I'd like to turn it over to Patrick Stonehouse from the Chicago Department of Public Health. Thank you.

Patrick Stonehouse: Thank you very much. We'll be starting on in the official slide there, slide 30. So again, my name is Patrick Stonehouse I'm the Director HIV prevention for the Chicago Department of Public Health. Moving on to the next slide of the overview. We'll just do a quick look at prevalence in Chicago, and then

we'll go on to what we've been doing and what we're about to do related to PrEP and trying to support PrEP efforts.

Next slide please. So you can see from slide 32, this is just a snapshot of the people living with HIV in the city of Chicago as of 2013. By select characteristics you see that our epidemic is overwhelmingly male, is by and large within the 30s to 59 range, African American disproportionately impacted and the majority of our individuals are identified as being men who have sex with men.

Next slide please. And you will be looking at our continuum as we look at it. We feel like we have done a fairly significant job of identifying individuals who are living with HIV but we also recognize that we do need to expand our efforts on linking individuals into care and retaining individuals into care. In particular, we are seeing disproportionate rates of people falling out of care, especially amongst African American and Latino population.

And while we acknowledge that there's a significant amount of work that we can do on this side of the continuum, the opportunity that PrEP presents to us of creating a continuum related to individuals who are engaging in behaviors that puts them at increase vulnerability for acquiring HIV. It's something that we really want to be supportive of in pushing awareness of, not just PrEP, but PrEP as a portion of the array of services that are involved in primary prevention for these populations.

Next slide please. So we have included—a couple of years ago, we started including—questions related to PrEP in our National HIV Behavioral Surveillance. And what you see in this slide is progression from 2011 to 2014 amongst different populations. This is amongst men who have sex with men in particular. And seeing the stark increase amongst each of the different

populations for the number who have heard of PrEP, have taken PrEP, and are willing to take PrEP with some very specific exceptions that we see that the sheer number of individuals—African American—has decreased between 2011 and 2014. But the percentage of individuals who were asked these questions has increased.

And also seeing that we are now having more people who are taking PrEP and a significant increase in the number of people who are interested in taking PrEP. Furthermore, we found that through—beyond that, in more detail looking at the NHBS, we found that the number of people who are aware, interested in and have taken PrEP was decidedly more erring on the side of a younger population as well Caucasian population.

And this is not terribly uncommon, we understand. But what we're seeing -- and we're saying that it's fairly common amongst our PrEP implementation practices as well. A lot of the work that we're doing around PrEP is finding the convenience unfortunately of those individuals who have access to services and supports, who are aware of new technologies and new strategies, and who are accessing some semblance of healthcare.

So predominantly, we're seeing these informations and these strategies going out to individuals who are slightly more affluent, who are Caucasian generally, and we're seeing a lot of information being shared around the north side of the city which, while it does have a high prevalence in incidents rate, it also has a high amount of services that are in place.

The next slide, please. This should be slide 35. So talking about our community partnerships, the Chicago Department of Public Health has been investing in a number of different partnerships. Everything from our interactions with our community planning council—it's an integrated planning

council between prevention and Ryan White. Our interactions with them have been involved in both trying to integrate the different strategies and the different mindsets amongst the different elements of the continuum. By which I mean, there were a couple of individuals who became members of our planning council who were doing PrEP work, who we recommended: You might want to try instead of going to the primary prevention community that we have, looking at the linkage and retention to care communities or the access to anti-retroviral therapy and viral suppression communities because those strategies and those techniques that might be involved, and the structures that might be involved in successfully linking retaining people in care and getting them virally suppressed could be applied in the same sort of way to individuals who are HIV negative and interested in accessing pre-exposure prophylaxis.

We also recently did a day long summit with the Black Treatment Awareness Network of Chicago. It was under theme of Black Lives Matter and all about pre-exposure prophylaxis and community-based, African American-centered orientation to how can we increase awareness, increase access and increase uptake of PrEP? What are the other factors involved in preventing an individual from accessing PrEP or being aware of PrEP? And it was a very rich, very emotional as well as scientific discussion that happened over the course of the day. There was about 150 individuals in attendance on this particular day.

And it was the example of the community partnership was that in process of having these conversations, we were actively changing some of our policies and protocols that we're going to be putting into place in the funding opportunity that we're about to put out under CDC's PS1506. To be perfectly blunt with it, as people were talking, I was writing down notes in the draft of the RFP. That that level of community participation, to really get at the hub of

what the people are seeing on the ground level on how we can then implement that into our funding opportunities to support the affective efforts they have shown.

We have community partnerships with our west side and south side HIV resource providers. This is basically about gathering information related to what they're seeing on their specific regions of the city. Interestingly enough, we recently had a meningitis outbreak in the city of Chicago. And one of the many lessons that was gathered out of our response to that meningitis outbreak was the importance of language when interacting with marginalized populations.

So the meningitis outbreak was predominantly among African American men who have sex with men, some of whom were HIV positive, most of whom were HIV positive. And the manner in which we got word out to these different populations about what was going on and how the outbreak was spread, it really taught us a lot in terms of layering of information. In that, one of the more effective ways that we can be involved in any of this is to have sort of high level information about transmission and risk factors coming from the health department and sort of, more subtle information sharing through our community partnerships that have more of a peer-related, or peer-based communication of risks.

