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### HIV Can Be Prevented—Are You Doing Your Part?

#### Announcer

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#### Dr. Flash:

What if I told you there was a pill that could prevent HIV infection for those at risk? There is. Unfortunately, though modern clinical practice is increasingly focused on preventative medicine tools to optimize and control our wellness, HIV is one area in which best practices in prevention are lagging. We are here today because until we have an effective vaccine against HIV, it is critical that clinicians are confident in using all the tools in their arsenal to prevent HIV in their patients at risk. Listen as Dr. Isolde Butler and Dr. Charlene Flash, who specialize in HIV care and prevention, discuss the effective use of one of those tools, pre-exposure prophylaxis, or PREP.

Hello and welcome to the CME program in which we will discuss the keys to preventing HIV infection among vulnerable populations. I'm Dr. Charlene Flash, Associate Chief Medical Officer at Legacy Community Health and Clinical Assistant Professor at Baylor College of Medicine in Houston, Texas, and I'm joined today by Dr. Isolde Butler, an Infectious Disease and Internal Medicine Physician at Crescent Care in New Orleans, Louisiana. Hello.

#### Dr. Butler:

Hello.

#### Dr. Flash:

Dr. Butler, would you start us off by providing an overview of the populations that are most at risk of HIV infection?

#### Dr. Butler:

Absolutely. There's over a million people living with HIV in the United States and, you know, it's estimated that about 162,000 of them don't know their HIV status. This becomes a major problem for people living with HIV because, as it turns out, if somebody's treated for HIV, if they have access to the antiretroviral therapy and are able to become undetectable, we know that they no longer transmit the virus. What this means is that 162,000 who are not currently aware of their HIV status are actually accounting for about 40% of the new infections that we see, really highlighting the importance of HIV testing. But we feel that providers can have a large effect on the HIV epidemic. For one, they can work on decreasing cultural stigma in their practices, so those people who are at risk for HIV feel comfortable coming and accessing health care. And simply, they can start increasing the amount of HIV testing done. We feel that not enough HIV testing is really being done in the primary care setting as it stands now and increasing those rates will help us to identify those folks who are living and don't know their diagnosis. And, of course, what we are going to talk about today is really PREP and how to incorporate PREP into a primary care setting. So, HIV, unfortunately, affects populations differently across the country. What we know is that it particularly is affecting vulnerable populations in the south and elsewhere. I think many providers are aware there is an increased prevalence of HIV amongst men who have sex with men, but if we really dig into that data a little closer, we find even more disparities across racial lines, particularly. Unfortunately, 1 in 2 African-American men in the US today are at risk for developing HIV in

their lifetime, which is a really shocking statistic and I think is telling toward many of the issues that we're facing in the HIV epidemic in terms of how do we help people who need help to get into care. We see this also amongst women – 1 in 5 HIV cases is among women, which is not something that is often thought about, I find, but even amongst that population, we see much higher rates amongst African-American women than we see amongst Caucasian women. But, I think providers can do a lot to help combat the HIV epidemic, even on the primary care level. One simple thing would be to make your practice some place that's open and inviting for people who may be at risk for HIV, so including men who have sex with men, perhaps transgender folks – really making it a warm, open, loving kind of practice where people feel comfortable to discuss their sexual health and maybe come for services. On top of that, making sure to incorporate HIV testing into your everyday practice. It is a CDC recommendation to test everyone between age 13 and 65, and I think the more that that is done, the better we'll be at finding the folks who don't know their diagnosis. On top of that, what really is the topic for today's presentation is to discuss PREP, right? Talk about PREP in your practice. Consider prescribing PREP in practice.

