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PRE-EXPOSURE PROPHYLAXIS

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[video transcript]

00:09
Dr. Tarashon Broomes-Pennicott is an adult journal Neurology nurse practitioner with a subspecialty in HIV AIDS care, and is a certified HIV specialists with the American Academy of HIV medicine. She received her Doctorate of Nursing Practice at Rutgers University in 2016. Currently, she practices at Mount Sinai Hospital Institute for Advanced medicine Jack Martin fun clinic, where she provides PrEP, plush PEP services and HIV care and works at the Mount Sinai infectious disease clinical trials event. During the Coronavirus pandemic, she had the opportunity at Mount Sinai Hospital to be part of the various COVID clinical trials. These trials include cold convalescent plasma remdesivir Guin Salam o so good man. Thank you, Sarah lube and hyper mean glob in studies, and koban vaccine trials including Pfizer and Janssen. She is also per diem at Holy Name hospital where she provides primary care, home care special services to the geriatric population. She previously worked at New York Blood Center and was a research clinician that conducted the HIV vaccine trials and HIV prevention studies such as HPn, oh eight three injectable PEP study. She is also an active member of the association of nurses and AIDS care and black nurses Rock North Jersey chapter. Thank you so much, Doctor Broomes-Pennicott for presenting today, and I'll let you take it from here.

01:43
Good afternoon, everyone. So today we're going to talk about pre exposure prophylaxis PrEP. So I have no disclosures. And the learning objectives for today is to review the efficacy of pre exposure prophylaxis, described pre prescription screening, including contraindications and laboratory testing, discuss best practices for patient monitoring and clinical management, and discuss the future of PrEP and agents in development.

02:28
Okay, so let's talk about the current status of the HIV epidemic. 1.2 million people live with HIV in the US in 2019. One in eight people in 2019 were living with HIV and did not know they had it. 2% of transgender people accounted for the new HIV diagnosis in the US in 2018. And one in 69 is the lifetime risk of HIV diagnosis in New York State. Based off these statistics, I think it's safe to say that it's very important that we have PrEP. And PrEP needs to be definitely needs to be utilized in order to help decrease these numbers. So nearly 1 million cisgender males had an indication for PrEP medication 2020. However, only 26% of these patients were prescribed PEP medication. So there's still an issue where not enough people are utilizing PrEP. So we'll talk about that a little bit later. of the new diagnosis among the most effective population in the US and and dependent areas and 2019. HIV affects Black and African American communities more than any other racial or ethnic group. As you can see here in this chart. Black African American men, male to male sexual contact was 9123. And then you look go down the list here compared to white men melting male contact 5805. So black men are disproportionately affected by HIV

41% Of the estimated 34,800 new HIV infection in the US in 2019 41%. Were among Black and African American people. So we want to talk about how we can increase PrEP utilization in areas where it's mostly affected. So let's talk about PEP utilization in New York state. So 77,061 is the number of individual with PrEP prescriptions in New York State cumulative from January 2014 to December 2020. So on this graph here, you see how it is 20 in 2014 was just 3380 people. And as the years go by, it started to increase. So you got to see a slight dip between 2019 and 2020. We're in 2019 was 39,921. And then in 2020 39,282, I know from my experience during the pandemic, a lot of my patients stopped their PrEP prescription, a lot of people were scared of COVID weren't going out and didn't feel that there was a need for them to use PrEP.

05:47

Okay, so let's talk about PrEP use by race. So in New York State, you'll see here that there's a huge difference between racist and PrEP utilization. So remember what the previous lies I talked about how African Americans are disproportionately affected by HIV. But although in the state of New York, you'll see that Black and African American uptake of PrEP is 5536, compared to white men 17,475. So there's a huge difference. And we want to improve that in the state of New York. And oh, and by improving that, but you also help decrease the numbers of HIV. So in New York State, they had a goal to reduce the number of new HIV diagnosis by 55%. So they target was 1550. But in actuality, and 20 21,933, new HIV diagnosis. So there's still much work that needs to be done. So question number one, which of the following statements are false? PrEP is much less effective when it's not taken as prescribed, when taken as prescribed PrEP reduces the risk of getting HIV from sex by about 90%. PrEP is for individuals who are HIV negative among people who inject drugs, PrEP reduces the risk of getting HIV by at least 74%. Okay, so I see there's a tie between B, and D were 32%. thought the answer was B. And 32%? thought the answer was D. So the correct answer is actually B, because it's not by 90% is by 99%. So that says PrEP is very effective if taken as prescribed. Okay, so let's talk about the PrEP efficacy trials. So several trials that were done to evaluate how effective purpose one of the popular studies was the I PrEP study, which was a double blinded study. And in this study of seeing this chart here, they found 36 infections among 1224 persons, and those infections were at the time of enrollment. And you also see here the efficacy. So it shows that the efficacy was about 44%. And as you go down, you see other studies here, you have partners PrEP, you have femme PrEP. The next slide, you're gonna see I'm gonna talk about the severed PrEP. But I'm gonna go a little bit more in detail about the effectiveness of these trials one moment.

