Staying Current, Navigating the Latest Advances in PrEP Options

CMEO Podcast Transcript

Christina M. Madison, PharmD, FCCP, AAHIVP:

Hello and welcome. On behalf of CME Outfitters, I would like to welcome and thank you for joining us for this CME Outfitters (CMEO) Snack titled, *Staying Current, Navigating the Latest Advances in PrEP Options*. This program has been supported by an independent educational grant from Gilead Sciences Incorporated. Today's activity may include discussions of products or devices that are not currently labeled for use by the U.S. Food and Drug Administration (FDA). As a reminder, this is a global program. Indications and availability vary by regulatory authority. Clinicians should consult local guidance when confirming approved pre-exposure prophylaxis (PrEP) options.

Thank you for joining us today. I'm Dr. Christina Madison, Founder and Chief Executive Officer (CEO) at the Public Health Pharmacist, and I'm delighted to be joined by an incredible panel for this discussion. They will provide their global and regional insights as we begin to navigate through new territory. I'll start with Dr. Orkin and allow each faculty to introduce themselves. Dr. Orkin?

Chloe Orkin, MBE, MB BCh, MSc:

Hello, everybody. My name's Chloe Orkin. I'm Professor of Infection and Inequities at Queen Mary University of London, and a clinician at Barts Health National Health Services (NHS) Trust in London.

Sunil Suhas Solomon, MBBS, PhD, MPH:

Hi, everyone. I'm Sunil Solomon. I'm a Professor of Medicine and Epidemiology at the Johns Hopkins University School of Medicine in Baltimore, USA.

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

Hi, everyone. I'm Boghuma Titanji. I am an Assistant Professor of Infectious Diseases based at Emory University in Atlanta. I am an HIV physician practicing within the Emory healthcare system.

Christina M. Madison, PharmD, FCCP, AAHIVP:

Our learning objective for today's program is to evaluate the latest data on PrEP options, including efficacy, safety, mechanism of action, and mode of administration. So, let's begin by navigating this changing route. Dr. Solomon?

Sunil Suhas Solomon, MBBS, PhD, MPH:

Sure. I think most of us remember the late 1980s when we did not even have highly active antiretroviral therapy and behavioral interventions such as condom use was primarily the only thing we had. But that being said, I think condom use is something that's very underrated. It actually is extremely efficacious if used properly. But we also recognize that people's needs have evolved and each person is different and choices are always great. So, over the past two decades, we've had a couple of breakthroughs. So, we have treatment as prevention, which is the undetectable is equal to untransmittable, but really the prevention toolbox has expanded. So, what

started off as daily oral PrEP, which is one regimen, we now have two different regimens and we've transitioned to on demand oral PrEP, as well as we have injectable PrEP. And we have two different combinations of injectable PrEP that are currently approved by the FDA, both injectable cabotegravir (CAB) and injectable lenacapavir.

Chloe Orkin, MBE, MB BCh, MSc:

And I think it would be great now at this point to really bring us back to clinical practice after that amazing introduction from Dr. Solomon. So, Dr. Madison is going to start us off by revisiting how we talk about PrEP and post-exposure prophylaxis (PEP) in the clinic, and that's something that still confuses many people and also people at risk of HIV.

Christina M. Madison, PharmD, FCCP, AAHIVP:

So, here's our reminders, and level setting for today's presentation. We know that PrEP is proactive if we start it before an exposure and take it ongoingly. We know that PEP is reactive, which can be started within 72 hours and continued for 28 days. Both require a prescription. PEP is definitely more urgent, and PrEP can be routine. When taken as prescribed, we know that PrEP reduces HIV risk by up to 99%. There's so few things in this world that have that level of certainty.

Now that we've distinguished between PrEP and PEP, let's look at the PrEP options themselves. Dr. Solomon, can you walk us through the current PrEP formulations and how their differences shape clinical decisions? I'd like to emphasize again for our global audience to check your local guidance.