Dr. Flash:

So, let's review the components of an HIV prevention strategy that's comprehensive. So, the first portion of that would be pre-exposure prophylaxis, or PREP, which is a once daily medication that contains two ingredients, tenofovir and emtricitabine, and that's given to people who are not infected with HIV but are vulnerable. Now, using this one tablet once a day strategy doesn't stand alone, and a comprehensive strategy also includes regular HIV testing, screening for sexually transmitted infections, as well as harm reduction counseling. So, talking about things like condom use, partner selection, positioning. In terms of thinking about the data that supports PREP use, that brings us back to the seminal trial that demonstrated PREP efficacy amongst men who have sex with men, that trial was called the iPrEx Trial. So, amongst people who had high enough levels of drug in their blood that suggested they were indeed taking a medication, the efficacy was 92%. And so, that is when this all started, and we thought, well, PREP is actually something that's viable to address some of the challenges we're having in overcoming the HIV epidemic. We soon also found out, however, that PREP isn't just something that's consigned to populations of MSM but is also something that has demonstrated efficacy amongst heterosexual men and heterosexual women, as well as people who inject drugs.

Dr. Butler:

So, what I'm hearing you tell me is that this is a very effective medicine in multiple populations, and it can work to really prevent HIV acquisition. So, the question now becomes how do we incorporate that into our primary care practices? And, I think again, the first step to that, which I mentioned before, is really the universal HIV testing. This opens the avenue of discussion of HIV and HIV-related risks with patients. Again, it is recommended for everybody ages 13-64 by the CDC. But, on top of that, you want to be able to have a conversation with your patients about their sexual history. What sort of activities are they engaged in that might put them in a situation where they could acquire HIV. But to do that, you have to be able to have an honest conversation with your patients about their sexual practices. And some folks find this difficult but making it a routine part of practice really makes it easier over time. Once you've identified that somebody might have some of these HIV risks, some other things that you might think about that could trigger these discussions would be things like has somebody coming in for an STI, if they're coming in to be evaluated for contraception – all of those are things that might suggest perhaps they are participating in activities that would put them at risk for HIV. Thinking about it from the IV drug user's standpoint as well, if somebody's coming in looking for suboxone therapy or things of that nature, it might be something to consider as well. So, once you've decided, okay, I've had this conversation with my patient and I do think that they might benefit from PREP, well the next conversation is to see are they clinically eligible? Do they have any contraindications to the medication?

Dr. Flash:

Now, one thing that we need to be very clear about is sometimes when we talk about HIV and we talk about medication, people assume that the medication you're talking about is actually for treatment for people who already have HIV. That's a whole other conversation, and that is very pivotally important; however, when thinking about PREP, PREP is appropriate only for people who are not infected with HIV – so, HIV-negative people. Now, how is that determined? Well, by first doing an HIV test. There are different types of FDA-approved HIV tests. If someone's using fourth generation testing, that test needs to be conducted within one week of starting PREP. The test contains both HIV antibody and antigen and is able to detect HIV much sooner than our older tests, or third generation HIV tests, which some places are still using. Now, depending on what kind of test you're using – that window period, the time between being infected and having a test that actually shows that you're infected, can vary. And so, it's still important for providers to be able to have those important conversations. So, in those conversations and during that physical exam, we still need to screen for signs and symptoms of acute HIV infection, or early HIV infection, so we still have to talk to our patients. Another element that is important in terms of determining clinical eligibility for PREP is making sure that people have healthy kidneys and that they have normal renal function prior to initiating. So, how do we define that in this context? Well, the renal function needs to be an estimated creatinine clearance of greater than 60 mL per minute. When drawing the serum creatinine and making that determination, we know that there are different ways to calculate someone's renal function, but the recommended approach in this setting is to use the Cockcroft-Gault Equation. Another important detail when thinking about initiating PREP is also to evaluate someone's hepatitis B status. So, why would

