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Pre-Exposure Prophylaxis: Addressing Provider and Patient Barriers

- Summarize the priority populations where PrEP implementation is likely to have the greatest impact.
- Identify how to help at-risk patients with limited awareness of PrEP make informed decisions about accepting PrEP.
- Describe an unbiased approach to prescribing decisions about HIV pre-exposure prophylaxis.

Guest Faculty Disclosure

Dr. Krakower has disclosed that he has performed contract research for Gilead Sciences, Inc.

Unlabeled/Unapproved Uses

Dr. Krakower has indicated that there will be references to the intermittent use of tenofovir-emtricitabine for use as PrEP.

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Podcast Transcript

BOB BUSKER: Welcome to this eHIV Review podcast.

I'm Bob Busker, managing editor of the program. Our guest today is Dr. Douglas Krakower, assistant professor of

medicine and population medicine at Harvard Medical School. And our topic is pre-exposure prophylaxis — specifically about Addressing Provider and Patient Barriers to PrEP.

eHIV Review is presented by the Johns Hopkins University School of Medicine. This program is supported by educational grants from Gilead Sciences, Inc. and ViiV Healthcare.

Learning objectives for this audio program include:

- Summarize the priority populations where PrEP implementation is likely to have the greatest impact.
- Identify how to help at-risk patients with limited awareness of PrEP make informed decisions about accepting PrEP.
- Describe an unbiased approach to prescribing decisions about HIV pre-exposure prophylaxis.

Dr. Krakower has disclosed that he has performed contract research for Gilead Sciences, Inc. He has further indicated that there will be references to the unapproved use of intermittent tenofovir-emtricitabine for PrEP.

Dr. Krakower, thank you for joining us today.

DR. KRAKOWER: I'm glad to be here.

MR. BUSKER: HIV pre-exposure prophylaxis: we know that PrEP works. We know it's safe. And we know that PrEP is significantly underused in at-risk populations. In your recent newsletter issue, you described the current research into Addressing Provider and Patient Barriers to Engagement in PrEP. Today I'd like to discuss how that new information might impact clinical practice. So please start with a patient presentation.

DR. KRAKOWER: The first case is a 34-year-old white Latina woman who comes in for an annual visit in primary care. She requests HIV testing because she's recently begun a new relationship with a man who is living with HIV infection. The patient is otherwise very healthy and takes an oral contraceptive pill but no other medication.

MR. BUSKER: Would it be appropriate to prescribe PrEP for this patient? How do you make that assessment?

DR. KRAKOWER: The most important thing is to conduct a comprehensive HIV risk assessment as part of the clinical encounter. Ideally, this would be done with nonjudgmental language, which can facilitate an honest, comfortable discussion with patients. You can also begin the conversation by asking permission to engage in this sort of risk assessment, given that these are sensitive topics. That can create a nice tone for having these kinds of communication and also assure the patient that this conversation, just like all the rest of the medical care that you're discussing during the visit, is fully confidential. And so, some of these preparatory maneuvers can create a comfortable environment for these discussions.

MR. BUSKER: Asking permission, assuring confidentiality, speaking nonjudgmentally — once you've established some sort of comfort level, what are some of the specific things you would ask the patient about?

DR. KRAKOWER: Some of the specifics would include talking about all of the sexual partners that she may have. Just because she mentions that she's entering a relationship with a main male partner, some people will have more than one partner, so it's helpful to get a global sense of the types of partnerships she may be engaging in sexual contacts with. Then it's important to ask about substance use history to see if she may have any injection drug use; that would be another risk factor for HIV acquisition; or if she's having sexual encounters while she is using substances, which can impair decision-making around other forms of protection, such as barriers or condoms.

It's also important to ask about a history of any sexually transmitted infections she may have had, which can also be a risk factor for HIV acquisition and can also potentiate HIV transmission in terms of some of the biology of having a bacterial sexually transmitted infection or other sexually transmitted infections, as well.

Then it's important to ask about what kinds of things she is already doing to protect against HIV acquisition, such as using condoms with this partner or with other partners, or if she may have explored any other strategies. Then, digging a little deeper into some of the sexual behaviors she's having with her partner or partners can also help assess the risks for HIV acquisition. For example, we know that anal sex is one of the more efficient ways that HIV can be transmitted during sexual encounters, so asking about those behaviors as well as vaginal sex and oral sex will get a more comprehensive picture of the type of risk behaviors she might be engaging in with her partner.