Sunil Suhas Solomon, MBBS, PhD, MPH:

There are a couple of different options, as I mentioned already. So, we have two oral options, which is essentially a combination of tenofovir (TDF) and tenofovir alafenamide, which is TAF, both in combination with emtricitabine, which is FTC. So, these are both oral daily medications. So, TDF/FTC has a broader recommendation, it's recommended by the FDA, European Medicines Agency (EMA), World Health Organization (WHO), and several guidelines for sexual transmission, both unprotected anal intercourse as well as unprotected vaginal intercourse. F/TAF, which is TAF and FTC, has a similar indication, except it's currently not indicated for the prevention of HIV transmission in unprotected vaginal intercourse.

We also have two new long-acting formulations. One is cabotegravir and the other one is lenacapavir. Both of them are injectables. Cabotegravir is once every 2 months and lenacapavir is once every 6 months. Both of them have an indication for the prevention of sexual transmission of HIV. They're both approved by the U.S. FDA. There also is the dapivirine vaginal ring, which is a monthly ring that is inserted by women, which is also approved by the EMA and the WHO, but it's not currently approved by the FDA.

The one thing I do want to point out is there is guidance that all these products can be used, especially F/TDF, for the prevention of HIV acquisition by injection drug use. But as of now, there are currently no drugs that have an FDA indication for the prevention of HIV acquisition by injection drug use.

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

And I'd like to chime in and add to that by saying that although we now have a variety of options, and it's really exciting to have these numbers of options to offer to our people who desire to access PrEP, what remains most widely available is oral PrEP because in most parts of the world, there's still access barriers to getting injectable formulations of PrEP, and that's still an area that we'll have to continue to work on globally.

Christina M. Madison, PharmD, FCCP, AAHIVP:

I really appreciate you saying that, Dr. Titanji, because I do think that, yes, it's exciting that we have these injectable products, but we do have to remember that oral PrEP still remains a foundation for the global community.

Dr. Orkin, let's start with the oral PrEP options, since for many clinicians this is the most familiar entry point before expanding the PrEP toolkit.

Chloe Orkin, MBE, MB BCh, MSc:

Yeah, absolutely. And as Dr. Solomon has already said, we do have two potentially daily oral PrEP options, which can also be used on demand. But let's focus on TDF and FTC first, widely used for HIV treatment, and has been approved for PrEP a long time ago, in 2012. TAF/FTC, more recently approved for PrEP, 2019, but not indicated for people at risk based on receptive vaginal sex. And the important thing to say here is that both are highly effective when taken as prescribed. You can see 99% effective when taken as prescribed. There are some key safety differences. With TDF/FTC, renal function monitoring is important, and there can be small reversible bone mineral density (BMD) changes/ but with TAF/FTC, renal and bone biomarker effects are generally smaller compared with TDF. So, I guess the bottom line here is that both require adherence to oral therapies daily, and therefore the fit for these regimens really comes down to what is right for the person in terms of their preference, their routine, and their context.

Christina M. Madison, PharmD, FCCP, AAHIVP:

I couldn't agree with you more. We really have to meet our patients where they are and make sure that we're doing our prescribing based off of shared clinical decision-making.

We've reviewed the oral options, but access depends on geography. Regulatory approvals and prescribing limitations vary widely. So, let's talk about the global landscape and what that looks like.

Chloe Orkin, MBE, MB BCh, MSc:

I think one of the important things is that while oral PrEP has an efficacy rate of more than 90%, it's close to 99%, when it's used in what we call the real world, the effectiveness drops to 60%. And this is a huge issue. It can't be overstated how important this is. And we just have to remember that the outcomes don't equate to clinical trial efficacy. And I think we have to think about this is not across the board, there are some populations that find it a lot easier to take oral therapy. And we often see that adherence is worse in the studies including cisgendered women, regarding adherence to oral therapy. We see it in socioeconomically disadvantaged people, we see it in younger people, and we may see it in people who are struggling with substance use. So, I think this is a very, very important consideration.