be even talk about that? We're talking about HIV, why do I bring up hepatitis B? Well, at present, in the medication that's FDA-approved for use as PREP, both ingredients also have activity against hepatitis B, and so you want to make sure that someone isn't 1) already infected with hepatitis B, and 2) you want to ensure that if they're not infected that they're not at risk and aren't immune. So, how do you do that? Hepatitis B testing can be somewhat complicated, but for the purposes of PREP screening, you would check a hepatitis B surface antigen. That will denote whether or not someone is infected and has evidence of hepatitis B virus. And if that were the case and it were positive, you would then refer them for treatment or take care of them yourself, if that was within your scope of practice. The second test that's important to get is a hepatitis B surface antibody. So, hepatitis B surface antibody indicates whether or not someone has been successfully vaccinated against hepatitis B and if successfully vaccinated, then is demonstrating immunity to the hepatitis B virus. So, if their hepatitis surface antibody is positive, you say, very good, you're immune. We don't have to worry about it anymore. If it's negative, then you go ahead and initiate the vaccination, which is a three-shot series. Another important detail is that for women that also may be eligible for PREP – we often think about PREP as something for men but, as we were discussing earlier, 1 in 5 infections in the United States actually also occurs amongst women, and so pregnancy screening becomes an important additional element of identifying what patients are eligible and what are the kinds of conversations we need to have with those patients. I say that because pregnancy isn't in and of itself a contraindication to PREP use. However, patients who are pregnant deserve the counseling and the informed decision making to understand that they're now taking this medication in the context of actually having a pregnancy on board as well. Let's talk a little bit about potential provider biases. So, when I think about what are the barriers that providers might have to doing this, it's not the medicine, because as we've described, it's not really that complicated and it's not harder than many of the other things that primary care providers do on a daily basis. The part that sometimes can be challenging for people, however, is that taking of the sexual history. Because when taking the sexual history, it's important to ask about not only the patient's behavior, but also potentially their partner's risk behavior, as, at times, you may unknowingly encounter a patient who sounds as though he or she is not at risk because they don't have multiple sexual partners or the type of sex they're having isn't considered risky sex, and whatever that means, but that person may have partner who has several sexual partners and may be in a particularly high-risk sexual network, and so that puts that person that's in front of you at undue risk as well. So, the challenge that some providers face is doing that routine assessment and having those sexual health history conversations. The key is for primary care providers to gain confidence in sexual history taking, in recognizing the elements of the sexual history that are an important part of screening for eligibility and understanding what additional HIV prevention harm-reduction counseling needs to take place. Then the final element is making sure that providers aren't just comfortable identifying patients and doing the counseling, but also in the follow up. Now, Dr. Butler, we've talked a lot about PREP use in primary care settings, what are the potential biases that might exist for infectious disease clinicians who care for patients with regard to PREP?

Dr. Butler:

You know, as an infectious disease physician myself and somebody who works with a number of infectious disease physicians, I do think it can be easy to become very focused on the treatment of our patients, which, of course, is what we train to do and is part of our practice.

Dr. Flash:

Absolutely. You know, we get so good at taking care of our patients HIV and talking about that in a context of them having long, healthy lives, that sometimes we forget to also tell patients that as I get your virus under control, I also can protect you from transmitting virus to other people. And then, sometimes when we really think that we're doing a good job, we feel that maybe there's no need for PREP because I'm already doing a great job treating your HIV, so why do you need anything else? Not recognizing that people may have expanded sexual networks and maybe the patient that's well-controlled sitting in front of me is not the only partner that that other person has and so PREP may still be part of the important context for that person.

You know, we've talked about a lot of important things as we've talked about PREP and primary care, and PREP amongst infectious disease providers, but if you had to determine what are your two top or primary takeaways, what would you say?

Dr. Butler:

Well, I think first and foremost, and we brought it up at the beginning of our conversation, is HIV testing. Without testing, you know, everything else in the HIV prevention spectrum kind of falls apart, so really making sure that testing is happening, and it can serve as a segue to discussing prevention. And secondly, to understand that prep is something that's very doable within a primary care setting.

Dr. Flash:

Absolutely, I 100% agree, and thank you, Dr. Butler. This has really been an informative discussion. And thank you for joining us for this CME program

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