Episode 13 - HIV Pre-exposure Prophylaxis (PrEP)

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Episode Summary:
In this episode of Everyday Medicine, Christopher Chiu is joined by clinical pharmacist Lindsey Lee, who provides an in-depth overview of PrEP (Pre-Exposure Prophylaxis), its effectiveness in preventing HIV, the populations that should be considered for PrEP, and the disparities in its usage. They discuss various PrEP medications, including oral options like Truvada and Descovy, and the injectable Apretude, addressing their indications, side effects, and monitoring requirements. Lee also talks about prescribing practices, counseling patients, and ensuring adherence to PrEP regimens, as well as resources for patients who face financial barriers to accessing PrEP. The episode highlights the importance of primary care physicians in managing and discussing PrEP with eligible patients.

In-Depth Show Notes:

Introduction
In this episode of Everyday Medicine, Dr. Christopher Chiu interviews Clinical Pharmacist Lindsey Lee about Pre-exposure Prophylaxis (PrEP) for HIV prevention. The discussion covers patient selection, medication options, monitoring requirements, and practical implementation in primary care settings.

Understanding PrEP and Patient Selection
PrEP (Pre-exposure Prophylaxis) medications are approximately 99% effective at preventing HIV transmission through sexual exposure and 74% effective for injection drug use prevention. Despite approximately 1.2 million Americans being eligible for PrEP, only about 30% currently take these medications, with significant disparities in usage among racial and ethnic groups.

Key patient populations who should be considered for PrEP include
- Sexually active individuals with recent bacterial STIs
- Those with HIV-positive sexual partners (particularly with detectable viral loads)
- Individuals using condoms inconsistently with multiple partners
- People who inject drugs
- Anyone engaged in transactional sex

Medication Options and Selection
- Oral PrEP Options:

    - Truvada (and generics):
        - First-line choice due to generic availability and better insurance coverage
        - Can be used in all populations
        - Requires creatinine clearance ≥60
        - May cause small decreases in renal function and bone mineral density
    - Descovy:
        - Alternative option for patients with reduced renal function (CrCl ≥30)
        - Only approved for patients assigned male at birth
        - May cause lipid elevation and modest weight gain
        - Not approved for receptive vaginal sex
- Injectable Option (Apretude):
    - Administered every two months after initial loading doses
    - Option for patients unable to take daily pills
    - No renal function monitoring required
    - Requires strict adherence to injection schedule
    - Maintains detectable levels for up to one year after discontinuation

Monitoring Requirements

- Baseline Testing:
    - HIV antibody test (within one week of starting)
    - Comprehensive STI screening
    - Renal function
    - Hepatitis B serology
    - Hepatitis C testing for high-risk populations
    - Lipid panel (for Descovy)
- Follow-up Monitoring:
    - HIV testing every 3 months (antibody and viral load recommended but can be modified based on barriers)
    - Hepatitis C testing for high-risk populations
    - STI screening every 3-6 months based on risk
    - Renal function every 6-12 months
    - Annual lipid panel for Descovy users
    - More frequent monitoring required for injectable PrEP

Special Considerations

- The 2-1-1 Method:
    - Alternative dosing strategy for MSM using Truvada
    - Involves taking doses before and after sexual activity
    - Limited to specific populations and requires careful patient selection
    - Requires continued monitoring despite intermittent use

Practical Implementation

- Medication Access:
    - Most insurance plans cover PrEP medications
    - Manufacturer assistance programs available
    - Generic Truvada available through discount programs
    - Patient assistance programs can help with costs
- Patient Counseling:
    - Time to protection varies by exposure type (7-21 days)
    - Importance of adherence
    - Need for continued condom use for STI prevention
    - Regular monitoring requirements
    - Management of missed doses

Conclusion

Episode 13 - HIV Pre-exposure Prophylaxis (PrEP)

PrEP represents a crucial tool in HIV prevention that can be effectively managed in primary care settings. Success requires careful patient selection, appropriate medication choice, consistent monitoring, and attention to adherence. Primary care providers should proactively discuss PrEP with eligible patients and develop systems to support ongoing monitoring and management.

