WEBINAR VIDEO TRANSCRIPT

Partnership for Care HIV TAC

Taking a History of Sexual Health: Opening the Door to HIV/STI Care and Prevention

9 September 2015

ADRIANNA SICARI: Hello. This is Adrianna Sicari from the National LGBT Health Education Center, a program of the Fenway Institute in Boston, Massachusetts. We're pleased to have you with us today for the webinar-- taking history of sexual health, opening the doors to effective HIV and STD prevention and treatment. The webinar will last 90 minutes. We encourage participants to interact with our present throughout the presentation using chat, hand-raising, and the polling questions. Additionally, we'll have time at the end of the session for questions and answers. So that being said, I'd like to turn the mic over to Ruthie Browning at the HIV TAC to get today's webinar started.

RUTHIE BROWNING: Again, welcome to today's webinar hosted by LGBT Health Education Center in collaboration with the Partnerships for Care HIV TAC team. My name is Ruthie Browning and I'm a part of the Partnership for Care project. The Partnership for Care project is a three-year multi-agency projects funded by the Secretary's Minority AIDS Initiative Fund and the Affordable Care Act. The goals of the project are to expand provision of HIV testing, prevention, care, and treatment in health centers serving communities highly-impacted by HIV, to build sustainable partnerships between health centers and their state department, and to improve health outcomes among people living with HIV, especially among racial ethnic minorities. The project is supported by the HIV Training , Technical Assistance, and Collaboration Center-- HIV TAC.

Today's webinar is led by Doctor Kevin Ard, who earned his M.D. from Washington University in Saint Louis and his MPH from Harvard School of Public Health. He completed the Doris and Howard Hiatt Residency in Global Health Equity and Internal Medicine at Brigham and Women's Hospital as well as the fellowship in infectious diseases at Brigham and Women's and Massachusetts General Hospital. Doctor Ard also served as the chief medical resident at Brigham and Women's Hospital. He is the recipient of the Edward H Kass award for clinical excellence from the Massachusetts Infectious Disease Society and the Soma Weiss award for excellence in teaching from Brigham and Women's Hospital. Currently he is a faculty member in the Division of Infectious Diseases at Massachusetts General Hospital and an Instructor in Medicine at Harvard Medical School.

Doctor Ard has written and lectured widely on LGBT health disparities, intimate partner violence in LGBT relationships, and HIV prevention. His current interests include LGBT health

education, the intersection of clinical medicine and public health, and the care of patients with HIV and Hepatitis C. We now turn the presentation over to Doctor Ard.

KEVIN L. ARD: I want to thank you very much for that kind introduction. And also I want to think Partnerships for Care for helping to sponsor this webinar today, which is focused on taking the history of sexual health while opening the door to HIV and STI care and prevention. I want to reiterate that please ask questions or make comments during the course of the presentation. Certainly don't save them all to the end. I will try to address issues as they come up rather than batching them for the end.

I don't have any financial relationships to disclose. The goals of our session today are first to describe how to take a sexual history that includes all sexual orientations and gender identities. And then once we've done that, in the second part of the session we'll talk about what we can do with the information we've gained from the sexual history. And we'll discuss recommended screening and prevention methods for HIV and STIs in MSM and transgender women. And we'll also discuss some fairly recent data that's come out that pertains to these issues.

When doing a webinar it can always be difficult to find out who's attending. And I have this audience response question for you to respond to. So I want you to go ahead and answer using your keyboard. If you're a nurse, a nurse practitioner, a PA, a physician, a social worker, a non-clinical staff member, or something else, please go ahead and answer this question. And then we'll look at the results together. All right.

So let's go ahead and post those results. But I hope there is a diversity of different people involved today. Actually I just got the results now-- so about 21% of you are nurses, 21% are social workers, 14% are non-clinical staff members, and 43% are something else. I'd be interested to know what that something else is, so please feel free to use the chat function or the Q&A function to identify what role you serve in health care settings.

As we're going on now we'll first talk about the sexual history. And I think if you have a desire for more information after the session today, please feel free to check out our website, which is shown here at the bottom of the slide. And we have several resources, one of which is shown here. It's a publication that highlights many of the different things I'm going to talk about in terms of the sexual risk assessment.

So in terms of approaching a sexual history for patients of different sexual orientations and gender identities, I think it's important to keep in mind that the core history for LGBT patients is the same as for all patients. But it's important to use inclusive and neutral language so that you don't shut the doors to communication right off the bat by making an assumption. So for instance, instead of asking a male patient about a girlfriend or a wife, ask him if he's in a relationship or if he has a partner so that you don't necessarily assume that he's in a heterosexual relationship when you're asking those questions.

And for all patients I think it's important to make it routine. It's important to make sure that people know why you're asking these questions. I often tell people I'm asking these questions so I can take the best care possible of you. It's important to make no assumptions, as we discussed. And then of course, assure them that all the information they're telling you is entirely confidential.

The CDC have developed a diagram that highlights the key components of a detailed sexual health assessment. Some people call this the five Ps-- partners, practices, past history of STDs, protection from STDs, and pregnancy plans. And we're going to talk about these in a bit more detail.

First in terms of partners-- it's important to find out if people are having sex with one or more people. And if they're having sex with one or more people, are they having sex with a man, a woman, or both men and women. It's also important to find out if any of their partners are known to have HIV infection, and if they are, if we know those partners are being treated for HIV. Because that certainly impacts their risk of HIV infection.

In terms of practices I ask people if they use drugs or alcohol in conjunction with sex, which can increase their risk of sexually transmitted infections. And I also ask what types of sex they engage in-- do they have oral sex, anal sex, vaginal sex, and so forth. Because that impacts both their risk of infection and also how you might screen them for sexually transmitted infections.

It's important to ask about a past history of sexually transmitted diseases. I'll often ask people if they've never had any illness spread by sex, and I might list a few common ones such as chlamydia, gonorrhea, or syphilis. With regard to HIV prevention, syphilis might be particularly important, because-- as we'll discuss a bit later-- syphilis is associated with a higher risk of subsequently developing HIV.

