HIV Testing for an AIDS-Free Generation Webinar/Conference Call
Tuesday, June 26, 2012 2:00 p.m. Eastern

Mr. Miguel Gomez: Hello everyone and welcome to today's "HIV Testing for an AIDS-Free Generation" webinar. I'm Miguel Gomez, the Director of AIDS.gov, and your facilitator for today's webinar. Today's session was planned to do three things: one, we want to provide you an overview on the state of HIV testing in the U.S. and globally. Two, we want to allow our stakeholders, federal staff and grantees to talk with federal leadership about HIV testing for an AIDS-free generation. And we want to identify resources for HIV testing.

Our lead speakers are going to be Dr. Jono Mermin from the CDC, Dr. Caroline Ryan from the Office of the Global AIDS Coordinator (PEPFAR), [and] Mr. Richard Klein from the FDA. Closing us out will be Dr. Grant Colfax who is the Director of the Office of National AIDS Policy at the White House.

Due to the high number of people who registered for today's webinar, some of you may only have phone access, but if you want, you can follow today's slides at http://aids.gov/news-and-events/webinar/. Later in today's call, we're going to be taking questions live and we already received some questions from Twitter. Today, we'll also have some additional federal staff to help answer questions -- from the VA, from HUD, from SAMHSA and HRSA. We have about approximately 1,500 registered sites around the US for today's call. This call is for AIDS service providers and our federal staff. All are welcome. If you're from the media and you have questions, please direct your questions to the HHS Press Office.

As you all know, tomorrow, June 27 will mark the 18th observance of National HIV Testing Day which was started by the National Association of

People with AIDS. The theme is “Take the Test. Take Control”. The CDC is the lead federal agency that guides federal support for National HIV Testing Day. I want to let folks who follow Twitter to know that later at 3:00 pm today there'll be a CDC Twitterchat called “Silence, Stigma and Shame”, so go to Twitter to follow that.

I also want to encourage everyone to view and share the new National HIV Testing Day video from AIDS.gov, which you can find on our web page about HIV testing resources.

As we step back, we know we've heard from our national leadership who have spoke to the issue of an AIDS-free generation -- from President Obama to Secretary Clinton to Secretary Sebelius. It's important that we all step back and look at where we are with HIV testing and where we're going, so we can move towards that AIDS-free generation and that conversation about HIV testing will continue in late July at the International AIDS Conference: AIDS 2012.

Well, let's get started. I'm going to introduce our first speaker and then each speaker is going to introduce the next. I really want to thank and welcome our colleague from the CDC, Dr. Jono Mermin. He is the Director of the Division of HIV/AIDS Prevention at the National Center of HIV/AIDS, Viral Hepatitis, STD and TB Prevention. Dr. Mermin, can you start us off?

Dr. Jonathan (Jono) Mermin: Yes, well, good afternoon, Miguel. It’s very appropriate on National HIV Testing Day that we have some of the distinguished speakers on the phone representing agencies that aren't just involved in testing but also treatment, care, diagnostics and pharmaceutical agents related to HIV because testing is the starting point for both prevention and care for people with HIV.

And really testing and diagnosis both are involved in prevention and care. On the first slide, you can see that we've just did some new analyses of national data which indicate that there are about 82% of the people living with HIV in the nation know that they have HIV -- they've been diagnosed. And about 18% of people don't yet know that they have HIV. Those 18% are associated with about 50% of sexual transmission because they both don't know that they have HIV - and when people with HIV find out that they have the infection, they reduce their risk behavior that could be associated with transmitting the virus to others. But also they get access to HIV-specific care and treatment and recent information indicates from randomized study that antiretroviral therapy reduces the risk of transmission by about 96%. So, good treatment is good prevention. And good behavioral prevention linked into the care setting can be very effective.

The next slide shows the continuum of HIV care and here you can see how testing really is the starting point of helping people with HIV live longer, healthier lives. We have about 1.1, or a little bit over 1.1, million people living with HIV in the nation. About again 82% of those folks know that they have HIV. But you can see, there's a drop-off as we go down the continuum of care. Only a proportion of those people have been linked to ongoing care services. A fairly large proportion of people with HIV who have seen a doctor about their HIV at one point end up falling out of care for a variety of reasons. Only a proportion of those who do stay in care are actually actively taking antiretroviral therapy. And then ultimately the single common goal related to treatment and prevention is for people with HIV to have a suppressed viral load, in other words, the amount of virus in their blood is at the lowest level possible. And in that whole continuum you can see only about 28% of people with HIV in the nation actually have a suppressed viral load, so we have a long way to go to improve on that number but we can see all the different places within this continuum where improved service efforts could also

improve both survival and prevention for people living with HIV in the nation.