Transcript:
This transcript has been edited for clarity

[00:00:00] Introduction to Everyday Medicine

[00:00:00] **Christopher:** Welcome to Everyday Medicine. I'm Christopher Chiu. This is a podcast from the Division of General Internal Medicine at The Ohio State University, where I'm the Director of Education for the Division. This podcast is focused on primary care and aims to provide current information to medical professionals from experts in Ohio. We're also graciously sponsored by collaboration with the Ohio Chapter of the American College of Physicians.

I have a wonderful guest with me today. We're going to talk about PrEP therapy. The reason why I wanted to talk about this is because there have been some fairly "newish" recommendations on this and I thought who better to bring on than the person I learned all the things I know about PrEP than the pharmacist that we had here in the clinic.

[00:00:53] Guest Introduction: Pharmacist Lindsey Lee

[00:00:53] **Christopher:** So I have pharmacist Lindsey Lee.

[00:00:55] **Lindsey:** Yeah, my name is Lindsey Lee. I'm a clinical pharmacist at OSU General Internal Medicine. And I was very involved in the development and implementation of our pharmacist led PrEP services. So getting patients on PrEP medications is something I'm very interested in, so thanks for having me.

[00:01:10] **Christopher:** Yes.

[00:01:10] Understanding PrEP Therapy

[00:01:10] **Christopher:** So let's start off with what does PrEP stand for? Because it's an acronym.

[00:01:15] **Lindsey:** Yeah. So it stands for pre-exposure prophylaxis. It's a group of medications that greatly reduce risk of acquiring HIV through sexual exposure or also injection drug use. So we know they're about 99 percent effective at preventing it through sex and at least about 74 percent effective at preventing it through injection drug use.

[00:01:34] Who Should Consider PrEP?

[00:01:34] **Christopher:** Now, who are the people we're going to try to get on PrEP? Who are the people we should be looking at talking to in the clinic?

[00:01:39] **Lindsey:** Good question. Yeah. The CDC said that there's about 1. 2 million people in the United States are eligible for PrEP, but only about 30 percent of those are actually taking PrEP

medications and there's a lot of inequity within that. So, disproportionately lower usage amongst our Black and Hispanic patients.

As of 2021, about one quarter of those groups who are eligible for PrEP were taking medicines, compared to about three quarters of our white patients who are eligible that are taking PrEP.

[00:02:06] **Christopher:** Of these patients that we're looking at, who should we be offering this to?

[00:02:10] **Lindsey:** Yeah. So it's recommended to inform all sexually active patients of PrEP as an option. That way they can make the decision for themselves, but there's a few higher risk groups that we want to look at. So first looking at sexual exposures. So patients that have had anal or vaginal sex in the past six months, if they have any additional risk factors.

So they've had a bacterial STI in the last six months, whether that's chlamydia, gonorrhea, syphilis. Caveat there would be chlamydia in women. Because it's so common, it doesn't necessarily predispose them to HIV, like the other STIs, but this is a good thing to look at because if they've had an STI, that probably means they're having unprotected sex and at risk.

[00:02:49] **Christopher:** Now, when we're taking history, it matters what type of intercourse they're having, whether vaginal, anal, or even oral.

[00:02:55] **Lindsey:** It's good to get that information because the type of sex is going to impact their risk of getting HIV. There's a really great tool on the CDC. It's called the HIV Risk Reduction Tool.

And you can play around with it when you're talking to patients, but you input the type of sex they're having, if they're using protection, if they're on PrEP, and it shows their risk of getting HIV.

[00:03:15] **Christopher:** Are there any other history things that we should be getting from our patients to help us decide whether they should be a candidate for PrEP?

[00:03:21] **Lindsey:** Yeah, so if a patient has an HIV positive sexual partner, specifically someone who has a detectable or an unknown viral load, can benefit from PrEP. If they're undetectable, risk of transmission is effectively zero. And then the other group to look at would be patients who are inconsistently using condoms or not using condoms with multiple partners.

[00:03:41] **Christopher:** Now we can offer this to even high risk patients outside of just sexual history, is that correct?

[00:03:46] **Lindsey:** Correct. So patients who inject drugs, specifically those who may have an HIV positive injection partner, if they're sharing injection equipment, a lot of those groups are vulnerable for sex in exchange for resources, so looking at those as well.