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

And to add to that, I think that it's also important, going back to the point of the regulatory issues and the barriers of access to a variety of PrEP options continues to be an issue in countries where you may not have access to long-acting therapy and where it's stigmatizing to be on a daily preventative medication for HIV, because particularly taking the context of Sub-Saharan Africa, a lot of people still associate being on PrEP to being a reflection of how sexually promiscuous a woman may be. And really being able to have those other options that are discreet, that are easy to be adherent to is absolutely key in these populations.

So, again, going back to Chloe's point that in real life scenarios, you get lower efficacy. That may be because people are still struggling with issues around stigma, feeling they need to hide their medications, maybe not going to the PrEP clinic at the frequency they need to go to pick up their medications, impacting adherence. When you have adherence to oral PrEP, it's very highly efficacious at 99%. But the moment that adherence drops off and becomes more patchy, then we start getting to the 60% levels that we see in real life. And there's a lot of room for improvement, and that would come with addressing these barriers that I have expanded on.

Sunil Suhas Solomon, MBBS, PhD, MPH:

And the only thing I would probably add on is really tailoring PrEP to the individual, and it's a constantly evolving process, because someone may start off with daily oral PrEP and then they may want 2-1-1 PrEP, then they may go back. So, really having that conversation and that decision on PrEP being made between the provider and the client, depending on what's available in each country within the regulatory environment is a critical way to try and improve effectiveness.

Christina M. Madison, PharmD, FCCP, AAHIVP:

I think that was truly illustrated very well. A few years ago, there was a poster that was published at the Conference on Retroviruses and Opportunistic Infections (CROI) looking at dynamic choice, and those sentiments that you've all mentioned were a part of that. When folks had the ability to change, they definitely were more likely to stay adherent to their therapies. So, I really appreciate the point about understanding and determining what folks want based off of their lived experience and that that could change based off of what's currently going on in their life.

So, at this point, I wanted to switch a little bit and talk about access. And obviously we know that access is not only one part of the equation. So, Dr. Orkin, can you speak to this and how that could obviously impact our real-world efficacy, as you mentioned before?

Chloe Orkin, MBE, MB BCh, MSc:

Yeah, I think that just the issue is, once again, that even when PrEP is available, real-world outcomes don't mirror the clinical trial efficacy. And the daily oral PrEP definitely will exceed 90% efficacy when taken as prescribed, but the real-world efficacy is lower, and this really does center on adherence. And I think we often think about challenges in terms of access purely in terms of accessing services, but not knowing where to get it or PrEP literacy, as we can call it. But in reality, taking daily pills just does not fit everyone's lifestyle and isn't possible for many people.

Christina M. Madison, PharmD, FCCP, AAHIVP:

Dr. Solomon, would you like to expand further? And then others, would you like to talk about expansion into your clinical practice? Could you perhaps discuss the new data out of CROI in regards to long-acting injectables?

Sunil Suhas Solomon, MBBS, PhD, MPH:

Sure. Maybe we'll start with cabotegravir. So, I think most of you are aware, cabotegravir is a long-acting injectable. It was approved by the FDA in December, 2021 for PrEP in adults and adolescents. Its mechanism of action is like it really prevents the integration of HIV with the host DNA, and it's given as a gluteal intramuscular injection. The initial injections are 1 month apart, but following that, it's every 2 months. I think what was really fascinating in CROI 2025 was really the real world cohorts that presented data from the OPERA and the Trio Health cohorts, which was about 1,300 people who were on long-acting cabotegravir for PrEP. And I think what they really saw was that 85% of them were injecting on time, there was 69% on time injection. And it really was, I think, to the point that Boghuma mentioned earlier was something that was discrete was an injection every 2 months. So, there really wasn't a lot of stigma around this, and they actually reported reductions in stigma.

So, overall, it really is a safe, tolerable, injectable study. Definitely has more data available on real-world use compared to lenacapavir, which was approved much more recently. But I think one of the challenges is integrase, especially outside of the U.S., remains your staple first-line regimen. Even in the U.S. it is, but when you go to the President's Emergency Plan for AIDS Relief (PEPFAR) programs, they generally just have one regimen where most people are started on, which is the combination of tenofovir, lamivudine, and dolutegravir. So, if you have breakthrough infections and you have integrase strand transfer inhibitor (INSTI) resistance being transmitted from cabotegravir, it could be challenging for first-line regimens. And that's something we are monitoring, I think the scientific community is monitoring closely, surveilling for INSTI resistance among the CAB breakthrough infections. But most of this data really comes from the HPTN 083 and HPTN 084 trials, which really informed the FDA approval of PrEP.