The next slide shows that we're seeing remarkable improvement in some aspects of diagnosing people with HIV, but also we can see a lot of work in our future. If we look at the proportion of people who were diagnosed with HIV who either are diagnosed concurrently with AIDS or have an AIDS diagnosis within a year (in other words they've been diagnosed too late for treatment to be as fully effective as it could be when they start treatment earlier), you can see that that proportion is getting lower and lower. So in 1996, about 43% of people diagnosed with HIV were diagnosed with AIDS within the first year following their diagnosis and in 2009 that was down to 32%.

So, we're doing better, but we haven't achieved what ideally would be much lower proportion of people because ideally we would like everyone to be diagnosed very close to the time that they were infected. Part of this reason is that not everyone who is at risk for HIV or has HIV has been tested for HIV, so in 2009 only about 40% of all adults had ever been tested for HIV. But in addition, people at high-risk for HIV aren't being tested frequently enough and CDC recommends in our guidance for routine screening in clinical settings that everyone between the ages of 13 and 64 who are in a [inaudible] populations where the undiagnosed rate is about .1% or greater receives an HIV test at least once. And that people at increased risk such as MSM, people who have had STDs, people who have multiple sexual partners, they should be tested at least once a year, if not more frequently. And so, both getting more Americans tested and getting those people at higher risk tested more frequently are major goals for all of the different agencies within the Department of Health and Human Services.

In the last slide that I have, I wanted to highlight that there's been a great deal of progress regarding the ability of tests to actually diagnose HIV close to the time of infection. Can you switch the slide to the next slide please? Thanks.

So here you can see on the left at time zero is when we imagine people are infected and you can see in these different lines what's happening within people's bodies that can be - that can detect that infection. So the first is you have HIV, RNA or essentially virus reproducing in your body. That's the pink line and that really peaks at about 30 days following infection but can be detected with very sensitive tests within 10 days from infection, if not some time sooner. The next is what's called HIV p24 antigen. It's a test that looks at a part of HIV and then the yellow line is HIV antibody which is our body's response to getting infected with HIV. And if you can press the slide forward, we'll get something on …The first generation of test you can see started to be able to diagnose people about 60 days following infection. And that's why our initial recommendations were always that people should get another test if they've had recent sexual behavior, even if they have a negative test at that point because it might not have really produced enough antibody to be able to be detected.

If you can press again the next slide, you see the second generation testing improved on that. Next slide. Can you press the button again please? And so - exactly, so you'll see in the third generation test greatly improved the sensitivity of the test to diagnose people close to the time of infection. And now with the current fourth generation tests which are increasingly being recommended, we can actually diagnose people very close to the time that the virus is actually detectible in their body, generally within five days.

And that increasing sensitivity of tests means that we'll be able to diagnose people at the time when they are both most likely to be infectious and not give

people false negative results. So the technology of testing is improved, the frequency of testing is improving. More Americans are getting tested, but there's also a lot of work to be done. And I think National HIV Testing Day is an important time for us to reflect that even though we've had progress, it is important for - to achieve the goals of the National HIV/AIDS Strategy and ultimately to reverse the HIV epidemic -- that we focus on this very important nexus between prevention and care and that's HIV testing.

Miguel Gomez: Sir, thank you so very much. We're going to turn to Dr. Caroline Ryan who is the Director of Technical Leadership at the Office of the Global AIDS Coordinator at PEPFAR. She will talk about how HIV testing is part of the response to the global epidemic. Dr. Ryan.

Dr. Caroline Ryan: Thank you, Miguel, and thank you for the organizers for inviting me. I'm happy to have this opportunity to briefly discuss what PEPFAR's doing internationally in HIV testing and counseling programs. An estimated 33 million people worldwide are living with HIV/AIDS and yet it is estimated less than 20% of them know they're HIV-positive. Services to help individuals, couples and families learn their HIV status is a cornerstone to the provision of HIV prevention, treatment and care and is essential to achieving an HIV-free generation. Next slide, please.

The overarching goal of PEPFAR's HIV testing and counseling programs is to provide services for individuals, couples and partners and families to learn their HIV status, with particular emphasis on identifying HIV-infected individuals and HIV serodiscordant couples. The second goal is to implement strategies for ensuring that these individuals, couples and families are linked with the appropriate follow-up for HIV treatment, care and support or prevention services based on their HIV serostatus. Next slide.

We have two approaches to testing and counseling. The first is looking at who initiates the request, or provider-initiated counseling and testing, and that occurs through a healthcare provider as a standard component of medical care. The second is through client-initiated counseling and testing which occurs to actively seeking testing by a client in settings where these services are available. Next slide.