[00:03:59] **Christopher:** Gotcha. I think when we just think about most of the things that we think are traditionally high risk for HIV, it seems to fall under most of these categories. Is that correct?

[00:04:07] **Lindsey:** Yes. And, even if a patient falls outside of these categories, if they're interested in PrEP, by all means, there's not really any reason not to prescribe it as long as they don't have any contraindications.

[00:04:18] **Christopher:** And so I guess we should start talking about medications then, because I do think that different indications are allowed different medications. And so it makes a difference in terms of the history, which medicines we go with. Is that correct?

[00:04:29] **Lindsey:** Correct.

[00:04:30] Oral Medications for PrEP

[00:04:30] **Lindsey:** So I can hop right into the oral medications. We have two orals. Those are Truvada and Descovy. I typically go with Truvada. In most cases, because it has a generic, and I've just found that insurance is covered a little bit better, contraindication or reason not to use Truvada would be a patient with a creatinine clearance less than 60.

[00:04:49] **Christopher:** And that's one thing that I've run across in my own patients is someone who was sort of on the cuff before, and then their renal function is slowly worsened over time and I've had to switch them. And so what's the other medicine that we can use of the orals?

[00:05:02] **Lindsey:** Yeah, so the other oral would be Descovy which we can use down to a creatinine clearance of 30. Main thing to keep in mind with Descovy is that you can only use it for patients assigned male at birth. So it's not been studied in receptive vaginal sex, so we can't use it in our female patients.

[00:05:19] **Christopher:** Oh, interesting. So what are some of the side effects that we have to deal with or worry about when we counsel our patients when using either of these medications?

[00:05:27] **Lindsey:** So looking at some of the longer term side effects with Truvada. There's been some small decreases in renal function seen in studies. This is most likely to be reversed when the medication is discontinued, and higher risk is going to be amongst those older patients, so patients over 50 and those who may have had some renal dysfunction at baseline. But again, we can use the orals down to a creatinine clearance of 30. So that's just one of our deciding factors here. Another thing that was seen with Truvada was small decreases in bone mineral density. So about a 1 percent decline in the first few months after starting Truvada. But that stabilized or returned to normal after discontinuing the medicine and no real increase in fragility fractures or clinically meaningful adverse effects.

[00:06:07] **Christopher:** Is there anything else we have to worry about with these oral medications at least?

[00:06:11] **Lindsey:** With Descovy, there's been some increases in lipid levels, specifically in the triglycerides, and also a small amount of weight gain. So about one kilo gained after 48 weeks in trials.

[00:06:23] **Christopher:** So it sounds like we'll talk about monitoring in a second. I want to get to some other medications for PrEP because there's another form of PrEP that we can use. I'm not as familiar with this. Can you just explain that a little bit?

[00:06:34] **Lindsey:** Yeah.

[00:06:34] Injectable PrEP: Apretude

[00:06:34] **Lindsey:** So the other formulation is Apretude. It's an injectable intramuscular that is given every two months. This is an option for patients that can't take a daily pill. We'll talk about this a little bit more later, but it is very important that patients are on time with their injections with this medication.

[00:06:51] **Christopher:** And these injections, can they be self administered? Do they have to come to the clinic like we do with a depo or?

[00:06:57] **Lindsey:** They do have to come into the clinic. And so this does mean more frequent clinic visits because they're every two months compared to our every three month visits for the oral PrEP and so again, picking good candidates for this medication that are going to be adherent to coming in and getting their labs and getting the injection is super important with the Apretude.

[00:07:14] **Christopher:** I don't know if I missed this, did you say something about renal function with this medication?

[00:07:18] **Lindsey:** No, so that's another good thing about Apretude is if they have a creatinine clearance less than 30, we do have this option of using the injectable Apretude, we don't even have to monitor renal function for these patients.

[00:07:28] **Christopher:** Any other contraindications for Apretude?

[00:07:31] **Lindsey:** Nope, no other contraindications.

[00:07:32] **Christopher:** Fantastic. Maybe we should, are we doing any of these in our clinics right now?