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

Yeah, and I would like to add that we have actually seen just how impactful having the long-acting injectable cabotegravir has been as a PrEP option for our client population. Previously, we do have a … we have a program within our healthcare system that rapidly enrolls people into PrEP programs, people who are, who desire PrEP or who are eligible for PrEP. And previously, when the only thing we had available to offer where the oral options, we frequently had lots of African American women decline to be on PrEP.

And since we've had cabotegravir as part of our toolkit, a lot of our clients are now a lot more willing to have the conversation, again, because it's discreet, they don't feel that they have to address the issues around stigma, and they also like the convenience of not having to take a pill every day. So, this already is allowing us to be able to get more people connected to PrEP care, and particularly among populations that have traditionally not been the ones that have had the best access to PrEP in the United States. We know that uptake for PrEP is pretty low in African American women, whereas they are one of the target groups that have the highest rates of new HIV infections within the context of the U.S.

Christina M. Madison, PharmD, FCCP, AAHIVP:

Thank you very much, Dr. Titanji for bringing that up. It's something that I'm personally very passionate about as far as getting access specifically for African American women around PrEP. And I do think that having these long-acting options has really changed the narrative around showing that that population has options that are able to overcome some of the possible issues around stigma and maybe not thinking, "Oh, that's not for me," just because of the fact that we know that a lot of the oral medications have been heavily marketed towards other groups in the past.

So, Dr. Orkin, can you dive a little further into summarizing some of the key findings? And then obviously I would love to have Dr. Titanji weigh in as well, if you could expand upon further data around the cabotegravir efficacy and safety data.

Chloe Orkin, MBE, MB BCh, MSc:

Sure. I'd love to do that. But I think before I do that, I just might say that my experience in the United Kingdom (UK) really chimes with what both of you are saying in an interesting way, because we don't have access to cabotegravir. Well, we're starting to, it's being approved, but we're just starting to use it so we don't have lots of people on it yet. But interestingly, we are doing the PURPOSE 5 study, which is lenacapavir 6-monthly injectable study for UK and France. What we noticed is that women came forward, cisgender women came forward for the first time, women that we've not been able to engage in PrEP, they did want it. It's not that they didn't understand that they needed it, they didn't want oral therapy. So, it's fascinating to see how when you actually give an offer that is a wanted offer, suddenly it's taken up. So, it was really fascinating for us to see that.

But going back to cabotegravir, so as Dr. Solomon mentioned, there are two large studies, randomized studies, which have underpinned the development of cabotegravir, namely the HPTN 083 study, which was a large study of about 4,500 people. And the participants were cisgender men who have sex with men and transgender women who have sex with men. And it was done in a number of countries and HPTN 084, a slightly smaller study, 3,200 participants. And this study was people that were assigned female sex at birth in seven countries in Sub-Saharan Africa. And in both of the studies, there was a study design which compared cabotegravir rilpivirine 2-monthly in a double-blind, double-dummy fashion. And there were non-inferior active controlled studies, which meant that the participants either received pills plus an injection placebo or cabotegravir injections plus pills placebo, and the tablets were TDF/FDC.

So, TDF/FTC was compared against cabotegravir rilpivirine, but the participants really had to be committed because they had to take a placebo of an alternate placebo. And what was found in the HPTN 083 study is that cabotegravir reduced the HIV incidence by 66% compared with daily TDF/FTC. So, very, very significant results meeting criteria of superiority. And in the HPTN 084 study, similar findings, an 88% reduction in HIV incidents compared with TDF and FTC, once again, evidencing superiority. And the adherence was much, much, much, much, much better in both studies versus oral TDF/FTC. And the injection site reactions are as expected in the cabotegravir as treatment program. They tend to last between a median 3-7 days, and they tend to be largely grade one and two, they go away quite quickly. So, I think those are the most important findings to report from those two studies.