I ask people if they use condoms with sex, and if so do they use it all the time, just some of the time, only with certain partners and not others, or only with certain sexual acts and not with other sexual acts.

And then the CDC also recommends that you ask people about their pregnancy plans. Now if someone is only sexually active with members of the same sex, then the risk of pregnancy is low and you don't necessarily have to discuss contraception with them. But many patients, including LGBT patients, have future desires to have families. And they can do that in several different ways. So I think as part of the care of these patients it's important to ask what their wishes and goals are in terms of having a family.

Some people would add a sixth P, and that is for partner violence and for payment for sex. And here the questions would be, have you ever experienced physical or emotional violence with someone you were involved with. It's important to remember that intimate partner violence is at least as common in same sex relationships as in opposite sex relationships, and may actually be more common in the experience of many transgender individuals. And then payment for sex

or transactional sex is associated with an increased risk of sexually transmitted infections. And so knowing that might help you decide at what risk someone is in terms of contracting those infections.

Now I thought that perhaps people would be most unfamiliar with how to take a sexual history from transgender patients. And so I want to show you this video-- it's about six minutes long-- that features transgender patients at the Fenway discussing their experiences with providers in terms of having the providers ask about sexual history. And it talks about things that they found helpful or helpful.

[VIDEO PLAYBACK]

-I think to really make a patient comfortable and willing to share their sexual health history is to start off with no assumptions-- especially with trans patients, because there tends to be an assumption that if you transition to being a man it's because you're sexually attracted to women or vice versa. And so understanding the separation between the gender identity and the sexual attraction is really important from the get-go. And then also just showing no surprise-- I guess I'd say-- as you start and being willing to dive a little bit deeper and understanding the attractions and understanding that they change throughout the course of care as well.

-In general it bothers me when someone asks me what surgeries I've had, and if I've had "the surgeries," assuming that there's just a set of them. So going back to people having this linear trajectory of their trans experience I think it's upsetting and it's also disrespectful for someone to assume that they can access to that information without having it actually be relevant.

-I would want providers to ask questions about what kind of partners I'm having. Like am I having sex with males, females, other transgender people. What is involved in those? What kind of sex-- is a penis involved, is a vagina involved, is it fingers, is it oral. Because we all have different body parts and sometimes we want to use those body parts. And vice versa with the partners that we have. And they need to be honest, they need to be open to the possibility of us doing all different kinds of things. Because all those things have different impacts and influences on our sexual health.

-It's like a lot of conversation all just leads back to STDs, and HIV, and stuff like that. And being that trans is such a minority, it's like they feel is if to say every trans girl, every trans man, is going to be prone to some sort of sexually transmitted disease or whatever. And I like to be weaned away from it so that they know that not everybody is promiscuous. And a lot of girls aren't sexually active, a lot of trans men aren't sexually active like that. I just like for them to talk about my overall health, opposed to just the things that are placed upon the trans community.

-I would want my provider to know that I am poly-amorous. So I engage with multiple partners. But the way that I engage with each of those partners may be different. So understanding that

I'm attracted to people with different genders, and that doesn't necessarily inform the body that they have or the sex that we have. So really just understanding that I'm very queer and my sex is too, so not using terms like your boyfriend, your girlfriend, your wife, your husband-- because I don't have any of those, and I doubt I will. So recognizing that partners appear in different ways. And because a person is engaging in a lot of sex or has a lot of different partners does not mean that they aren't engaging in safer sex practices.

-I would want a provider to ask me how I identify my gender, how I identify my sexuality, how do I feel in my body, which is really important. Because a lot of times I feel very dysphoric, and doctors will go to grab me and I'm not a touchy-feely type of person. And so that feels invasive. So preparing me for whatever they need to do in order to figure out what's going on for me. I feel like especially because they're speeding through, there's not a lot of, how can we trust each other, get comfortable with each other. I mean being in a doctor's office to me is very-- I mean we're taking off clothes, and the doctor is not my partner. The doctor is not me, or my mother, or my parents. So it's a very vulnerable place to be. And so the relationship to me has to be affirming and understanding. And so if I'm going to disrobe in front of you, I don't want to get funny looks, I don't want to get any of your negativity towards me. Because this is a very, very vulnerable space. And so it's really important that you adjust your own self before working with me.

-One thing I would really like providers to ask me is my reproductive desires. And I don't think it necessarily comes up, because there tends to be an assumption that if you're trans you don't necessarily want to have kids. And I don't think that's true. Like I would love to have children, but it's never been asked. And especially just having the discussion prior to initiating any type of hormone use I think is really important. And just assessing what are your options prior to, what are your options later in life. I think that one was really important for me, and it wasn't discussed.

-Having a provider that is trauma-informed and also seeks consent throughout the process. That was very important to me. And so it was a lot of little things that made it a positive experience for me, of just constantly checking in. Because I hadn't had a pap in a while. So asking me, is this OK, this is what I'm going to do. So informing me of each step so that I wasn't surprised and making sure that I was comfortable throughout.

-What I'd really like providers to know about my sexual health needs is that I do want to discuss them, even if it may be somewhat uncomfortable for me to do so. There's a lot of history tied - in with being trans and with body discomfort. And even if I'm not very open about it, it's not because I don't want to discuss.

[END PLAYBACK]

KEVIN L. ARD: Great. So if you have any questions or comments about that video, please feel free to go ahead and post them now. I think that the things that I take away from that video are, first, it's important not to make any assumptions about the types of partners people have,

the types of sex they're engaged in, and even their reproductive desires-- as one of the individuals there mentioned. And I think it's important to go into this simply with an open mind and to learn from the patients so that you can best take care of them.

So now I want to review some algorithms for taking sexual histories. And I think ultimately these should not be necessary in clinical care. But it is helpful to think through them once to think about how these different scenarios may play out in the clinical setting. In order to take a sexual history, I think first you have to set the stage-- bring it up as part of the overall history, explain that you ask these questions of all patients and that they're important in order for you to take the best care possible of the patient. And of course, ensure confidentiality. You can begin with three screening questions. One is, have you been sexually active in the last year? Do you have sex with men, women, or both? And then, how many people have you had sex with in the past year? And it's not really important, I think, to come up with an exact quantification. I think what needs to be differentiated is no partners, a single monogamous partner, or more than one partner. And we'll talk about those different scenarios.