[00:07:36] **Lindsey:** We're doing some, but kind of how I alluded to, it takes a very special patient to be able to come in and do these extra visits. Once Apretude is injected, it stays in the body for about a year. But we note that after two months, the concentration is too low to protect against HIV. So it has this very long tail, where the patient's at risk of HIV, risk of resistance. And so the bulk of our patients tend to just do a little bit better with the orals.

[00:08:00] **Christopher:** All right. Well, let's start talking about what happens after we start a medication or at least as we're looking at starting medication.

[00:08:06] Baseline Labs and Monitoring

[00:08:06] **Christopher:** So are there baseline labs that we should get before we decide on the medication. Obviously it sounds like renal function is a big thing, but are there other things that we need to be checking?

[00:08:14] **Lindsey:** Yeah. So before starting the oral PrEP medications, like you said, renal function, also doing STI testing at baseline. We're going to check for hepatitis B serology.

Reason there is that Truvada and Descovy can treat hep B infection. So we want to know early on if they have that. That way, if we discontinue in the future, we're mindful of any hepatitis flares and monitoring that. Hepatitis C serology for patients at risk, so men who have sex with men, people who inject drugs, transgender women. Lipids for Descovy because like I said, they can increase the lipid levels. And then the most important thing here is HIV testing. So within a week before starting oral PrEP, we do want to do an HIV antibody test, and then also assess any symptoms of an acute infection.

[00:08:57] **Christopher:** So one question I have is when you say STI screening, can you explain that a little bit? Is it like which STIs is my screening for? And especially, we're probably going to talk about gonorrhea chlamydia. Are there special sites that we're supposed to look at, or other sites that we don't have to worry about?

[00:09:11] **Lindsey:** Mm hmm. So, gonorrhea, chlamydia, syphilis are the STIs that we're checking for on a regular basis. When we're doing a sexual history with a patient, we want to know what type of sex they're having, and that determines the sites that we're doing this testing at.

So if they're having anal sex, we want to do a rectal swab. If they're having vaginal sex, doing a urine or vaginal swab, oral sex and oral swab. Dr. Magana, I know, did a really great presentation on STIs, further in detail, so that would be good to look at as well.

[00:09:39] **Christopher:** I just want to be clear that... we can use self swabs in these cases most of the time.

[00:09:43] **Lindsey:** Yeah, so the patients are able to self collect the rectal and oral samples, and then they typically just leave a urine sample as well, so that can all be done at the lab. Walk in, no appointment needed.

[00:09:54] **Christopher:** Excellent. So these are the things that we're going to start. They otherwise look pretty good based on renal function. We might decide which oral medication, or even possibly injectable that we use.

[00:10:04] Counseling Patients on PrEP

[00:10:04] **Christopher:** How do we really counsel the patients on. What happens after we start the medication? Is there a time when they're not supposed to have sex or do other things?

[00:10:13] **Lindsey:** So, once everything comes back within normal limits, we can then send in a 90 day supply of their medications. So the first counseling point with the patient is that they do have to be seen every three months for these labs and monitoring.

That's why we're only sending in the 90 day supply. As far as potential side effects, more commonly might cause some headache, nausea, stomach upset those first couple of weeks, but that typically gets better with time. Can take some over the counters to help with those. It does take some time to reach protective levels, so about seven days for receptive anal sex and about 21 days for receptive vaginal sex and injection drug use.

So during those times, really limiting high risk behaviors, making sure to use other forms of protection. Unfortunately, not any data out there on insertive anal sex or vaginal sex for time to protection.

[00:10:59] **Christopher:** Gotcha. And so, what if, we sort of talked about adherence a little bit, especially with injectables. What do we counsel patients in terms of if they miss doses? What should they do after that? Are there things they have to worry about?

[00:11:11] **Lindsey:** Mm hmm. Yeah, so adherence to these medications is very important. We know that when you miss doses, the efficacy starts to wear off, especially if it's been seven to ten days. So when I'm talking to patients, I always tell them, you know, if you have an insurance issue or you forgot the medicine

when you were traveling and you were off of it, call us before restarting. That way we can do those baseline labs again, HIV testing and everything before you restart it.

[00:11:34] **Christopher:** All right. Any other things that we should counsel patients about?

[00:11:37] **Lindsey:** The last thing I always mention is to continue to use condoms to protect yourself from STIs because PrEP will only protect them against HIV.