The second approach is looking at place. Testing and counseling is feasible and works in a wide variety of settings. In clinical settings such as ANC clinics, TB clinics and voluntary medical male circumcision settings or in non-clinical and community-based setting such as home-based testing and counseling via an index patient or a door-to-door, mobile or outreached or standalone voluntary counseling and testing sites. Next slide.

PEPFAR sponsors a wide range of activities, including support for testing and counseling sites, training, country and program assessment, test kit procurement, testing promotion, quality assurance, and monitoring and evaluation.

The following examples illustrate how PEPFAR works in partnership with countries to support HIV testing and counseling. In Kenya, mobile testing and counseling is being expanded throughout the country to the general population and youth, as well as to special populations, including nomads. In Uganda, community healthcare workers are being trained to visit the homes and offer home-based HIV testing and counseling services to household members. The program then links the HIV-positive family members to treatment and care programs and delivers prevention interventions to HIV-discordant couples. In India, PEPFAR supports outreach activities to encourage testing and counseling for key risk populations, such as sex workers, injecting drug users and men who have sex with men. And in Nigeria, testing and counseling in

ANC sites has rapidly been scaled up by trained nurses and lay workers who provide testing for family and patients in medical wards. Next slide, please.

As of December 11, 2011, PEPFAR has supported HIV counseling and testing for 149 million people. Testing in Kenya, Ethiopia and South Africa accounts for over 40% of this number. In 2011, over 40 million people were tested and received their results. Next slide.

Several challenges remain: strengthening linkages to other services, quality assurance and quality improvement, task shifting where lower cadre health personnel and lay personnel can administer rapid tests, and maintaining adequate supplies of test kits. Guaranteeing adequate supplies is not just a question of funds, but of adequate systems for forecasting and supply chain management. Thank you.

At this time, I would like to welcome our next speaker, Mr. Richard Klein. Mr. Klein is from the FDA where he directs the Patient Liaison Program, Office of Special Health Issues. He will talk about home testing and FDA approval.

Mr. Richard Klein:

Thank you, Dr. Ryan and good afternoon to everyone. I wanted to speak briefly about home testing for HIV. Until 1996, the only way to get tested for HIV in the United States was under a doctor's supervision. Right now, there's just one FDA-approved home collection test system. This test, sold as either the Home Access® HIV-1 Test System or the Home Access® Express HIV-1 Test System. It allows people to take a small blood sample at home, using a tiny finger stick and send it to a laboratory for testing. A positive test result is confirmed at the lab with a second Western blot confirmatory test using the same sample. This test is as reliable as going to a doctor or a clinic for an HIV

antibody test. It offers privacy and confidentiality for people who might feel uncomfortable going to a healthcare facility for testing. The test is anonymous. Results are obtained in about a week by telephone, along with counseling and medical referral if needed, using a code number that's provided with the kit. This kit costs about $45.

Quicker results are available using the Home Access® Express kit with a one day turnaround at the laboratory. This kit costs about $60 and it's exactly the same kit but it comes with an express mailing envelope and quicker processing. The test is available without a prescription, either through retail pharmacies or it can be purchased online through homeaccess.com.

Right now, FDA is considering a new over-the-counter rapid home test use kit that would give users the test result at home after about 20 minutes. The test uses an oral swab to take a sample of oral fluid which is tested with the included test kit.

Last month, FDA consulted with its Blood Products Advisory Committee (or BPAC) to address questions about the safety, efficacy and accuracy of the test. While this test kit also offers privacy and confidentiality of testing at home, a presumptive positive result means that a second confirmatory test should be done through a doctor's office or at a clinic.

Data that was presented at the Advisory Committee meeting suggested that the test may not be as sensitive as being tested at a clinic, but FDA determined through extensive risk benefit analysis based on computer modeling that the test can have a positive public health value since people who might not otherwise be tested may choose to use this test. Identifying people with infections will ultimately bring more people into treatment, help change

behavior and reduce the number of new infections. The test is still under review at FDA and a decision is pending.

These tests detect the presence of antibodies to HIV produced by the body. Exactly when and how those antibodies develop varies from one person to another. Some people might take up to three months to develop a detectible antibody so in any HIV testing, it's important to remember that there is a window period when a person might be infected, but might not yet have developed levels of antibodies that can be detected. So, please take into consideration that during the window period someone can test negative, yet still have an active infection and be able to pass along the virus to others. And now I'd like to turn it back to Miguel.

Mr. Miguel Gomez: Richard, thank you so much and all of our panel[ists] who have spoken so far. And as I mentioned, we'll have now in a moment time for questions and we'll take some questions. We'll share with you some questions we received from Twitter. We will close out with Dr. Grant Colfax, the Director of the Office of National AIDS Policy, who will also highlight the importance of testing and the National HIV/AIDS Strategy, but he'll also join some of our panelists and others to answer questions if he wishes. From the VA we have Dr. Maggie Czarnogorski; from HUD, Mr. David Vos; from HRSA, Dr. Deborah Parham Hopson; from SAMHSA, Dr. Linda Youngman.