And very important for having a long-term relationship with a male partner who is living with HIV is her partner's HIV treatment history, if that's something she's aware of. It may not be information she's privy to, depending on the type of communication they have in the partnership. But if he is willing to share that information with her, it can be very helpful to assess risk of transmission because we know that people who are living with HIV, take HIV treatments, and have a low viral load are much less likely to transmit HIV to their sexual partners. So figuring out what she knows about his adherence to his HIV treatment, medication, and any levels of viral load testing he may have recently had can add to the picture of her risk.

And at the end, the idea is to put all of these factors into a calculus to sort out if she's at high enough risk where she may benefit from pre-exposure prophylaxis.

MR. BUSKER: What might baseline testing prior to prescribing PrEP include?

DR. KRAKOWER: The guidelines recommend a number of tests before initiating PrEP in a patient. First is HIV testing. You want to make sure your patient is HIV uninfected before starting PrEP because it's not a complete HIV treatment regimen, but rather only part of a full regimen.

Ideally, you want to make sure they're uninfected by getting a fourth-generation test, an antibody antigen test, to demonstrate that someone is not infected with HIV. There is a window period for that sort of testing to make sure someone isn't HIV infected but still in the window period where the tests would be negative. You also want to assess if they have any symptoms that could be consistent with acute or recent HIV infection. If you do elicit any of those symptoms — which could be anything from flu-like symptoms to rash or sore throat; anything that could be consistent with acute HIV — then you want to check an HIV RNA test, which is the most sensitive test with the shortest window period before starting PrEP.

It's also recommended to assess the patient's creatinine to know their renal function. PrEP is not recommended in patients with a creatinine clearance less than 60 mL/min, because tenofovir has been associated with renal harm with long-term use.

It's also important to assess the patient's hepatitis B status by checking their serologies. If someone is surface antigen positive — that is, they have chronic active hepatitis B — it doesn't mean you can't use PrEP, but it's important to know their status because the PrEP medications are also active against hepatitis B. So if someone has chronic active hepatitis B and they use PrEP, you are actually treating the hepatitis B as well as administering PrEP. There is nothing wrong with that, and it may actually be beneficial for their health overall, but it's important to know because if people stop hepatitis B treatment, they can have an abrupt increase in their hepatitis B viremia, which in rare cases can cause hepatic inflammation. So it's important to know their status, and if a clinician is not comfortable managing hepatitis B, to consult and expert in hepatitis B management when prescribing PrEP.

If someone has hepatitis B testing that demonstrates that they're susceptible to hepatitis B, it's good clinical practice to offer them a hepatitis B vaccine. It's also important to check a baseline hepatitis C test as part of general sexual health care. And if someone could potentially be pregnant, you should get a pregnancy test.

PrEP can be given to people who are intending to become pregnant, could become pregnant, or are pregnant, but the guidelines suggest that there's limited evidence in this population, so it's important to have an informed discussion with women.

MR. BUSKER: PrEP and pregnancy. Your patient asks you whether she could safely conceive with her HIV positive partner. How would you answer her?

DR. KRAKOWER: We know from research that many HIV serodiscordant couples — that is, where one member of the couple has HIV infection and the other member is HIV uninfected — express fertility desires and intentions. Like anyone else, some people want to have children, and people living with HIV and in partnerships with those living with HIV also express these intentions. So it's really a good conversation to have to provide the best quality of care for people in serodiscordant couples.

The CDC has some guidelines about the options for these scenarios, and I would assure the patient that there are definitely options she may consider accessing. The first one is sperm washing, where the sperm from a man living with HIV infection can be washed and cleaned to remove the HIV and then it can be safely used to inseminate the female partner in the couple.

One challenge with sperm washing, even though the risk of HIV transmission is extremely low because the sperm washing is quite effective, is that access could be problematic for some patients. The expertise for conducting the sperm washing is very specialized and so not all geographic areas will have someone who is expert in doing that. And the expense of the procedure may be prohibitive for some patients, or at least problematic.

We definitely counsel that there are other options where people can safely try to conceive children. The number one most important thing is HIV treatment for the HIV infected partner. As mentioned earlier in our discussion, if someone is living with HIV but takes HIV treatment, it makes it very unlikely they will transmit HIV to their partners. That's one of the strongest interventions for couples to conceive children where the person with HIV is on treatment.