We are also actively involved in the Chicago PrEP working group, which is a city wide effort made up of service providers, medical providers, community based organizations, activists, and interested parties. And our role in that is just sort of, to balance ourselves in our complete efforts to make sure that the efforts of the working group and the efforts of the health department are complimentary as opposed to being duplicative. And then lastly we share just a ton of information, back and forth, with our delegate agencies—meaning the

agencies that we fund for prevention—about PrEP and about referral strategies and about what they're hearing back from the communities and how we can best integrate PrEP into our full array of prevention efforts.

Moving on to the next slide. This will be a pretty simple, I guess the barriers that we're experiencing or that we're seeing, I don't think it's going to be any surprise to people that the level of individual barriers—everything from stigma to cost access and concerns about how to interact with a provider. But some of the more, sort of, nuanced ones are things that I've heard directly from individuals, which are things like, “If I have to go to a provider every three months, if I have to take a pill, why don't I just go ahead and get HIV and then I can get the supports that come along with the Ryan White plan.”

Those kinds of concerns are the product of a resignation of a number of members of highly impacted communities feel, that it might actually be an easier thing for me to do if I just accepted it and acquired HIV, gotten the care and I wouldn't have to worry about any of this stuff. Amongst community based organizations, it's largely a question of their capacity to successfully link people to medical providers who are willing to prescribe PrEP, which is in turn a question of the capacity, like how many medical providers we have in the city of Chicago who are able to provide PrEP or who are doing it.

There is some kind of conflict between purely community-based as opposed to a hybrid medical community-based organizations. That there is somewhat of a adversity to going too far in the medical route and leaving behind the community or the individual behavioral concern. And as well as community partners of ours stating that, you know, PrEP is fine but it doesn't actually address the underlying concerns and problems, such as: unemployment rates, mental health and substance use and the lack of treatment, unstable housing, racism, stigma, homophobia, and the like.

Moving on to the next slide please. So we have two marketing campaigns going on - or one that's about to start that's a product of the Chicago PrEP working group—again, that we've been actively involved in—and this is a very sexy, very sensual, human-oriented, awareness raising for individuals. And it's about to roll out. It's going to be flashy, it's going to be regular as well, by which I mean it's going to be normal people involved in, just sort of, raising awareness that PrEP can be something that can be used by any individual, provided that they have all the health needs.

The health department on the other hand is going to be issuing a marketing campaign that's more following a behavioral change process. So coming off of some of the ideas involved in community-level interventions, how are we going to be able to craft a marketing campaign messaging specifically to move the high-risk populations along the transtheoretical model towards being able to handle the change and being supportive of the change involved in accessing and then adhering to PrEP.

Going to the next slide. In 2015, January of 2015, the Chicago Department of Health funded three PrEP demonstration projects. These were intended to be—the idea behind it was that we were going to try and fund three PrEP hubs basically, within the city of Chicago. One on the north side, one on the south side, and one on the west side. They were going to be collaborations between non-clinical community partners and clinical partners, outreach and education to potential PrEP candidates, and conducting outreach education to PrEP providers.

We fund three agencies: University of Chicago, which was focusing on high risk African American population on the south side; The Core Foundation, which is operating on the near west side, out of an STI clinic that has later

become sort of a collaboration of a number of different clinics involved in the Cook County health and hospital services; and then Howard Brown Health Center on the north side, which was a collaboration between Howard Brown's existing PrEP program and another program from Chicago House, which was a PrEP recruitment and awareness process, with focusing on all range of at-risk individuals on the north side.

One of the initial things that we've found from this—and this goes towards our capacity and our need to build up more individuals involved or more providers—was that out of the seven full applicants that we received for the funding under the PrEP demonstration projects, four of the non-funded proposals, all but one of them were effectively proposing that they were going to be referring to either the University of Chicago, The Core Foundation or Howard Brown Health Center. So that's demonstrating the real need to increase the number of providers that are going to be providing PrEP.

In our STI Specialty Care Clinics—moving on to the next slide—in September of 2014, we implemented an Act of Referral program between our Lakeview Clinic and Howard Brown Health Center on the north side. Initial eligibility was for high risk men who have sex with men. It is since expanded to include all of our STI clinics and to include two more medical providers who are going to be providing after referral services around pre-exposure prophylaxis.

And moving on to our next slide, for the sake of time. So the Chicago Department of Public Health looks successful in receiving funding from the CDC for PS15-1506. And we're in the process of finalizing an RFP to go out to our community partners that will issue a little over \$2.2 million towards expanding PrEP acts and some support to the city of Chicago.

These are going to be community and medical partnerships, focusing on the south and west sides of the city, which are where we see under resourced communities, involving pure Navigator program, identifying health disparities that will also benefit from the increasing health access. A fourth generation of HIV testing, either rapid or lab based, and utilizing the social network strategy for both the initial testing of individuals and for recruiting more individuals into PrEP programs, as well as trainings for community partners and medical partners.

All of these were lessons that we've gathered from our demonstration projects -- from the three demonstration projects that were funded beginning in 2015. In addition, we're going to be increasing the supports out of our STI clinics by housing three support Navigators, one at each of our full time clinics will be able to provide support from our side of the active referral programs into different PrEP programs.

And that concludes the presentation, thank you.

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