So what I'd like to do is let folks know they can ask live questions and the operator will help you with those questions by hitting the # sign and “one”. We did get some questions already. So as people get ready in the queue to ask questions, I'd like Dr. Mermin to answer one of our questions which is “what can we do in our communities to encourage HIV testing when stigma continues to be such a dramatic issue?”. Sir.

Dr. Jonathan Mermin: Well, thank you Mr. Gomez, let me - one of the major ways we can reduce stigma about HIV testing is actually to normalize it, to make it something that's expected. When one goes to the doctor, there are guidelines that recommend cholesterol screening every three to five years. People expect that that's going to happen. The doctors or nurses will initiate cholesterol testing routinely and the same thing happens for things like looking for high blood pressure and checking, you know, your blood pressure when you go to the doctor. If HIV testing became as normal as a cholesterol screen, then people would start seeing it as a normal, healthy part of life to be tested for HIV and that's certainly one thing that's going to help. I think the continual improvement in the effectiveness of antiretroviral therapy has also helped de-stigmatize HIV. At this point, you know, someone who's diagnosed with HIV at the age of 30 is expected to live at least to the age of 70 which is really comparable to the age that someone who smokes would live to.

And I think we need to start seeing that as the treatment improves, perceiving HIV infection as essentially a mortal illness with - certainly without a cure is completely inappropriate and at this point it's become an infectious disease that has chronic disease manifestations that if people can access sustained, good quality care, they can live normal lives. And so that will also help. And then the third aspect is to mobilize our communities to respond to HIV and to fight back against discrimination and other aspects of society that increase stigma and really in many ways, that's best done at the community level.

Mr. Miguel Gomez: Thank you sir, and operator, do we have any questions in the queue?

Operator: Yes, our first question is from Maria. Your line is open.

Maria: Hi. My question was just a basic one. Is this webinar going to be available after today's presentation?

Mr. Miguel Gomez: Yes, just go to AIDS.gov and you will find information on this webinar and be able to view it and have a report on the webinar.

Maria: Great, thank you so much.

Mr. Miguel Gomez: No, thank you and remember hit “star one” on your phone if you have questions. Is there another question in the queue?

Operator: Yes, our next question is from Lawrence Lewis. Your line is open.

Mr. Miguel Gomez: Lawrence.

Lawrence Lewis: Thank you. I'm calling from St. Louis, Missouri and I have questions about the current OraQuick® and Clearview® test. When I saw the information about the first, second, third, fourth generation test, I couldn't help but think should we be changing our procedure and language around the follow-up test based off of what generation OraQuick® and Clearview® test, particularly in settings where we do rapid testing?

Mr. Miguel Gomez: I'm going to turn to Dr. Mermin.

Mr. Jonathan Mermin: Well, also, Dr. Klein may have other thoughts from the FDA perspective. If I'm understanding correctly, you're saying that some of the rapid tests and other tests are diagnosing people accurately enough that you're wondering whether the terminology that we historically use of confirmatory tests is appropriate?

Lawrence Lewis: That's a great question. That's not the one I was asking.

Dr. Jonathan Mermin: Okay, so what were you asking? I'm sorry if you could repeat it.

Lawrence Lewis: The one I was asking at this time is: if a person has high risk behavior a week ago from today and they come in for a test, we have historically told them to come back in three months. Should we now be telling them to come back within two weeks due to the increased sensitivity of the later generation test?

Dr. Jonathan Mermin: I see. Thank you very much for the question. I think it does vary on the test itself because some of the rapid tests are - really act like second generation tests and so it actually is several weeks before they - the estimated time that they would detect a new infection compared to some of the combined antibody/antigen tests that are the third and fourth generation as you can see on the previous slide. So to some extent you don't want to have a different recommendation based on the test because some people may not know exactly what kind of test was used. But given that, even the older tests are more sensitive than some people have thought and so I do think that having - giving people accurate information about how accurate the test is compared to their last exposure would be useful.

Lawrence Lewis: So do we change our language - our counseling to the client about when they should come back? Do we continue the three month statement or do we reduce that timeframe?

Dr. Jonathan Mermin: I'm not sure what the recommendations are for most counselors right now. Three months is a useful conservative estimate, but in the long-run I think, you know, we can reconsider certainly at the counseling level about - especially if one knows which test one is using, how long one is recommending for people to come back. I agree that, you know, most people's exposure to risky situations has been over time. It's not necessarily been the most recent events. But some people get very concerned about a specific event

and in those circumstances, they want to be sure that that's been covered by the test itself.