Using PrEP for the HIV uninfected partner is also a useful tool that can be adjunctive to HIV treatment for the infected partner. It's not clear how much additional benefit there is in using PrEP if the HIV infected partner has an undetectable viral load, as that's such an effective intervention, but it's certainly something I think clinicians should offer to patients so that patients can take control of their own sexual health. Also, some patients may not be 100% confident that their sexual

partners will be adherent to their HIV treatment. Their partners could be viremic and they wouldn't know it. That's another reason that discussing and offering PrEP for women, such as the case example here, is really important.

Couples can also time their condomless intercourse to times of peak fertility of the menstrual cycle, and then at other times when fertility is lower they can use condoms; that decreases the number of acts that are condomless and thus where HIV transmission can occur, while trying to optimize the chances of a conception.

Finally, screening and treating both partners for any sexually transmitted infections they may have is also useful because these infections can potentiate HIV transmission.

MR. BUSKER: Please give us an overview of other populations at high risk for HIV acquisition where PrEP should be considered.

DR. KRAKOWER: A number of populations are likely to benefit from PrEP, and clinicians should try to have this discussion. If they're taking care of any men who have sex with men who are engaging in condomless receptive anal intercourse, or any anal intercourse, that's a population in which we know that there's a disproportionately high burden of HIV, so discussions about PrEP are important.

Men who have sex with men, also known as MSM, who are having sexually transmitted infections diagnosed, is another population that may benefit from PrEP. If they're having sex while under the influence of substances, particularly crystal methamphetamine, those are also patients where the benefits of PrEP may be high.

Other important populations include persons who are using injection drugs, who are sharing needles, or who may be engaging in risky sexual encounters while using substances, because we know that substance use can impair sexual decision-making. And some people may be trading sex for drugs, goods, services, or other things they need, so it's a population worth having these conversations.

Also, if someone is using injection drugs but has recently entered treatment for their substance use, such as a treatment program or the use of medication assisted therapy, this is a population that also may benefit from a PrEP conversation because some people who recently start treatment may be at risk for relapse of their substance use and injecting behaviors, so the CDC guidelines suggest considering PrEP in those who have been entered into a program into the prior six months.

Other populations include heterosexuals who may have sexual partners who are themselves engaging in risk behaviors. For example, a woman who is in a relationship with a male partner who has sex with other men or uses injection drugs may also be at risk for HIV acquisition because of her main partner's behaviors; therefore she might be an appropriate candidate for PrEP.

People who also engage in transactional sex work may be candidates for PrEP. It's important to keep in mind the local epidemiology of patients you may see in care as a clinician, which can help decide whether conversations about PrEP are most helpful.

For example, there are some notable racial disparities in HIV epidemiology with black and African Americans being at increased risk for HIV acquisition in some communities. In particular, young black men who have sex with men and Latino men who have sex with men experience disproportionately high rates of new infection. So, if clinicians can be mindful of that epidemiology and provide conversations about PrEP to those patients, that can be giving patients really good quality care.

MR. BUSKER: Thank you for that case and discussion. And we'll return with Dr. Douglas Krakower from Harvard, in just a moment.

MR. BOB BUSKER: You've been listening to eHIV Review, a combination newsletter and podcast program delivered via email to subscribers.

Newsletters are published every other month. In each issue, an expert author reviews the current literature in an area of specific importance to clinicians treating patients with HIV, including infectious disease specialists, primary care physicians, nurse practitioners, physician assistants, and others.

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Thank you.

MR. BUSKER: Welcome back to this eHIV Review podcast. We're with Dr. Douglas Krakower from Harvard Medical School. And we've been discussing how some of the new information presented in his newsletter issue —about Addressing Provider and Patient Barriers to PrEP — can best be translated into clinical practice. So, if you would, please doctor, let's continue with another patient scenario.

DR. KRAKOWER: This patient is a 43-year-old white male who engages in active injection drug use. His health complications of injecting include a diagnosis of hepatitis C, which has been untreated. The patient had a prior overdose requiring resuscitation and has had multiple skin abscesses.