[00:11:46] **Christopher:** Now, you said something about providing only 90 day supplies of medications. Is this something that will always be what you do or, you know, obviously we want to try to promote adherence. And so giving longer dispenses of medications with refills seems to make a lot more sense in these patients. But, obviously you want to be able to monitor them. So you sort of keep a little grip on them. What would you recommend in these cases?

[00:12:08] **Lindsey:** Yes, you can send a 90 day supply, with zero refills over to the pharmacy. A lot of insurances cover those 90 day supplies. That way they only have to go every three months. Of course, if a patient's going to be like a couple of days late getting to their labs, we don't want to withhold the medication. So sometimes we'll send over a short bridge supply to last until their appointment.

[00:12:25] **Christopher:** So tell me what do follow ups look like? I think you said 90 days. So is it always 90 days can ever be more lax than that? Sounds like if it's a little more, especially in terms of prescribing refills, you might need to bridge.

[00:12:36] **Lindsey:** Yeah, so follow up is going to be every three months. That's what the CDC recommends for repeat HIV testing. So at those visits, we're doing the HIV testing. HIV testing at follow ups is a little bit different because we're checking both the antibody and the viral load in addition to those acute symptoms. Reason for this is that PrEP can suppress the early viral replication and delay the time to a positive HIV antibody. So the viral load is a little bit more sensitive for a test to use.

[00:13:05] **Christopher:** Now tell me this viral load is sort of a newer recommendation, right? And so, it can be sort of expensive for some patients, especially doing it every three months.

Is this a hard, fast rule? I've heard you've even reached out to the CDC on this. Can you. Talk about the story a little bit and what's going on with this.

[00:13:22] **Lindsey:** Yeah, well, specifically at OSU, one of the barriers we've run into is the viral load takes several days to come back. So we're often waiting on that before sending the refills. So I called the CDC PrEP hotline. They have PrEP experts that can answer questions. They're super helpful. They agreed that the viral load is recommended in the guidelines with the purpose of being extra cautious. But they did tell me if this is a barrier to care, if the patient can't afford it or they're not wanting to wait until it's back to get their refill sent in, they feel comfortable only assessing the antibody before refilling PrEP.

[00:13:54] **Christopher:** Are there other tests that we should do on a routine basis for these follow ups?

[00:13:58] **Lindsey:** Yeah. So STI testing every three to six months, just based on risk factors. Renal function, we're going to check every six months for those patients at higher risk. So if they're over 50 or if their creatinine clearance is less than 90 at baseline. Every 12 months for all other patients.

Lastly, every 12 months, we're going to check the lipids for those patients on Descovy and again, testing hepatitis C status for those higher risk populations.

[00:14:23] **Christopher:** So one question I have, because so many of these medications always say, you know, creatinine clearance. I never calculate the creatinine clearance and I look at the eGFR. I don't think our labs report creatinine clearance. What do you do in your practice?

[00:14:37] **Lindsey:** I do calculate creatinine clearance. I use a website called GlobalRPH and they have a calculator built in. Put in the patient's age, weight, all that. I know within Epic, IHIS, you can type like dot CRCL and sometimes it'll pull up for you too.

[00:14:51] **Christopher:** Oh, I've never used that. I don't have to use that. Anything else you want the audience to know when it comes to these follow ups?

[00:14:59] **Lindsey:** At each visit we're also counseling on the importance of adherence. Letting us know if they do have any symptoms of HIV, STIs, that way they can reach out to us sooner than those every three month follow ups.

[00:15:10] **Christopher:** Alright.

[00:15:11] Intermittent PrEP: The 2-1-1 Method

[00:15:11] **Christopher:** Now, tell me about, what's the 2 1 1 method?

[00:15:14] **Lindsey:** Yeah, so this is also called intermittent or event driven PrEP. It's an oral PrEP option for men who have sex with men using Truvada, specifically those who have infrequent sex or those who can anticipate sex. So they'll take two pills, between two and twenty four hours before the sexual event, one pill twenty four hours later, and then one more pill, forty eight hours after that initial.

Again, I want to emphasize this is only for men who have sex with men using Truvada and it is off label. But the CDC guidelines recommend prescribing no more than 30 pills at a time and then still doing that regular HIV and STI testing.