So if someone has multiple partners or a new partner, this is really the person that a lot of things we're going to discuss in the second half of the session applies to. So you would want to ask this person about protection against sexually transmitted infections, about the types of partners and the types of sex that they're engaged in, about substance use during sex and any history of STDs, and all the other things that are listed there in that blue square. I should also mention-- it's not part of the CDC diagram, but it's important to ask about sexual function and satisfaction. Many patients want to discuss those issues but may not bring them up if providers don't ask. And again, this is the patient for whom a lot of the things that we're going to discuss in terms of STD screening, and prevention, and care pertains to. And we'll talk about that more in a bit.

Another scenario is someone with a long-term monogamous partner. There you might ask about pregnancy plans and protection, trauma or violence, sexual function and satisfaction. I think it's also important to ask if that partner has been tested for HIV or is known to have HIV, because that might impact how you care for the patient.

And then finally for people who are not sexually active you can ask about past partners. It could be that someone has never been screened for STDs based on their prior exposures, and so screening might still be warranted for this patient. And then you can ask if there are any other questions or concerns.

So with that background I want to move on now to talking about the screening prevention and care of HIV and sexually transmitted infections. And we'll begin with a bit of epidemiology. MSM-- or men who have sex with men-- account for 2% of the male population, but an outsized share of syphilis infections and HIV. About 3/4 of primary and secondary syphilis diagnosed in the US is among MSM, which far outstrips their share of the US population. And then MSM also account for about 2/3 of new HIV infections every year. And there's one demographic group in which the incidence of HIV is going up-- in every other group it's staying the same or going

down-- and that population is young black MSM. And certainly I think that more prevention efforts need to be focused on that population in order to try to reduce that rising incidence.

In addition, there is some antibiotic-resistant gonorrhea among MSM as compared to men who have sex with women. Fortunately this is still fairly rare, but some small outbreaks have occurred. And then outbreaks of hepatitis C have also been reported in HIV-infected MSM. In general, we think of hepatitis C as primarily transmitted through blood exposure and especially through injection drug use. But there have been outbreaks among MSM-- again, those with HIV-- which have not been due to injection drug use but instead appear to be related to sex.

As I mentioned before, if you could only ask about one prior sexually transmitted infection, perhaps the most important in this context is syphilis. And that's because syphilis seems to predict a higher risk of subsequent HIV infection. This data comes from a study of MSM and transgender women. And you can see that among those who had no syphilis HIV incidence was lower compared to those who had a history of syphilis. We don't really know if this is biological, or behavioral, or both. But I think if any MSM or transgender woman is coming and is newly-diagnosed with syphilis or has a recent history of syphilis, I would think of that person as being at particularly high risk of HIV going forward. And you might want to, again, discuss prevention efforts fairly aggressively with that person.

MSM also face an increased risk of anal cancer, which in many ways is a sexually transmitted infection because it's associated with human papillomavirus, or HPV. In the general population, as you can see on the left-hand side of the slide, the incidence of anal cancer is very low, although it is increasing. If you look at HIV positive MSM over on the right-hand side of the slide the incidence of anal cancer is much higher. In the middle of the slide you see the incidence for HIV negative MSM, which is certainly higher than the general population but not as high as those who are HIV infected. And then I've also put up the incidence of cervical cancer in women, both before and after the advent of Pap smears. And I do that so that you can compare these different instances. Cervical cancer and anal cancer are thought to have the same biology. They're both HPV-associated and both associated with oncogenic types of HPV. And so many people use this as a rationale for the screening of MSM for anal cancer. That is controversial though, and we'll talk about that more in a few more slides.

The question is, most of these questions become very sensitive and can create discomfort for the patient and the provider-- would it be helpful to ask for permission before getting into details with a blanket question like are you aware of safer sexual practices in respect to your health and that of your partner or partners? Then build on that response. I think that that's perfectly fine. And you want patients to be comfortable and you also want to be comfortable yourself. One thing that I often tell patients is sexual health is a very important part of your overall health. And in order for me to best take care of you, I need to ask you some questions about your sexual health and your sexual practices. Is that OK with you? And then I give the patient that introduction and see how comfortable they feel. So I think that's a fine way to preface this. Very good point that someone raised.

We'll move on now and discuss screening for sexually transmitted infections. And I first have a audience polling question for you that you can go ahead and now answer on your screen. So the poll is open now. And I'm going to go ahead and read this question. The CDC recommends which tests for sexually active MSM? Is it A-- an HIV viral load, a treponemal antibody, which is a simplest test, or gonorrhea and chlamydia NAAT? And that stands for nucleic acid amplification test. Is it an HIV viral load, a herpes antibody, and a chlamydia and gonorrhea test? Is it an HIV antibody, a syphilis test, and then gonorrhea and chlamydia testing? Or finally an HIV antibody, a herpes antibody, and gonorrhea and chlamydia testing? So please go ahead and select a response. There are recommendations put out by the CDC on which of these should be used. And we'll now pull up the poll responses and see what you said.

As we're waiting for those to come up, I'll tell you that the correct answer is actually C. In general we don't use an HIV viral = for screening, which was part of the choices in A and B. And in general, herpes antibody screening is not useful as a general screen. If someone has lesions that are consistent with herpes then we can diagnose those usually in a different way. And 80% of you got the correct answer, so very good job with that.

And again, these are the tests. The HIV serology. I would also suggest a preference here, if you have the option, for the HIV antibody antigen test. That's a fourth-generation assay. And the reason for that is that this test includes testing for the p24 antigen, which allows you to diagnose earlier HIV infections and essentially shorten the window period. The syphilis serology as we discussed. And then the testing for chlamydia and gonorrhea.

Where you test for this depends on the person's sexual practices. You can test their urine, swabs can be sent from the rectum or the pharynx-- although you don't have to test the pharynx for Chlamydia trachomatis. The pharyngeal and rectal testing are not FDA approved, but labs can become certified in doing those tests. And they are recommended by the CDC. And then it's recommended that you test regardless of the history of condom use.