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

I think that the only thing I would add to what Chloe has so very clearly and brilliantly summarized is one of the most exciting things about the cabotegravir data is that we have robust data from cisgender women in Sub-Saharan Africa. A lot of the early PrEP studies were primarily focused on other risk groups in European countries or higher income settings, notably men who have sex with men. So, this, again, emphasizes the fact that when you have options that are adapted to what women want or what a particular population wants, you get not only adherence, you get also to show that that intervention is effective. But I would also go back to the access issues we continue to see in Sub-Saharan Africa to emphasize that while we have these data that show that it is robust, it is effective, in this particular population, a lot of women in these settings continue not to have access to this particular intervention because there's still issues and barriers in terms of approvals locally, as well as being able to make these medications available to the communities that want them and need them.

Christina M. Madison, PharmD, FCCP, AAHIVP:

Dr. Solomon, can you walk us through the highlights here specifically for lenacapavir?

Sunil Suhas Solomon, MBBS, PhD, MPH:

Great. And I think lenacapavir really is the newest kid on the block for long-acting PrEP. It was approved by the FDA in June, 2025, really based on the data coming out of PURPOSE 1 and PURPOSE 2. So, both those trials were actually halted by the Data and Safety Monitoring Board (DSMB) for efficacy. I did not think in my lifetime I would ever see a product that was 100% efficacious, and that's what the finding was for PURPOSE 1, and where amongst cisgender women in Africa there was zero new infections in the lenacapavir arm. And it was superior to oral F/TDF. So, the design really was comparing it to a background incidence, and so it met the primary endpoint criteria.

I think what is also interesting with the whole PURPOSE program is there's also a PURPOSE 3, PURPOSE 4, and a PURPOSE 5, which Dr. Orkin talked about. So, PURPOSE 4 really is looking at the acceptability in pharmacokinetics of lenacapavir among people who inject drugs in the U.S. And the reason I point that out is because in terms of roots of administration, there were additional roots in addition to the abdominal area that were shown to be favorable for injections of lenacapavir, including the thighs. And so we are using alternative routes for injection subcutaneously. And so, it does expand the options and the feasibility of actually using it in clinical practice, but it also lends itself to, could we deliver this on vans? Could we deliver this in people's houses? And so, it's really opening up avenues to improve access to lenacapavir.

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

Within our clinic, we actually just had our first lenacapavir client user. So, that's very exciting. In the U.S., depending on where you are located, of course, there are issues around insurance and coverage, which again is another barrier to accessing treatment. But it's very, very exciting to have this option because just the added convenience of being able to only need the intervention twice a year and having that level of efficacy is something that I think even with the way in which we've seen the demographic shifts in terms of demand with cabotegravir, we are going to see a lot more African American women engaging with PrEP care because when we have lenacapavir more widely available, it's just such a transformative option to be able to offer to people.

Chloe Orkin, MBE, MB BCh, MSc:

I'm going to make a more study-related point, and that is that I'm just really glad that Dr. Solomon pointed out the difference in study design between HPTN 083 and 084 and the PURPOSE trials, because the cabotegravir studies were compared against oral therapy, oral PrEP, whereas the lenacapavir (LEN) studies were compared against background incidents. So, it's important that one can't cross-compare the studies directly because they are fundamentally different in their study design. They're both very effective, incredible improvements on oral PrEP. And I think that is fundamentally important to say.

What I can say from my experience with the 18 people that are taking LEN in our study is that, as you say, they are clamoring for it. The exact people that we've been working with for years and doing surveys around hypothetical interest came forward, as they said they would, and have remained engaged and still receiving their injection several injections along. So, it's really positive what we've seen.

Christina M. Madison, PharmD, FCCP, AAHIVP:

So, moving on to some of the efficacy and safety data, Dr. Orkin, Dr. Titanji, what stands out for you from these data?