Mr. Miguel Gomez: Thank you for your question and we'll make sure that our report on the call also addresses this issue. Thank you from St. Louis so much. Is there another question in the queue?

Operator: Yes, our next question is from Helene Bednarsh. Your line is open.

Helene Bednarsh: Hi. With all the discussion in terms of being able to find and diagnose earlier, you've been talking about the test becoming normal, a routine part of standard of care. So what about alternative test sites such as dental facilities that are already doing medical screenings within the office? It could be glucose, high blood pressure. What are your recommendations for rapid testing in dental settings?

Mr. Miguel Gomez: Dr. Mermin, do you want to handle that, sir?

Dr. Jonathan Mermin: Sure I can, very briefly. Thanks for the question. We do recommend that, you know, that any place that can accurately provide HIV testing in a clinical setting should consider it. And so we actually have a variety of different efforts supported by CDC and local health departments and community organizations that actually do provide testing in a variety of settings. For example in pharmacies, in retail pharmacies, there's a new pilot project we have where HIV testing is being offered. And in dental clinics if that's something that can be done accurately, it's certainly a place where people would expect care to be provided. And if - and following the existing recommendations, it would be a perfectly appropriate situation to think about offering HIV testing.

Mr. Miguel Gomez: Thank you so much, sir. And from email and Twitter, actually for our VA, we hear from Nancy who is a mental health social worker who used to work at the VA and noted that there were different levels of awareness when it came to HIV testing, especially in inpatient settings. And she wanted to know what new was happening at the VA when it came to testing and education of your workforce. Doctor, could you answer that?

Dr. Maggie Czarnogorski: Oh sure, great question, thank you, Miguel. Some of you on the phone may be aware but in 2009, the VA aligned its HIV testing policies with the 2006 CDC recommendation. By that, we mean we eliminated the need for written informed consent and moved to a routine HIV testing policy where it's VA policy to offer HIV testing to all veterans, regardless of risk factors, age, gender, race, ethnicity, sexual orientation, during routine medical care.

Now we've promoted routine HIV testing in all medical settings throughout the VA system, so that includes in primary care, in women's health clinics, ERs, homeless programs and also in mental health, but that has required a significant culture change in VA. We do have numerous social marketing efforts out there targeted to both veterans and providers to help change the culture and educate all involved that routine HIV testing is a part of high quality medical care that VA should provide to veterans and that veterans should demand.

And we really have promoted routine HIV testing of all veterans. Now I just want to take this opportunity to say that in the two years since these policy changes have gone into effect, we've actually doubled the number of veterans with a documentation of an HIV test in their medical record. We have over 1.2 million veterans who have documentation of an HIV test and I think this is tremendous progress and I really applaud the efforts of all our providers in the field and also the veterans who have participated in routine HIV testing.

But we really still have a long ways to go. We have over six million veterans in care currently and this National HIV Testing Day we are promoting escalation of routine HIV testing. And for all of you on the phone who work at a VA facility or interact with a VA facility, we really encourage you to offer HIV testing. Get all your veterans tested for HIV. We have a long ways to go, we're making progress, but we really need your help to continue this effort.

Mr. Miguel Gomez: Doctor, thank you so much. I want to turn it back to see if there's additional questions in the queue by hitting “star one”. Are there any?

Operator: Our next question is from Fred Evans. Your line is open.

Fred Evans: Yes. I was wondering if you had any more information on the disparity factor for African Americans and if the rates are still exceeding what we thought they were years ago, and what's our plan for dealing specifically with that population?

Mr. Miguel Gomez: Sir, I'm going to turn it back to our lead speaker to address the issue of the impact of HIV and HIV testing in minority communities, in particular African Americans. Dr. Mermin.

Dr. Jonathan Mermin: Oh thanks, I'd like to speak briefly but then also turn over to Dr. Deborah Parham Hopson at HRSA to talk about some of their programs for African Americans who actually have HIV and how they ensure that they are accessing care. But from a surveillance standpoint, you're correct, sir, that African Americans are disproportionately affected by HIV in the United States. African Americans are about eight times more likely to have HIV than white Americans and that's a serious issue.

We at CDC have implemented a variety of different programs that try to reduce that inequity. Some of them for example are our Expanded Testing Initiative which has been a collaboration with state and local health departments and some community-based organizations over the past four years. When we look at the first three years of that program, we made 18,500 new diagnoses; 70% of them were among African Americans, the majority were linked to care. And actually that program itself was cost-savings for the nation that for every $1 put in, the healthcare system saved $2, so it's a good example of how you can both do good to fight inequity and also save money at the same time.