This patient injects heroin and fentanyl, and other medical issues include a history of depression. He uses an SSRI for this condition with very good adherence. He has some challenges with unstable housing, as well.

MR. BUSKER: Is this patient an appropriate candidate for PrEP? How would you make that assessment?

DR. KRAKOWER: Like the other patients we talked about, you'd want to create an atmosphere where conversations can go well about PrEP. You'd use nonjudgmental language and create a comfortable atmosphere for patients to disclose any drug use and sexual risk behaviors they may be engaging in because this patient population may be fearful of being judged by providers for their drug use.

You start by asking what he's already doing to protect against HIV infection, such as using clean or sterile needles and needle exchange programs. If he's not doing those, then you figure out if he's sharing needles or other paraphernalia with partners who may be infected with HIV, which can also increase the risk of HIV acquisition.

You want to ask if he knows anything about the HIV status of his partners, which can, of course, put him at higher risk if he knows he is sharing needles with people who are HIV infected.

Also ask if he has a recent entry into a substance abuse treatment program because of the risk of relapse for people who may have recently entered these programs.

You also want to ask if a patient has been exchanging sex for money, drugs, goods, housing, or any other things that he may need, which may also increase the chances of engaging in risky behaviors.

MR. BUSKER: Let's say this is a patient who is totally unaware of PrEP — he's never heard of it, never considered the idea. How would you introduce the concept to him?

DR. KRAKOWER: It's a really important question, because we know from research that awareness of PrEP among people who are injecting drugs is likely to be quite limited. It can be important to start with an open-ended assessment such as asking the question: "What have you heard about PrEP before today?" That way if people have heard about PrEP you can get a sense about what they know and any helpful or potentially unhelpful information they may have heard such as misconceptions about PrEP and you can address those as part of your conversation.

It can be helpful to ask if it's okay to share information about PrEP, because, again, that sets a really nice atmosphere of asking someone's permission to give information about something, and I think it makes people much more receptive to hearing more about PrEP and other things that may be new to them.

A great framework for talking about PrEP is informed or shared decision-making. This is the idea where people may not know if PrEP is right for them right off the bat, so it's helpful to provide information that's relevant to them, that's personalized to their lives, and try and assess their personal values and preferences around the different options they may have for protecting themselves against HIV.

Some people may find that taking a daily pill is a really attractive option, whereas other people feel that would be a huge inconvenience or they are skeptical of medications, and it may not be the right time to start something like PrEP. But by assessing their values and preferences you can move the conversation forward in a helpful, individualized way for each patient.

Patients probably will have a variety of different levels of health literacy and numeracy, so it's also helpful to keep in mind how you present information about the benefits or potential harms of treatments like PrEP, because people may not be as comfortable with numbers, talking about things like efficacy estimates and risk may not be terms that they're familiar with. So trying to adjust your language could also move the conversation forward in a helpful way.

Finally, informed decision-making as a framework would suggest if you can conclude with a patient-centered decision that works with where they are in their life at the time of the encounter, that is probably going to be the best way to build trust and a helpful relationship. Even if you think PrEP is something that might be of great benefit for them and they decline it today, if

you keep it in a patient centered manner, building that relationship will pay off dividends in the long run. They'll feel comfortable coming back to you, and over time you may be able to move them in the direction that you think is best for their health, which may include PrEP.

MR. BUSKER: The research reviewed in your newsletter discussed some of the barriers clinicians themselves might have to prescribing PrEP. Talk to us now about patient barriers to accepting PrEP, particularly among patients like this one who are injection drug users.

DR. KRAKOWER: A number of challenges are really important to keep in mind. Patients may face psychosocial challenges with their substance use. Co-occurring mental health conditions such as depression and anxiety can make it challenging for someone to adhere to a prophylactic medication such as PrEP.

It is important to keep in mind that as clinicians we shouldn't make assumptions about adherence before a patient has given things a try. Research has shown that clinicians may not be able to accurately predict which patients will be good or not as good at adhering to long-term medications. Giving people the benefit of the doubt is important in providing good quality care.

It's important to engage in a personalized assessment of adherence barriers. People who are using drugs, even though they may be members of the same population with respect to their risk behaviors, may have very different experiences in the social milieu in which they live and need to address taking a daily medication such as PrEP. So coming up with a personalized assessment of barriers is a good way to give individualized counseling that can move things forward in personalizing strategies to optimize adherence.