Chloe Orkin, MBE, MB BCh, MSc:

Well, for me, I think it's just that the population in PURPOSE 2 has expanded the population from PURPOSE 1. It's in more countries, it's in six countries. The efficacy is really robust across different populations. And just again, the adherence and retention is so high, and the injections are absolutely acceptable to the participants on the basis of the study. And adherence is super high and really not comparable, particularly in the PURPOSE 1 study to oral PrEP.

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

Yeah, and I will again reiterate that it was really nice to see that PURPOSE 1 focused on recruiting cisgender women in Sub-Saharan Africa, a population that has not always been the one that's been prioritized in these sorts of clinical trials. And we were able to see that the discontinuation rates were really low in PURPOSE 1 and the safety data was really robust. And of course, the intervention was highly efficacious. And we know that that is the target group that still represents the most vulnerable group in terms of the numbers of new infections that are reported every year in that part of the world. And I think that what we should take from this study is not only the fact that we've been able to demonstrate that the intervention is efficacious, but continue to leverage it as a way of advocating to actually getting these interventions widely available to people in Sub-Saharan Africa, notably cisgender women who continue to be one of the most impacted groups by HIV.

And I would close my point by saying that for the first time with these options for prevention, we really have tools that can effectively interrupt HIV transmission, and that is the way in which we end the HIV epidemic is by making sure that we're utilizing these tools to their maximal benefit and reducing the numbers of new HIV infections that we're seeing globally.

Sunil Suhas Solomon, MBBS, PhD, MPH:

And Christina, if I may just add, I think the one thing we should point out is there were some adverse events, but most of them were injection site reactions. But yes, they're common, they happen in quite a few people, but less than 1% of the participants, actually 0.2% in PURPOSE 1 and about 1.2% in PURPOSE 2 actually stopped the lenacapavir injections due to these injection site reactions. So, yes, it is great, but there are some injection site reactions your patients are going to complain about. But remind them that it's efficacious and very few people actually ended up discontinuing the medication due to these injection site reactions.

Christina M. Madison, PharmD, FCCP, AAHIVP:

I think that's a really great point because, again, we know that all medications potentially have the risk of having an adverse effect. So, being upfront with the patient I think is really important, especially when we talk about the nodules that could be potentially developed after injection, and the fact that they can last for a while, it could be months before you see some dissolution of that. So, I think it's just really important to talk with them. I mean, obviously risk versus benefit, the benefits definitely outweigh the tiny nodule that you may get at the injection site. So, I think a lot of patients are definitely more likely to stay on that therapy because of the fact that it wasn't enough for them to need to discontinue. So, I appreciate that.

Moving on, I did want to ask you, Dr. Solomon, if you could walk us through the current regulatory landscape as to where these long-acting injectable options are approved and what that means for implementation on the ground.

Sunil Suhas Solomon, MBBS, PhD, MPH:

So, I think as I mentioned earlier, CAB was approved in 2021 by the FDA and lenacapavir in 2025. So, CAB obviously has a lot more approvals. They have about 30 approvals covering 62 countries with one pending, and the most recent was Vietnam that was added to the list. Lenacapavir has about 15 approvals and eight pending. And as Dr. Orkin already mentioned, it's much more challenging to get long-acting therapies in the UK. Cabotegravir is available, via PURPOSE 5, they have access to Lenacapavir. So, I think what that really means is it's a constantly evolving landscape of what is available in your country. So, looking at local regulatory authorities or resources like PrEPWatch to tell you what is available in your particular setting will help you make an informed decision with your patient who's sitting in front of you, "What is the best medication for you given what we have here today?"

With that being said, I think regulatory approvals is one thing, access is a different thing. So, while these regulatory approvals are happening, it's also important for programs without thinking about access, whether it's programs such as PEPFAR or the Global Fund or local government programs, like, "Who are the right populations? How do we roll it out?" So, I think those conversations need to be happening as these regulatory approvals and processes are in place.

Christina M. Madison, PharmD, FCCP, AAHIVP:

We know that many of our primary care providers may feel unprepared to prescribe or to discuss PrEP options. I wanted to take a moment to discuss some clinical pearls that we can extend to our global audience to make them feel maybe a bit more comfortable.