The CDC also says that you should test every three to six months in those at highest risk. Who is that? I think certainly people who use alcohol or drugs in conjunction with sex, people who have multiple sexual partners-- especially anonymous sexual partners-- and people who are engaged in commercial sex work would fall into that category. In my opinion, those who appear to be at lower risk based on their history could also be tested less often. For instance, someone in a long-term monogamous relationship may only need to be tested once and not necessarily thereafter, unless a concern arises.

So what about anal Pap smears? I mentioned that this is an area of controversy. And there is one body has put out a recommendation to do this for a subset of patients. And we'll talk about who that is. But there's otherwise no national recommendation to do this test. The potential pros of doing that are that anal cancer is HPV-associated and has the same biology as cervical cancer. Since Pap smears can help prevent cervical cancer, perhaps they would also help prevent anal cancer. As we discussed, rates of anal cancer are significantly increasing in MSM, especially those with HIV. And then it is recommended for all HIV infected MSM. And that

recommendation is put out by the HIV Medicine Association, which is part of the Infectious Disease Society of America. So that recommendation does currently exist.

The cons for doing anal Pap smears are that as of yet there is no randomized trial showing that they help. It's not that there has been negative data, it's just that we do not have the data from such trials yet. There is one trial that is currently underway, but the results may not be available for eight years or so. So again, we simply don't have good data yet to say that this can prevent cancer or save lives. And we also don't really know whom to screen or how often. For instance, should all MSM be screened, just those who have HIV, just those who've had genital warts or penile warts? We really don't know the answer to this question.

If you are going to do an anal Pap smear, this is how to do it. It's actually fairly easy to do. You can place the patient in the lateral recumbent position. You can insert a cotton swab five to six centimeters into the anus. I often wet the swab before you do the test. You apply lateral pressure and then rotate the swab around the anal canal as you withdraw it. And you can submit the specimen as you would a cervical Pap smear. It's processed the same way and you get back the same type of result-- no evidence of intraepithelial lesion or malignancy, low-grade squamous intraepithelial lesion, and so forth.

If there is an abnormal anal Pap smear, the typical next step is something called high resolution anoscopy, which is the analogous procedure to colposcopy in the anus. And that can be used to identify lesions that look abnormal, to biopsy them, and then also to treat them with photocoagulation or with cautery. If you do not have access to high resolution anoscopy or someone who does those procedures, then I would not do anal Pap smears. Because you really have no recourse for an abnormal result.

Let's move on now to talk about prevention in a patient with multiple sexual partners. And again, here we're focusing in particular on MSM, but also on transgender women. So here I have an audience polling question for you. MSM status is an indication for vaccination against which disease? For which disease is MSM status specifically mentioned? And I'll let you go ahead and answer this question. The possible answers are hepatitis A, influenza, pneumococcal conjugate-- or PCV-13-- and then the human papillomavirus vaccine. So please go ahead and select answer. We'll go ahead and then close the poll and see what you selected.

As we're writing for the results to come up, I'll tell you that the correct answer here is hepatitis A. Hepatitis A can be transmitted by oral-anal contact in MSM. And MSM are listed as a group that should receive that vaccination. Influenza is recommended for all individuals, so not specifically for MSM. Pneumococcal conjugate vaccine is also not specifically recommended for MSM. And it looks like about 60% of you chose human papillomavirus. And I think that you can have partial credit for that answer, because MSM are mentioned in the indications for that vaccine. But it should be given to all boys up to age 21, although MAM are listed as a reason to give it up to age 26. 30% of you chose hepatitis A for that question, 10% influenza, and then 60% human papillomavirus.

So the vaccines that are recommended for MSM are hepatitis A, hepatitis B-- which can be sexually spread-- the quadrivalent HPV vaccine, and then also now the 9-valent HPV vaccine. And again, in general it's recommended for boys up to age 21. But those who are immunocompromised or who are MSM can be vaccinated up until age 26. And then some jurisdictions recommend the meningococcal vaccine. That's because there have been some outbreaks of meningococcal disease in certain locations. New York City is an example. There there's been an outbreak of meningococcus among MSM-- especially HIV infected MSM-- and it's carried a high mortality rate. So there's no national recommendation for meningococcal vaccine, but again it is recommended in some places.

As we move on now to talk more about prevention, I want to share with you a case of a patient that I've cared for that highlights some of the issues that come up with prevention. So this is a 36-year-old man who presented to me to establish care. He was feeling well and really was coming for a routine checkup and preventive care. He was generally healthy. He had some high cholesterol and had previously had a shoulder surgery. He was a business executive. He didn't smoke. He occasionally drank alcohol, but not to excess. And he did not use any recreational drugs. And he was married to and sexually active with a man who had HIV. And they did not use condoms for sex and really never had. He recently had a negative HIV test when I saw him.

So as we're thinking about HIV prevention in this patient I have another audience polling question for you. And again, we can go ahead and open up the poll for you to answer this question. Which intervention most effectively prevents HIV transmission? Is it A-- condoms? Is it B-- treating HIV infected individuals with antiretroviral therapy? That's also called treatment as prevention, or TasP. Is it pre-exposure prophylaxis, or PrEP? Or D-- behavioral interventions? Which is most effective at preventing HIV? Again, go ahead and select your answer. And we'll close the poll and talk about the responses.

So the correct answer here is actually treating HIV infected individuals with antiretroviral therapy, or TasP. Appears to be the most effective way to prevent HIV transmission from a positive person to a negative person, although all the other things listed on this slide can be efficacious as well. Condoms are thought to be about 70% effective at preventing HIV transmission between MSM. For heterosexual sex that's thought to be about 80%, so slightly less effective. 42% of you selected condoms. I think the important thing about condoms is that very few people are able to use them consistently and correctly in every sexual encounter. Some studies of the natural history of condom use have found that perhaps one sixth of people could do so correctly over time. So I think that condoms are very important and we should emphasize their use and provide them free of charge if possible. But yet other HIV prevention modalities are also important. We'll talk a bit more about the data behind treating HIV infected individuals in order to reduce the transmission of HIV.