Another important barrier that may come up is, people who are using injection drugs may be in treatment programs or using medication assisted therapies such as buprenorphine or other medications to work on their substance abuse. They may have questions about whether the medication for PrEP, tenofovir/emtricitabine, interacts with those medications. Clinicians who have not prescribed PrEP concomitant with these medications may also have those questions.

The good news is that this medication for PrEP does not have any interactions with the currently used medications for substance abuse management with opioid disorders, and that can make it a little easier to prescribe PrEP in this population.

MR. BUSKER: Some good points, Dr. Krakower, thank you. I think we've got time for one more patient scenario.

DR. KRAKOWER: This patient is a 21-year-old black man who has sex with men, who was recently diagnosed and treated for rectal chlamydia but otherwise is healthy, without any medications or medical issues.

MR. BUSKER: How would you assess if this patient is an appropriate candidate for PrEP?

DR. KRAKOWER: I'd engage in a comprehensive, nonjudgmental risk assessment. This could include the number of partners he may be having sex with, any condom use behaviors, and any anal sex behaviors, including insertive or receptive anal sex.

We also want to ask about substance use such as crystal methamphetamine, poppers, or other substances. Studies have shown that some of these substances can increase sexual risk and also HIV incidence. It's important to ask about the HIV status of their sexual partners. It can be helpful to ask the patient where he meets his partners, such as online dating apps. Some people may engage in anonymous sexual encounters, which may increase their risk if they don't have conversations about their partner's HIV testing status.

Any history of sexually transmitted infections, particularly bacterial sexually transmitted infections such as chlamydia, gonorrhea, and syphilis. We know that those are associated with incident HIV infection, as well. People have used the term "syndemics" to talk about syphilis and HIV — these two epidemics are synergistic, with the increased risk of acquiring the other infection.

It's also helpful to keep in mind some of the racial disparities I mentioned earlier, where young black MSM have a high burden, as a community, of HIV infection. Part of this may be due to structural stigma: these young men may have less likelihood of accessing culturally competent health care. They may face health care provider related stigma and may not have the same willingness to engage in health care because of mistrust of their providers, so they may be less likely to have HIV and STD testing.

Assessing the HIV prevalence in someone's sexual network is also helpful. If someone is engaging in sexual encounters in a community where HIV prevalence is very high, such as in some urban centers, that may also increase the risk of HIV acquisition and the potential benefits of PrEP.

It's really important to note if the patient mentions that they have very low risk behaviors but still request PrEP, that clinicians should not withhold PrEP or dismiss their concerns because some patients may not feel comfortable disclosing sensitive information to their providers for fear of being judged and may still be engaging in risk behaviors. If someone requests

PrEP, my recommendation would be to strongly consider offering it and not withhold it.

MR. BUSKER: What tools are available to help clinicians assess whether or not a particular individual might be an appropriate candidate for PrEP?

DR. KRAKOWER: The CDC guidelines recommend for MSM using a risk screening tool called the HIRI-MSM, which is a seven-question tool in which a clinician can ask patients a number of questions about their sexual and drug use behaviors and come out with a rough sense about whether a conversation about PrEP may be warranted.

Other tools have been developed in a similar vein with other populations such as MSM. In San Diego, a tool called the SDET was developed in that population. Another tool developed at the University of Washington was a risk prediction tool for MSM presenting to sexual health clinics in the Seattle region, and couple of other tools are available online. These can be a handy way to come up with a risk assessment at the point of care.

An important thing to keep in mind, though, is that all these tools may lack sensitivity and specificity, so they shouldn't be used as a definitive answer about whether someone should or should not use PrEP. They're just one component of a comprehensive risk assessment that draws on all the information and the patient preferences that would have been elicited earlier in the conversation.

MR. BUSKER: How would you counsel this patient about condom use while undergoing PrEP?

DR. KRAKOWER: The CDC guidelines recommend that the best protection against HIV acquisition is condoms plus PrEP. We know that not all patients use condoms correctly and consistently, and studies suggest that many patients who use PrEP do not change their condom use behaviors.

People have worried that the use of PrEP will create an environment where people who were using condoms abandon them while using PrEP, and that's known as behavioral disinhibition or risk compensation. But most studies show that people who have started using PrEP were not using condoms consistently beforehand and don't use them consistently after. So just because someone isn't using condoms is not a reason to withhold or discontinue PrEP.