Mr. Miguel Gomez: And Dr. Mermin, I really thank you and I really appreciate actually asking our colleague at HRSA to help answer our question. And Dr. Parham Hopson when you - once you finish that, answer the first question, we've also gotten a second question for you about the status of their ADAP programs and ADAP waiting lists. As we encourage people to get tested, but we still have people on ADAP waiting lists, what are we doing to make sure we're taking care of everyone? Ma'am, if you could please start by addressing the health disparities question and then give folks a response to the ADAP question.

Dr. Deborah Parham Hopson: Sure, thank you Dr. Mermin and Mr. Gomez and thank you for the question. The Ryan White Program which is a program that i the largest federal program specifically dedicated to providing care and treatment for people who are living with HIV and AIDS. We provide funding to metropolitan areas, to states, to local community based organizations to provide life-saving medical care, medications and support services for over 1/2 million people each year. A large percentage of the people that we provide care and treatment for are people who are African Americans, so there are services available for people who are living with HIV in many communities around the country.

As I said, each state receives funding, many of the heavily impacted cities also receive funding and many community based organizations. So it's important, you heard people talking about HIV testing and certainly this is HIV Testing Day, for those who are HIV-positive, it is very important that once you do receive a HIV-positive test that you are linked very quickly to care. Because we know that if we can provide care and treatment for people who are living with HIV, we can help people to live long, healthy lives. So it's important that people do get tested and once you are tested, that you are linked to care.

I was also asked to address the question about the AIDS Drug Assistance Program which is one of the programs that we fund under the Ryan White HIV/AIDS Program. Yes there are some states that do have waiting lists, but the vast majority of states do have ADAP programs that are very well funded and they have no waiting lists. For those states - few states that do have a waiting list, it is a waiting list for the AIDS program. It is not a waiting list for medications. Everyone who is identified as living with HIV and is in care in a Ryan White Program, we work very hard to make sure that people do have access to the medications that they need. So if you are tested and linked to care, we make sure that you have the treatment that you need, including the medication so that we can keep you healthy for longer periods of time. Thank you.

Mr. Miguel Gomez: Thank you for dealing with both of those. Operator, do we have another question in the queue?

Operator: Yes. Our next question is from Heather. Your line is open.

Heather: Hi. My name is Heather, I'm a clinic nurse and I am working in Flagstaff, Arizona very much with the Navajo Nation and I know Native Americans

have a high precedence of HIV because of just lack of healthcare. My issue that I've been having is actually getting Native Americans to test because they have a belief that if they talk about it, they invite it in. And so I am trying to see if anybody has any recommendations of how I can approach that differently because I'm hitting walls still.

Mr. Miguel Gomez: I'll actually open that up for our panelists, but I'll also let you know that we're very excited about the programs offered by the Indian Health Service and their Director of HIV Programs, Ms. Lisa Neel and - who has funded some very innovative projects that we will share that information with you and others when we report out on this call. But would someone on the panel like to respond from our colleague from Arizona?

One of the things that I'd also like to share is that throughout our federal programs is that we have some innovative programs, both and experience serving all of the distinct communities that we need to reach and encourage HIV testing. And one of the things that I'll make a commitment to doing is making sure that in our report that we also provide links to those very, very important distinct and grounded programs because we know that if we don't test people now, we're not providing the gateway to HIV treatment.

And we really want to actually thank you for your work in Flagstaff and encourage you to continue the work and we will definitely follow you up directly after this call. I'd like to actually take our next question. Operator?

Operator: Yes. Our next question is from Paul Colbert. Your line is open.

Paul Colbert: Hi. I had a question for Dr. Klein. Can you provide or can you give us an idea of what the evidence is that people who don't now get tested for HIV will use a rapid home test kit?

Mr. Richard Klein: The evidence, it's. Well I think that a lot of people who don't get tested now don't get tested because of the potential stigma of going to a doctor's office or, you know, showing up at a clinic and saying well I want to be tested because then it sort of casts this sense that you're engaging in a risky behavior. So I believe that a lot of people who do not want to deal with that potential stigma would rather have a test at home. But I think a lot of people also look for the convenience and the ease and the privacy of using the test in their own home. Although I think, you know, there's not total anonymity because sooner or later, if you were to test positive, you would need to enter the medical system. But for people who believe they're at risk, it does offer a sense of anonymity, you know, if they end up with a negative HIV result then, you know, for the time being they re probably not HIV positive and wouldn't be entered into the system.

Mr. Miguel Gomez: Richard, thank you very much. And I'd actually - we're getting additional questions and again if you want to get in the queue, hit “star one”. We did get a question for HUD and just asking for an explanation of how your programs are integrating HIV testing at your facilities. And I thought it was quite interesting for Mr. David Vos, they also ask what is HUD - why does HUD support HIV Testing Day? So there's two questions there, sir.