Pre-exposure prophylaxis was selected by 17% and can be highly effective. And then only 8% of you chose behavioral interventions. And in general, those are perhaps the least effective of the things listed here, although in many ways every HIV prevention intervention is behavioral because it requires taking a pill, or using a condom, or some other behavior.

So a few of the things on that slide fall into the category of antiretroviral-based HIV prevention. And I want to talk a bit more about those types of prevention. And again, these are treatment as prevention-- treating infected people to reduce their infectivity. PEP, which is post-exposure prophylaxis for HIV-- that's taking antiretrovirals after a high-risk exposure for a limited period of time. And then PrEP, or pre-exposure prophylaxis, which is taking antiretroviral on an ongoing daily basis in a high-risk person with ongoing exposure. Based on data that we have, this is how these various interventions stack up.

Treatment as prevention appears to be quite effective. Post-exposure prophylaxis is estimated to be about 81% effective, although that comes from a very old study that has not been repeated. In general it's not thought to be ethical to do a randomized controlled trial of post-exposure prophylaxis or PEP, so we may never have better data on this issue. Condoms, as I mentioned, are about 70% effective. And then in one key study of pre-exposure prophylaxis it reduced the risk of HIV by 44%. There have actually been subsequent studies that have shown higher efficacy, up to 86% or even higher. And so it's possible that this number is overall higher.

So the most effective intervention appears to be treatment and prevention, or treating infected people with HIV. This is one important reason that underscores how crucial it is to get HIV infected people diagnosed and linked-to and retained in HIV care, in addition to-- of course-- improving their own health. So how effective is TasP? Well some of you may know that back in 2008 the Swiss Public Health Service issued a statement, which has since become known as the Swiss Statement. And they said that people who are virologically suppressed are not sexually infectious. This was a very bold statement at the time. But subsequent data has been released that does lend some support to this statement.

One such study was HPTN 052. That was initially published back in 2011. That study followed several thousand serodiscordant couples in which one person had HIV and one did not. And it found that by treating the infected person immediately the risk of HIV transmission within the couple could be reduced by 96%. In the original paper there was actually only a single HIV transmission, and that occurred very soon after the infected partner had started therapy and before they were thought to be virologically suppressed.

One criticism of this study in relationship to the case that I just presented is that almost all of the partners-- the couples in this study-- were heterosexual. So we don't have the same rigorous data for MSM. There is one ongoing study though, called Opposites Attract, that has followed 152 MSM couples. Again, these are serodiscordant, and the infected person-- in most cases-- is under HIV treatment. And there have been zero transmissions, despite around 6,000 episodes of condom-less anal sex. So the bottom line is that treating HIV infected people dramatically reduces the risk of transmission to others, assuming that that treatment is effective. I should mention that when we look at these efficacy rates they only describe linked transmissions-- so from the HIV infected partner to the uninfected partner. In some cases the uninfected person has gotten HIV but it's been from a different person, not from the treated partner that they were within the study.

I think it's important that sexually active MSM should know when and how to access PEP, or post-exposure prophylaxis. And there are really two key scenarios in which this is warranted. One is unprotected sex with an HIV infected person, especially if the success of HIV treatment in that person is unknown. And then anal sex with an MSM with unknown HIV status. And that rationale is simply because the prevalence of HIV is relatively high among MSM. It's important that sexually active MSM know about PEP in advance, because it must be started within 72 hours of exposure to be effective, and some would say even within 36 hours-- the sooner the better. So if someone comes to clinic and reports high-risk exposure one week ago, there's probably very little that could be done to prevent HIV transmission from that exposure at that time. It usually consists of 28 days of antiretrovirals, often tenofovir-emtricitabine and raltegravir. And then again, as I mentioned, it likely reduces the risk of HIV by at least 81%.

I want to move on now to talk about PrEP, or pre-exposure prophylaxis, because this is really the new kid on the block. And I think it may become a very important part of the care for many sexually active MSM who are at risk of HIV infection. PrEP is indicated for people at high risk-- and we'll talk about who that is. There's only one medication that's FDA-approved for PrEP in the US, and that's tenofovir-emtricitabine-- the brand name is Truvada. There's currently no other medication that's approved for this purpose in the US, but there are some other medications under development. And then concerns that people have had center on adherence to the medication, implementation on a widespread scale, and cost.

So before we say more about PrEP, I want to have a sense from the audience about your responses to this question. If you're a prescriber, please answer yes if you've prescribed PrEP or no if you haven't. If you're not a prescriber please answer yes if you have been involved in the care of a patient who has been prescribed PrEP or if the site that you work at does offer PrEP. So we'll go ahead and give you a few seconds to answer that. And now go ahead and close the poll. And we'll see what you said.

Although PrEP was approved by the FDA back in 2012 it's gotten off to a sluggish start, I think, for several of the reasons that we'll talk about in a bit, especially centered on cost, and awareness, and willingness to take it and to prescribe it. And it looks like here about half have prescribed or participated in the care of a patient who is on PrEP and half have not. So some variability of experiences in the group here.

I want to review some of the data behind PrEP because I think it's very helpful for us to know this information as we're thinking about who it might be useful for and how useful it might be. One of the first studies that was published-- it's called iPrEx . It followed around 2,500 MSM and transgender women in six countries. It was a randomized placebo-controlled blinded study of oral tenofovir-emtricitabine versus a placebo. Adherence to the medication regimen was moderate in that study. And it reduced HIV acquisition by 44%.

There was also the Partners PrEP study of nearly 5,000 serodiscordant couples, predominantly heterosexual couples in Kenya and Uganda. They were randomized to oral tenofovir-emtricitabine, tenofovir by itself, or a placebo. And adherence was very good in that study. And

in that study PrEP reduced HIV acquisition by 67% to 75%. The 67% was for tenofovir alone, the 75% was for tenofovir-emtricitabine. And statistically those numbers were not different.

And then another study was called TDF2 Botswana. This was a study of over 1,000 heterosexual men and women in Botswana not recruited as part of couples-- like in the prior study-- but recruited individually. And their oral tenofovir-emtricitabine was associated with a 62% reduced risk of HIV infection.