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

Yeah, you raise a very important point, which is I think one of the biggest barriers to PrEP is that we don't offer it enough. And that's because there's this notion that in order to be able to offer PrEP, you should be someone who is an HIV care provider or trained in infectious diseases. I try to emphasize to all clinicians that if you are a clinician and you are in contact with patients, that you are someone who should feel empowered to be able to offer PrEP because it is a preventative modality that practitioners should be familiar with and should be comfortable with offering. And I think that the first point of conversation is getting practitioners to be able to even have the conversation or think about who is eligible for PrEP. The person who is eligible for PrEP is anyone who has an HIV negative test and who wants PrEP.

You shouldn't require that the person prove that they have a certain risk profile for you to have the conversation about PrEP. And I think that there's so many missed opportunities when we interact with individuals in clinical practice where we fail to be able to have the conversation about PrEP because they're coming in for something else and you've not thought about it. And I think that in order to get to that point is continuing to remind providers that HIV is still very real, and more importantly, that we have tools that can help prevent HIV acquisition, and that thirdly, these tools are safe and highly efficacious. And lastly, that they can prescribe it without necessarily having formal treatment as HIV physicians or as infectious diseases experts.

Christina M. Madison, PharmD, FCCP, AAHIVP:

PrEP care is not specialty care, it's everybody care. And I feel we all deserve to have a sex life that is free from feeling like we may have been exposed to something because we're already protected. Dr. Orkin?

Chloe Orkin, MBE, MB BCh, MSc:

Yeah, I so agree with you. And I feel really frustrated at times because in the UK, there's a lot of teaching of medical students and an ethos in the hospital, "Make every contact count." We call it MEC training. And that means if you're seeing someone, you should ask them about smoking, you should measure their blood pressure. No matter what you're doing, you should try and use it as an opportunity for prevention to improve people's health. And somehow PrEP, which is such a simple intervention, just does not form part of this conversation. And I think this is just because we're not comfortable. We don't want to raise the idea of sex. We'd rather talk about measuring someone's blood pressure than this absolutely life-saving intervention, and it just hasn't made the cut in the way that it should do as being part of everyday conversations.

And I think this is a real issue because in reality, it's a drug that can be easily prescribed, oral PrEP, and you need some monitoring, a renal monitoring, but actually it's a very low risk intervention. And the injectables, again, are very tolerable. But people have got to take responsibility for having that conversation. And it's about how do we do that?

Christina M. Madison, PharmD, FCCP, AAHIVP:

Did you want to talk a little bit about the comorbidities and any of the follow-up that may be necessary?

Sunil Suhas Solomon, MBBS, PhD, MPH:

So, I think as Dr. Orkin and others mentioned, the biggest challenge really is getting them to be comfortable. I think we notice very often when I talk to people outside of the HIV field, sex is not a topic they're comfortable asking people about. So, that's the first thing that has to happen. But there are comorbidities and we also have to figure out, like I said, what's people's plans? How often do they want to come in? Do they want medications delivered to them? Which happens in many countries across the world. There are some toxicities to the bone and renal toxicities that people need to talk about, but those really can be addressed through educational programs like this. I think the challenge really with primary care practitioners (PCPs) and getting them really is to really get them to feel comfortable asking the person in front of them, "How's your sex life?" And I think that really is the biggest challenge we're facing.

Chloe Orkin, MBE, MB BCh, MSc:

Yeah, I couldn't agree more. And the algorithms, digital pathways in the UK where PrEP is provided, you click a link, you get assessed according to your complexity, you're given PrEP, you have your blood tests. It's not complex. It's just that we have our own barriers as healthcare providers about initiating these conversations, and we need to be honest that we'd rather talk about smoking than about PrEP. And that has a consequence to individuals who then end up acquiring HIV because of our discomfort.

Sunil Suhas Solomon, MBBS, PhD, MPH:

It's going to be an interesting time to see how these different products are used.