Some studies have shown that a minority of people disclose using condoms less after starting PrEP, but PrEP is highly protective if people use it consistently. So my recommendation would be that disclosing using condoms less is not a reason to withhold PrEP but in fact may be a reason to encourage him to be adherent to PrEP to get high level of protection from the medication.

It's important to note that sexually transmitted infection rates such as chlamydia, syphilis, and gonorrhea are at an all time high in the US, as reported recently by the CDC. So clinicians should ideally incorporate counseling about condoms and other ways to protect against other sexually transmitted infection in all their patients who may be using PrEP. This can include frequent screening tests and treatment for STIs as part of comprehensive PrEP care.

MR. BUSKER: PrEP, in its current form, is dosed daily. If a patient, for whatever reason, doesn't want to use a daily dose, are there other options?

DR. KRAKOWER: Currently the only option in the United States recommended by the CDC and approved by the FDA is daily oral tenofovir/emtricitabine. Studies have been looking at whether an on-demand regimen, where people take PrEP only right before they engage in sexual risk behaviors and then for a short time after, may be efficacious.

The IPERGAY study looked at a strategy where MSM would use a double dose of the tenofovir/emtricitabine tablets the day before or the day of a sexual encounter, and then another daily dose for two days thereafter. This was shown to be highly efficacious in the IPERGAY study.

The only challenge with those data is that the average number of pills taken per month by the men in the study was about 15, because they were engaging in frequent sexual encounters. Other studies of daily PrEP where people were less than adherent but were taking about 15 pills a month showed that that was still very highly protective. This leaves us in a situation where we don't really know if this on-demand strategy in someone is engaging in fewer sexual encounters and using fewer PrEP pills each month will actually get high levels of benefit.

A few participants in the IPERGAY study did use fewer pills and had less frequent encounters, and some preliminary data suggest they still got high levels of protection, but that hasn't been clearly established, and this is only one study. Therefore, currently it can only be recommended to use daily oral PrEP until we receive further guidance from the CDC or the FDA.

Hopefully in the future there will be more options for PrEP, and a number of investigational agents are being tested in clinical trials. These include injectable PrEP, where people can have a long acting depot injection of PrEP, maybe once every two months or so. Intravaginal rings are also being studied, as well as topical gels containing antiretrovirals to be used as PrEP. Hopefully the future will come up with a whole variety of options that can fit each patient's preference.

MR. BUSKER: Dr. Krakower, thank you for your insight into today's cases. Let's wrap things up by reviewing our discussion in light of our learning objectives. To begin: the priority populations where PrEP is likely to have the greatest impact.

DR. KRAKOWER: We reviewed case examples of patients with indications for PrEP from several major priority populations, including men who have sex with men, in particular young minority men who have sex with men; persons who inject drugs; and heterosexuals with HIV infected partners. Those would comprise the highest-risk populations who may be most likely to benefit from PrEP use.

MR. BUSKER: And our second learning objective: how to help at-risk patients with limited awareness of PrEP make informed decisions about accepting PrEP.

DR. KRAKOWER: We talked about coming up with open ended assessments of patients' knowledge of and interest in using PrEP for people at risk for HIV acquisition, trying to discuss the risks and benefits of individualizing PrEP in a manner that is appropriate for patients' health literacy and numeracy, and using a patient centered framework for discussions and decision making about PrEP. Those strategies can help a patient make informed decisions about PrEP.

MR. BUSKER: And our final learning objective: developing an unbiased approach to prescribing decisions about offering PrEP.

DR. KRAKOWER: We talked about engaging in nonjudgmental assessments of each patient's personal risk behaviors and considering these personal behaviors in the context of the epidemiology for important patient populations. We talked about engaging in patient centered decision making, as well as considering that some patients may not be comfortable disclosing their sensitive behaviors, such as personal risk behaviors, to their clinicians.

We also talked about how clinicians should ideally not withhold PrEP from persons who request PrEP because those patients may be uncomfortable disclosing high-risk behaviors to their clinicians.

MR. BUSKER: Dr. Douglas Krakower from Harvard Medical School, thank you for participating in this eHIV Review Podcast.

DR. KRAKOWER: Thank you so much for inviting me. It's been a great pleasure.

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