You may have heard, and I think it's important to review, that there have been two randomized controlled trials that did not show a benefit to oral PrEP. These were both studies done in Africa focused on young women. One of them was FEM-PrEP . It followed around 2,000 women in sub-Saharan Africa and did not show a benefit to oral tenofovir-emtricitabine. And then the VOICE study, which in addition to oral PrEP also assessed vaginal PrEP. And in this large study of 5,000 young women, again there was no HIV risk reduction with PrEP.

So why is this the case? Well I think it boils down to adherence. And adherence is really the Achilles heel of PrEP, as it is also for HIV treatment and for many other HIV prevention interventions. So how do we know that adherence is so important for PrEP? Well, in the studies that have been done so far, in addition to the main comparison between those in the placebo group and the experimental group, investigators also measure drug levels in a subset of patients. And they can look to see how well those people who always have detectable drugs are protected against HIV. So here I'm showing you the overall HIV risk reduction in the iPrEx study and Partners PrEP. This is information I've already shown you.

But then if you look at people who had detectable drug levels where was a 92% risk reduction for HIV in iPrEx and also a fairly high risk reduction for HIV acquisition in Partners PrEP. And the important point here is that in the VOICE trial and in FEM-PrEP fewer than half of participants ever took PrEP. Adherence was very poor. And if you don't take the medication it can't work. And we think that's why those two trials failed. It's also possible that there are some biological differences. We know that tenofovir achieves maximal levels in rectal tissue in seven days and maximum levels in cervical/vaginal tissue in 20 days. So it could be that imperfect adherence is more forgiving for people who are having anal sex than for people who are having vaginal sex.

These trials also show that in general practice PrEP is safe. Nausea may occur, but it typically goes away within a few weeks of initiation of the drug. One concern with tenofovir is kidney injury-- we know from the treatment of people who have HIV that tenofovir can cause a decline in kidney function. And that occurs very rarely in these studies of PrEP so far. But in order to be in these studies people had to have normal kidney function and they also tended to be young and healthy. We know that tenofovir can cause a small decrease in bone mineral density of around 1% to 2%. That's of unknown clinical significance. There were not differences in these trials in fractures between the different arms. But again, these were young healthy people who may not show the side effect to a great degree.

And then there have been concerned about antiretroviral resistance with PrEP. And so far that's been very rare, mostly occurring in people with unidentified acute HIV upon PrEP initiation. And the reason that resistance develops is because tenofovir-emtricitabine is not a full treatment regimen for HIV-- it's 2/3 of a regiment. So if people actually had HIV they would not be adequately treated with PrEP.

Since those randomized controlled trials have been published there have been some demonstration projects and open-label study that have shown that actually PrEP can work fairly well in the real-world setting, or in settings that are more like the real world than randomized controlled trials. Probably the most important of these studies is called PROUD. It was a study of very high risk MSM and the United Kingdom. They either got immediate PrEP or they were put on a wait list for PrEP to begin in about 12 months. And in that cohort, PrEP reduced HIV acquisition by 86%. Adherence was very good.

There's been a demonstration project in the US of MSM and transgender women that has shown an HIV incidence of 0.43 per 100 person years. There's no control group at this point, because we know that PrEP can work. So a control group wouldn't be, I think, fully ethical. But this HIV incidence was less than what would be anticipated for this cohort. And the same is true in this open-label trial in Botswana. Of 229 men and women there were zero HIV infections in that cohort on PrEP when five to six would have been expected based on the baseline HIV transmission rate.

Some other lessons from open-label study are that fortunately concerns about risk compensation have not been borne out. What is risk compensation? That's the idea that people may feel protected by PrEP and thus may increase their sexual risk behavior, which may ultimately negate the benefits of PrEP. And this was one of the big concerns that people had about rolling out PrEP. Randomized controlled trials could really not answer this question, because people did not know if they were getting a sugar pill or an active drug. But in open-label studies risk compensation has not been a major problem-- PrEP has still been efficacious. And in general, the number of STDs has not risen, which is used as a marker of sexual risk behavior.

We also know from some open-label studies that there are early signals that MSM at higher risk are preferentially accessing and adhering to PrEP. And here are some examples of that. There was a study of PrEP in Brazil that found that those who reported multiple condom-less anal sex partners were more likely to be taking up PrEP. And then a study of young people in the US which found that those who reported condom-less sex had higher blood levels of one of the ingredients in PrEP, tenofovir.

So if your setting is thinking about rolling out PrEP, I think it's important to think about who might want this intervention, who is high risk. And the CDC has really described three major risk categories. One is men who have sex with men, especially those with an HIV-infected partner, recent STIs, multiple sexual partners, inconsistent condom use, or commercial sex work. Heterosexual women and men comprise another risk group. And many of the same features

that make MSM high risk would also make these individuals high risk. And then injection drug users-- I did not mention that PrEP has been shown to work in injection drug users. And so that may also be a population that could benefit from PrEP.

With a bit more focus on MSM, the CDC says that people may be considered high risk and thus candidates for PrEP if they're adults and are not known to have HIV, if they've had any male sex partners in the past six months and are not in a monogamous relationship with their recently-tested HIV-negative man. And if they've had any anal sex without condoms in the past six months, any bacterial sexually transmitted infection, or if they're in an ongoing relationship with HIV-positive partner, like the person in the case I shared a few slides back.

So I want to talk about how PrEP can be prescribed, because it's actually fairly straightforward. And I think it's important for people to know this so that it can be easier to implement PrEP in your setting if that's a goal for where you work. So I'm going to open this polling question now and have you go ahead and answer it. Which test must be sent before starting PrEP? Is it A-- an HIV antibody, a hep B antibody, and a urinalysis. B-- an HIV antibody, hep B surface antigen, and a serum creatinine. C-- an HIV RNA, hep B surface antibody and a urinalysis. Or D-- an HIV RNA, hep B surface antigen, and a serum creatinine. So go ahead and answer that question. And we've closed the poll.