Mr. David Vos: Great and thank you Miguel for asking me to participate today and thanks for the question. As Dr. Mermin said, the HIV continuum shows the breakdown and access to care and often it's this issue of unstable housing or homelessness that's the presenting reason why people fall out of care and don't make medical appointments or are unable to access care and the very first step is getting tested and empowering yourself to participate in care.

HUD is part of this effort because we're joining with our colleagues in the other federal programs to try to get a better result, not only to end homelessness but to end the other kind of care issues that are presenting to our populations. And we in our programs have show that stable housing is that base from which care can be achieved successfully. So testing is something that we'll be new to, we've done it at headquarters, we can do it at health fairs, at our public housing developments and we want to promote that more widely. We've done some pilots to show that, but really I think it's done in the community and we want to invigorate our community partnerships to make sure it's not just the people who work in one housing program talking to each other, but it's this colleagues from other parts of our delivery system, that the people involved in HIV services and prevention activities are also participants in those local discussions and can help make sure these actions happen locally. And again thank you for asking that question.

Mr. Miguel Gomez: David, thank you. I want to see if there's additional questions in the queue. Operator?

Operator: Yes, our next question is from Lisa. Your line is open.

Lisa: Hi. I'm calling from Philadelphia and I wanted to know if the HIV testing is covered by healthcare providers and also the home testing?

Mr. Miguel Gomez: I'm sorry, there was some interruption on the line, ma'am. Could you repeat the questions, I'm sorry.

Lisa: Yes, I was wondering if the HIV testing kit and just the tests are covered by healthcare providers?

Mr. Miguel Gomez: Oh, that Dr. Klein from the FDA was referring to. Richard?

Mr. Richard Klein: Well, I don't - I'm not aware of health - I think you mean health insurance right, not providers? And - or I'm not aware of any health insurance that covers the home test kit. But I know that most of the insurance services do cover in-clinic or, you know, a doctor-administered HIV test kit. And there are a lot of free testing services that are available through counties and state offices or AIDS service organizations.

Mr. Miguel Gomez: Operator, is there another question in the queue?

Operator: Yes, our next question is from Rob Newells. Your line is open.

Rob Newells: I'm calling from Oakland and I'm actually just curious about what folks' views are on the necessity for or the availability of post-test counseling for the people who elect to use one of the home tests?

Mr. Miguel Gomez: I'll ask both our CDC rep and our FDA representative on today's call to respond and if anyone else would like to respond, please join them - starting with the CDC.

Dr. Jonathan Mermin: So thanks, there's a long history of the time that people get tested as a time to talk about HIV and people's personal risks for acquiring HIV infection. So post-test counseling for people who want to learn more or ask, you know, about HIV itself even when they're negative is important. It's critically important for positives, so - because people who find out that they have HIV, especially in the context as you're discussing if they're diagnosed at home, really need to be linked into a healthcare system that can then provide ongoing care and prevention services. So any - the current FDA-approved home test does actually have that counseling system built in because to get your result, you have to send in your sample and to get the result, you know, you talk on

the phone with someone and that provides an opportunity to link people into ongoing services and to gather more information. I can turn to Dr. Klein to talk about how the new potential over-the-counter tests would also enable people to be able to access further information. But CDC does see access to post-test counseling as an important opportunity for HIV prevention and care.

Mr. Richard Klein: And FDA is kind of the same approach that counseling is an important part of testing and when the original test was approved, that was a very large stumbling block with how are you going to be able to provide post-test counseling to people who were going to be essentially anonymous and on the telephone. And - but over time I think that the whole counseling paradigm has evolved quite a bit and one of the requirements that FDA was concerned about in this home test kit was the ability to be able to provide counseling to people who might need it who take that test and get the result at home, so the manufacturer of that test has a call-in center that people can access to get counseling and medical referrals.

Mr. Miguel Gomez: Richard, thank you so much. And from an online question we got for SAMHSA: given the potential mental health needs of those who test HIV-positive, what is SAMHSA doing for its grantees and what services or resources do you have available? Could we ask Dr. Youngman to respond?

Dr. Linda Youngman: Sure I'd be happy to respond. SAMHSA is committed and dedicated to promoting wellness and reducing the impact of mental and substance use disorders on America's communities. So our grant programs and our technical assistance opportunities are focused on people who are most at need, including those who are most at risk for living with HIV/AIDS. We want to - we have a number of grant programs that help to provide them with access to receiving appropriate behavioral health services. And that's including, by the way, responding to one of the gentlemen's earlier question, many of them are

targeted toward minority communities and ethnic groups that are the highest risk for HIV. So even our education programs encourage increasing protective factors which are things like feeling a part of the community, having family, having friends, focusing on wellness and reducing risk factors and that's including things like having unprotected sex. And for those groups that are having unprotected sex and having high risk factors, we encourage HIV testing for those who are at higher risk.