[00:15:49] **Christopher:** So, I'm confused. So this is in addition to daily Truvada or is it to replace so they can do it intermittently?

[00:15:57] **Lindsey:** So this is to replace. They do not have to take a daily pill. They can just do it intermittently so for those patients who can anticipate maybe they're going to have one sexual event every couple of weeks and they don't want to take a daily pill, they can use this option.

[00:16:11] **Christopher:** Now do you still follow these patients every three months like you normally would with anyone else who's doing the orals on a daily basis?

[00:16:18] **Lindsey:** Yep, we still do that every three month follow ups with them But again only sending over the 30 pills at a time If they're you know using up the 30 pills sooner than that might tell us we should do the testing a little sooner.

[00:16:29] **Christopher:** Is there anything else you want to tell us about Apretude?

[00:16:31] **Lindsey:** So I guess when you're starting Apretude, the first two doses will be a month apart, and then every two months after that, moving forward, like I mentioned. We talked about it being a good option for those patients that have creatinine clearance less than 30 or difficulty with taking a daily pill. But again, it is very important to be on time for the injections because of that long tail of the drug. Another kind of interesting thing with this medication is once the Apretude is discontinued, you do have to continue HIV testing every three months for the next year. So that's another thing the patient has to commit to, and you either want to put them on an oral PrEP if they're going to have continued risks or at least doing that testing for the following year.

[00:17:10] **Christopher:** I guess one option you could do is you can switch to an oral during that time, although it may not change the reasons why they chose a non oral to begin with, but, at least there is that option. It seems like there really needs to be a very specific patient for Apretude.

[00:17:24] **Lindsey:** Absolutely.

[00:17:25] **Christopher:** Are there any other things that we need to monitor when they're on aperture versus like any of the orals? Or is it pretty similar?

[00:17:31] **Lindsey:** So with Apretude before starting it, we're going to check both the antibody and the HIV viral load. Reason for this is, like I said, the drug lasts in the body so long. We want to use the most sensitive test to make sure they're HIV negative before starting. And then again doing STI testing baseline and then every two to four months after that, just based on those risk factors.

[00:17:51] **Christopher:** Gotcha. And if you're having a normal workflow, probably every three months, if you're just started doing that like all your other PrEP therapies.

[00:17:57] **Lindsey:** Every three months for the oral, every two months visits for the injectable.

[00:18:00] **Christopher:** That's right. Yep. Cause every two months anyway, so you're going to have to have a slightly different workflow.

[00:18:04] **Lindsey:** Exactly.

[00:18:04] Affordability and Assistance Programs

[00:18:04] **Christopher:** You have a patient, you want to do PrEP, you may even already have your labs, but do you ever run into problems with patients being able to afford these medications? And if you do, what types of resources can people maybe look to?

[00:18:17] **Lindsey:** Most insurances are covering the PrEP medications and labs pretty well, but I have run into a couple who have high co-pays, so the manufacturers do have assistance programs and coupons out there. And I've also found that generic Truvada is on GoodRx for like $25 a month, so that's a good bridge option when we're applying to some of those assistance programs.

[00:18:38] **Christopher:** Excellent. And what type of response from these assistant programs have you seen? Are most people able to get assistance? How long does it take for those things to get approved?

[00:18:48] **Lindsey:** The ones that I've specifically used are manufacturer coupon cards. And so those patients can just sign up for on the website. I know for Apretude, it's a bit of a longer process that our

medication assistance department assists with. So that typically takes a couple of weeks to get processed and approved.

[00:19:03] Conclusion and Final Thoughts

[00:19:03] **Christopher:** Well, thank you so much for talking to me on this excellent topic and especially with these new updates in terms of HIV testing. Are there any other takeaway points for our listeners before you sign off?

[00:19:16] **Lindsey:** My biggest takeaway would just be, you know, make sure you're having these conversations with your patients to determine if they're good candidates. Cause I think primary care is a great place to start and manage these medications.

[00:19:26] **Christopher:** Awesome. Well, Lindsay, thank you so much for coming on the podcast. Hopefully we can bring you on for some other talks.

[00:19:33] **Lindsey:** Yep. Thanks so much.

[00:19:34] **Christopher:** All right. Bye.

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