As I'm waiting for the results to pop up I'll tell you that the correct answer here is B. You need to screen the patient for HIV using a standard screening test, which is an HIV antibody. You must send a hepatitis B surface antigen. And the reason is that that's a test for chronic hepatitis B. Both tenofovir and emtricitabine, the components of PrEP, treat hepatitis B. And so you need to know if you're also treating that infection at the same time. And then a serum creatinine is important in order to establish that their renal function is normal in the beginning.

It looks like 50% of you chose D, 33% chose C, and 17% chose B. I think that D is also a reasonable answer. The issue here is whether you should send an HIV RNA or an HIV antibody. Certainly if there is any concern or question about acute HIV infection I would send the HIV RNA. Because those acutely-infected people are the ones most likely to not be detected by an HIV antibody, and thus to be put on PrEP in error and develop antiretroviral resistance. So in some circumstances-- again, if there's any suspicion for acute HIV-- an HIV RNA is warranted. But otherwise the standard guidelines put out by the CDC indicate that you only need to do B.

And then actually prescribing PrEP is fairly straightforward. There are four main steps. First documenting an HIV-negative test, confirming that someone's kidney function is normal, assessing everyone for chronic hepatitis B, and then checking fertile women for pregnancy. PrEP is not contraindicated during pregnancy. But if a woman were pregnant, that might change your risk/benefit analysis and the discussion that you have with the patient. Very easy to prescribe this medication-- there's only one dose. The CDC recommends that you give 90 days or less so that patients come back for HIV testing. And then going forward they should have a creatinine checked after three months.

And then if it's stable after six months they need an HIV test every three months-- and a pregnant test every three months for women-- and then routine STI screening every six months, and of course ongoing counseling about risk reduction and condom use. It's very important to make the point to them that PrEP protects against HIV but not other sexually transmitted infections like gonorrhea, chlamydia, and syphilis, and so condoms are still very important for those reasons.

There are many lingering uncertainties about PrEP. One is the time taking PrEP until one is maximally protected against HIV. And to be conservative, I tell people who are MSM seven days, because that's the time that it achieves the maximal levels in rectal tissue. But to be honest, we do not know the answer to this question. We don't know about the efficacy of less-than-daily administration. There was one study which showed among high risk MSM that episodic PrEP time with sex could still be beneficial. The risk reduction for HIV in that scenario was 86%. But the people in that trial were having fairly frequent sex and so were taking a substantial number of doses of PrEP per week. We don't know if more intermittent PrEP would work.

We're also not certain of the benefits if one's HIV-infected partner is virologically suppressed on ART. . So for the patient in our case he has an HIV-infected partner, he falls into a category of someone who should be considered for PrEP according to the CDC. But if his partner is completely virologically suppressed on ART-- and I've discussed with you how good that can be at reducing the risk of HIV infection-- we don't know if PrEP really adds any benefit on top of that.

There are some barriers to PrEP that I want to mention. One is certainly cost. With no health insurance, the medication for PrEP would probably cost about $1,000 a month. That does not include doctor's visits or the testing that goes along with it. So the vast majority of people who do not have health insurance could not afford it without some sort of assistance. In my clinical experience commercial insurance has in general paid for it. And where I practice in Massachusetts, MassHealth-- which is our Medicaid program-- also pays for it. But that may not be the case throughout the country. I know that some providers in Mississippi have had luck what a patient assistance program that's created by the maker of PrEP.

Certainly one barrier to PrEP has been a lack of physician or provider awareness or comfort with prescribing the medication. In general HIV providers are often very experienced using tenofovir-emtricitabine. But they may not be seeing a lot of HIV-uninfected people. The people on the front lines of care, primary care providers, may be seeing more patients at risk but may not have the same comfort level with this medication. And I hope that I've increased your comfort level a bit during this session today. And you can certainly ask me questions if they arise.

ADRIANNA SICARI: Doctor Ard, we do have a question that has come in. It came in privately to me, so I wanted to read it aloud to you if that's OK.

KEVIN L. ARD: OK, yup, that'd be great.

ADRIANNA SICARI: So the question is how will PrEP affect someone on birth control.

KEVIN L. ARD: So that's a great question. And I don't think that we know at this time that there is any interaction between PrEP and hormonal birth control like the oral contraceptive pill. But very good question. Any other questions that have come through right now, Adrianna?

ADRIANNA SICARI: Nothing yet. But I'll keep an eye out. And I'll be sure to interrupt you if there is one.

KEVIN L. ARD: Great. One of the last barriers to PrEP, I think, is patient awareness and willingness to take the medication. There was actually a recent study that was done in Atlanta among high risk MSM where the incidence of HIV is fairly high. In Atlanta among black MSM 11% per year are becoming HIV infected, which is very staggering. And in that study there was a big drop-off between the number of people who are sexually active MSM-- and thus could theoretically benefit from PrEP-- and in those who were aware of or willing to take it. There was about a 50% drop-off. And so I think that this is certainly an area that needs some more work if we want PrEP to have a significant impact from a public health standpoint.

I should mention that the future of PrEP, I think, will look quite different. There are several different modes of PrEP in development. One is injectable formulations of PrEP. And I've listed some antiretrovirals there that may be used in that context. The idea is that you could get an injection three or four times a year and that would provide protection against PrEP in the meantime. And it also obviate the need for daily pill taking in the meantime-- that may help with adherence. Another is the inclusion of PrEP in vaginal rings-- this might be another option for women. There are human studies ongoing right now to look at this formulation. One benefit is that PrEP could potentially be co-formulated with contraception in these vaginal rings. Rectal microbicides are being studied also. These would be gels that patients apply before sex in order to prevent HIV transmission.

And then I think we have a lot more to learn about episodic PrEP. Some patients may have a hard time taking a pill every day, but perhaps if they could take prep intermittently or only in conjunction with sex they might be more likely to adhere. And if that still provided protection, then that might be an option for some patients. And there are studies ongoing right now of episodic PrEP.