Christina M. Madison, PharmD, FCCP, AAHIVP:

Yeah. Can we maybe expand into staying with this concept of eligibility? We have some considerations, some baseline considerations that I'd love for you to discuss with us, Dr. Solomon.

Sunil Suhas Solomon, MBBS, PhD, MPH:

Sure. I think given that PrEP is to prevent HIV acquisition, probably the most important thing you want to do is ensure that whoever you are screening for PrEP is confirmed as not being infected with HIV, either with fourth-generation antigen antibody tests. And if there's recent exposure, consider an HIV RNA. You want to make sure the renal function is normal because some regimens have more favorable safety profiles, as Dr. Orkin mentioned. You also want to look at age and pregnancy because based on available data, available guidelines, you need to figure out what works for the particular person sitting in front of you. There are barriers I think that everyone has talked about, including stigma, patient level barriers, logistical barriers. So, trying to figure out which is the right regimen in the selection is something to consider.

The other thing I would probably include here is also looking at hepatitis B surface antigen. I think that's something that's very important to look at because two of these regimens, F/TDF and F/TAF, if you're giving it in people who are co-inflicted with hepatitis B, there is a risk of or hepatic flare when you stop it. So, you want to be very careful about starting and stopping F/TDF and F/TAF in people who are coinfected, versus people who are getting on CAB or lenacapavir, there is no action on hepatitis B, and so you probably want to monitor hepatitis B infections separately in these individuals.

Christina M. Madison, PharmD, FCCP, AAHIVP:

So, the prevention pipeline continues to evolve. So, Dr. Orkin, what's on the horizon? What should we be looking forward to?

Chloe Orkin, MBE, MB BCh, MSc:

Well, at CROI last year, there was literally you could have heard a pin drop, they told us that there may be the possibility based on Phase I data of once yearly intramuscular (IM) dosing lenacapavir as PrEP, therefore even further reducing the number of injections. So, that was a wow moment. Let's hope it happens. And then the other option is MK-8527, nucleoside reverse transcriptase translocation inhibitor (NRTTI), which is a once monthly oral option. Again, not everybody wants injections. So, actually giving this flexibility is really important. It's much lower frequency and it is a really viable alternative, very interesting as well. So, both of those things, super exciting.

Christina M. Madison, PharmD, FCCP, AAHIVP:

There are a range of patient education tools, many available on CME Outfitters' website. Dr. Titanji, what tools do you think we could use to help frame the basics?

Boghuma K. Titanji, MD, PhD, MSc, DTM&H:

Yeah, I always like to say that when I'm approaching a new client and offering PrEP is that my job is to offer you options and you choose what option best fits your life.

Christina M. Madison, PharmD, FCCP, AAHIVP:

So, to close, we want to leave you with three practical goals you can take back to your setting. The first, because, again, we want to make sure we have SMART goals here that are specific, measurable, attainable, relevant, and timely. So, the first is use a PrEP option counseling aid to initiate PrEP discussions and support shared clinical decision-making in your choice or practice team in the next 30 days. Implement a standardized PrEP initiation approach for both daily oral PrEP and long-acting options, including appropriate HIV testing and symptom assessment per local guidance within the next 60 days, and then to develop and apply a clinical workflow to support ongoing PrEP use, including plans for missed doses or injections with oral PrEP bridging when appropriate, patient follow-up reminders, use of patient education materials, and discussion of clinic resources to address cost and access barriers within the next 60 to 90 days.

I would like to personally thank our faculty for sharing their insights, and thank you to our audience for joining us today. We encourage you to explore the additional resources linked with this activity and continue the conversation in your own practice. We would also like to invite you to visit the CME Outfitters Infectious Disease Hub, which includes free evidence-based resources for both healthcare professionals and patients. These tools are designed to support practical implementation. As a reminder, this activity is part of a broader HIV prevention education series. We encourage you to explore these programs and to continue building on today's discussion.

Before we wrap up, just a quick reminder that to receive CME or CE credit for this activity, you will need to complete the post-test and evaluation online. Once completed, you'll be able to download and print your certificate immediately.