Mr. Miguel Gomez: And I know that they can go to our web page and your web page to learn more about the specific resources that are available from SAMHSA, which are really important.

Given time, I really want to turn to Dr. Grant Colfax from the White House and the Director of the National Office of HIV/AIDS Policy, who we're very pleased to have in his position for the last few months. Sir, I know you have some closing remarks and some comments to make and we really appreciate that you're also just going to share why National HIV Testing Day is important to you and your Office, so what I'd like to do is turn it over to you.

Dr. Grant Colfax: Great, well, thank you so much Miguel and really have enjoyed the conversation today and appreciate all the great questions that we've been getting today in terms of how do we advance HIV testing and really work on this critical health intervention to both prevent HIV and to prevent - and to help improve outcomes for Americans living with HIV and just to stress the importance of National HIV Testing Day.

It's really a part parcel of our work as a nation to address HIV. As people know and as has been mentioned on this call, we continue to have nearly 50,000 new HIV infections every year in the United States alone. And unfortunately about 1/5 of people living with HIV in this country are unaware

of their infection and we know that testing has come so far in the last 30 years in the epidemic. In the early days it was challenging to get tests, it was oftentimes hard to find a test site, the testing process was quite complicated and people had to wait a long time for their results which created quite a bit of concern and anxiety both for preventing people from getting tested at all and then during the testing process it could be quite cumbersome. We've really come a long time and I think that the take home message now is that testing is easier and more efficient than ever before. It's an experience that is relatively easy to get through, it's a routine part of medical care and really certainly there's ongoing stigma and discrimination with regard to HIV, but really making this as routine as possible. And taking the fear out of HIV testing is a critical piece and I really want to applaud everybody's effort in moving forward with making HIV testing a routine part of care so that all Americans have the opportunity to get tested.

Testing is certainly part of the Administration's National HIV/AIDS Strategy which has three primary goals: one is to reduce new HIV infections. And we know that by getting tested and diagnosed, people reduce their risk behavior and they also are much more likely and it's a necessary step to get engaged into medical care --which is the second goal of the National Strategy is to improve outcomes for people living with HIV to link them to medical care, get them the life-extending treatment that we know is so important. And obviously testing is part and parcel of that.

And then the third main goal of the Strategy is to reduce HIV-related health disparities and we know that unfortunately HIV continues to concentrate in certain communities in the United States, particularly among gay men and among people of color. And among people of color particularly black, gay men and women of color, HIV infection rates continue to be high.

So one of the goals of the Strategy and one of the goals of the Administration is to increase testing rates, particularly in communities most highly impacted by HIV. So the more discussions we have about testing, the more we can think about the different options for testing, making testing available in medical centers, making testing available in community-based organizations, continuing to think about how do we increase the flexibility of testing in terms of options with or without counseling. Options in substance abuse treatment centers, options at home really is an exciting conversation to have as we move forward so that everybody again - all Americans have an opportunity to get tested. It's simpler than ever, ask for the test, talk about the test and encourage your family members to get tested and really an exciting time to think about what we can do as a nation to really turn around the epidemic.

Mr. Miguel Gomez: Dr. Colfax, thank you so very much and I know that from a number questions that are actually still coming in from issues related to health disparities and some questions about AIDS 2012, I want everyone to know that they can continue to follow the conversation and we will continue to share information on where we are with our federal programs, policies, and resources as it relates to HIV testing. And I really want to thank all of our speakers today and I want to especially thank - because this year we included our global partners at State [Department] with the PEPFAR program. I want to thank Ms. Deborah LeBel who coordinated this call, for the thousands of people around the United States who are listening this afternoon. And I also just want to encourage folks as we move towards National Testing Day and every day, the federal government can link you to HIV resources through the HIV/AIDS Prevention and Service Locator which you can find on AIDS.gov and follow what our federal programs are doing through the AIDS.gov newsfeed. It's really important that we share information about what is coming up from our colleagues and of course, working directly with each of our federal programs.

We will send you an evaluation form. Please fill it out. We want your feedback. We want to continue to improve, to serve you better, to communicate better. And look to us on AIDS.gov in about a week for a podcast and a transcript on this call and some additional information based on things that were brought up on today's call.

We are at the end of our call, but I just wanted to see if as I'm about to close, if any of our panelists have any closing comments that they would like to make. Hearing none, I very much would like to close the call and thank everyone for their time and energy this afternoon as we continue to support National HIV Testing Day and help move towards an AIDS-free generation. Thanks everyone. Take care.

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