So I have a question for you. Going back to the case that I shared-- this is of a 36-year-old man in a long-term relationship with an HIV-infected person. They have sex without condoms. If you were seeing him as a provider, or if you're not his provider but if you're thinking about should he take PrEP, I want you to go ahead and answer this question. Should be on PrEP? A-- yes. Or B-- no. Give you a few seconds to answer that. And then go ahead and close the poll and see what you say. I think it would be important to find out how well his partner is being treated for HIV. If his partner is virologically suppressed and has been so for a long time that might impact

the recommendation that you would give to this patient. But this is really a controversial area. Looks like 86% of you said yes and 14% said no. I can tell you in a few moments what happened. But I did have this discussion with a patient and he ultimately opted to go on to PrEP.

And then finally I also want to hear from you what your biggest concerns are with regard to PrEP. Are you concerned about A-- cost? B-- efficacy? C-- medication adherence? D-- side effects? E-- the development of HIV drug resistance? Or something else? Please go ahead and answer this question. And then we'll tally up the answers and see what you said. So we'll close the poll now. All of these have been things that people have brought up as potential problems with PrEP. And I hope that I've been able to address some of them during the session today. And I'm certainly happy to take any additional comments or questions [? about the use of them ?] as they come up.

Cost is certainly an issue. I think that the efficacy has been established, assuming that people remain adherent. And looking at the responses that you gave, it looks like 22% were concerned about cost, 33% about medication adherence-- which I think is a concern. We have to find ways to support patients in being adherent. 11% were concerned about side effects, 11% about the development of HIV drug resistance, and then 11% about something else.

So to circle back to the case as I mentioned-- our patient's husband had an undetectable viral load on ART. I discussed with him that that provides very good protection for him, but we can't say that it's foolproof. I did talk to him about how the benefit of PrEP in this case is not certain. But he did elect to start PrEP, and he fortunately remains HIV negative to date.

So I hope that we've been able to achieve these goals-- first, to describe how to take a sexual history that's inclusive of all sexual orientations and gender identities. And again, I think the keys to that are to make it routine, to explain to patients why you're asking these questions, and to make no assumptions. And then I hope that we've discussed the recommended screening and prevention methods for HIV and STIs among MSM and transgender women. And those include the screening tests for gonorrhea, chlamydia, syphilis, and HIV. We talked about vaccines that are recommended for MSM in several different HIV prevention modalities, including condoms, post-exposure prophylaxis, pre-exposure prophylaxis-- which is recommended by both CDC and the World Health Organization, and then treatment as prevention-- which underscores the importance of linking people with HIV to care and retaining them in care.

So we have a few more minutes now and I'm happy to take any additional questions or comments that you have. And I want to thank you very much for your attention.

ADRIANNA SICARI: Thank you so much, Doctor Ard. This is Adrianna Sicari over at the National LGBT Health Education Center again. We do have a question, Kevin. Can you see it in the Q&A box there?

KEVIN L. ARD: Yep. So one question says, are you able to present the case for PrEP to a group of CHC-- I assume that means community health care providers-- to familiarize and educate them on the process. And I would certainly be happy to do that.

ADRIANNA SICARI: And in addition to that, we also have a lot of materials on our website. We provide a lot of education around HIV and LGBT health that Doctor Ard has written and participated in as well. So that would be good stand-in in between. And you can feel free to reach out to the HIV TAC to facilitate that presentation.

KEVIN L. ARD: Great. It also looks like there's one more question. How would you go about getting provider buy-in for PrEP from non-HIV providers? I think there are a couple of things. One is simply making people comfortable with the medication through education. This may be a medication that they've never prescribed before. And I think it's important to show that it is safe and that the steps to prescribing and monitoring PrEP are fairly well protocolized by the CDC. And so there certainly is a fairly easy pathway for doing this. I think showing also the efficacy and talking about even my own clinical experience providing PrEP can be helpful. And then in my experience many people have questions or concerns about how to bill for visits for PrEP or how to make sure that patients can access it because of cost. And certainly I'm happy to talk to providers about those issues.

I should say that in my practice I've not had a problem getting PrEP for someone who I thought needed it. I've actually never had to fill out a prior authorization for PrEP. And then also it is possible to bill for those visits, and I talk to people about how to do that. But I think probably the most important thing is education so that people feel comfortable with the process.

ADRIANNA SICARI: Great. We have the next 15 minutes. I want to make sure that people ask questions if they have them. And so I want to stay here as long as we can.

KEVIN L. ARD: If you have any questions that you also don't want to ask of the whole group, you're welcome to email me at email address on the slide. And again, as Adrianna mentioned, we have several resources on the National LGBT Health Education Center website that address many of the issues that we talked about today.

ADRIANNA SICARI: I do have a question about the video. And this one I can field. The question is whether or not the video will be available to stream at their health center. And the video is available on our website as well. And the link is included in the slide download that you'll receive. And so you can go directly to the page where we have the video. And you're welcome to use that as a learning tool as well.

CHELSEA: Adrianna, I did have a question. I wanted to ask--

ADRIANNA SICARI: Great.

CHELSEA: --if there may be an opportunity for non-clinical staff to be more involved. If Doctor Ard could talk about the involvement of non-clinical staff in the process of getting patients comfortable with engaging in PrEP or any other treatments. If you could speak to that.

KEVIN L. ARD: That's a great question, getting non-clinical people involved in these steps. And I think that certainly there would be roles for non-clinical people in improving awareness about PrEP. This could be done through community outreach, through events that are in places that LGBT individuals might frequent-- pride parades, and so forth. So outreach is certainly one thing. And then potentially-- although I don't know that this has been rolled-out anywhere-- there may be a role for non-clinical staff in helping to support adherence to PrEP through reminders for people who may be very good about taking their medication, reminders and help with getting patients back into clinic for the necessary testing that they need. I think those potentially could be roles for non-clinical staff, which I think in the end may play a very important role in trying to roll this out in a widespread way to people who could benefit from it.

CHELSEA: OK, thank you.

KEVIN L. ARD: Yep.

ADRIANNA SICARI: Great. So if we don't have any more questions in the Q&A, or the chat, or from Chelsea or Ruthie over at the TAC, I think that'll conclude today's webinar. Thanks again so much Doctor Ard for the presentation and to the HIV TAC for partnering with us on this one.

KEVIN L. ARD: Thank you very much.

CHELSEA: Thank you so much.

ADRIANNA SICARI: All right, take care everybody.