09:00

So in these studies, like I was mentioning before, this chart here shows the measures of efficacy by medication, parents and potential in the percentage reduction in HIV incidence. So in order for PrEP to be truly effective, you have to take it as prescribed. So if it's prescribed daily, you're taking it once every four or five days, you're not going to get that 99% efficacy rate.

09:32

So what they also found to in the Ipex study that there was a 92% reduction in sexual transmission when Sinatra fare was detectable in the blood. So in order for it to be detectable in the blood, you have to take the medication and build up those drug levels in the body. So this chart here is just showing the effectiveness the rate. So by each color, it talks about each study. So you see here, this is the I PrEP study. And you can find the color on the graph here, or the TD D TDF. To study you look for, you know the factors there. So you see that it's actually very effective if you take it as prescribed. So let's talk about who are the candidates for PrEP. So the candidates of PrEP is someone who have condomless, sex injection drug use, or someone who's attempting to conceive with a partner who has HIV. Someone who are involved or have partners who may be involved in transactional sex, including commercial sex workers and their clients, sexual partners of unknown HIV, one party mixed status, sexual activity in the high prevalence area of social network, someone who is self identified as HIV risk, or someone would pass a current sexually transmitted infections. I think it's very important when you do have a patient that you introduce PEP to everyone, and not make any assumptions because you just never know what someone's situation may be. And sometimes it's really disheartening when you have a patient and you tell them about PrEP. And he still do not know what PrEP is in PrEP may not be for them for that current situation, it may be for them down the line, or it may be for someone else that may need PrEP. So I think it's important that all patients should know what PrEP is. And if it doesn't, if it does not apply to them, that's okay. But you gave that information, they can use that information and spread it to someone else. It's 2022. And it's still we still have people have no clue or purpose. So that means there's still work that needs to be done about individual knowing that PrEP is available to them if the situation comes up where we need to use it. So it's important that we continue having these conversations with patients. So let's talk about the recommended laboratory tests, I'm going to start with the New York state guidelines. So prior to prescribing PrEP, there are certain testing that you should do. One of them is the you need to have an HIV test, you should at least have an HIV test one month after initiation and you should have one prior to PrEP within one month prior to initiation. And you should do it every three months going after once they start PrEP. Because PrEP is only for individuals who are HIV negative. So it's important to make sure that they're negative, because if they're not, they need to come off for PrEP, and they need to transition them to HIV therapy. We also recommend doing an HIV viral load for individuals who may have symptoms of acute HIV. And when there have been an interruption in PrEP in the past month or or potential exposure, it's important that you get that HIV viral to definitely be sure that there are HIV negative. Another thing that you should also do is you want to check the serum creatinine levels. Depending on what PrEP regimen there are, there are certain guidelines and you want to make sure that they are on the right regimen depending on what the Cretan level is. So it's important that you do that at least three months after and every six months thereafter, when they're either on Truvada or disobey for PrEP. Also, you want to do STI screening. So you want to have that conversation with your patient about what type of sex that they're having and what testing that may need to be done. So you want to make sure you do testing and all the appropriate sites and STI testing. They recommend at every visit for a patient present with symptoms and perform STI testing when appropriate. New York state guidelines also recommend that you do Syphilis and Gonorrhea testing and Clomid, Chlamydia every three months regardless of symptoms on a

patient requests. Also, with New York state guidelines, you want to do Hepatitis C at least once a year. For individuals at risk for pregnancy, you want to do a pregnancy test and you want to do a urinalysis annually. So let's look at the federal guidelines.

14:30
So here you're going to see a little bit difference with the federal guidelines if someone's of the age of 50 or greater and has a career and clearance of 90 or less. At PrEP initiation. You want to do this testing current and clearance every six months compared to someone who is age 50 or less who has a crown clearance and 90 or greater. They recommend that you do the credit and clearance testing every 12 months. So that is like the main difference between the New Year state guidelines and the federal guidelines. I just want you to be aware that the New York state guidelines is also in the process of updating it. So it can be so it can reflect the federal guidelines. Obviously, you want to keep in mind so you want to do a Hepatitis B serology as well. But it's important that you do that in addition to the Hepatitis C serology.

15:39
Okay, I see some questions in regards to PrEP, and I'm going to answer those questions towards the end. Okay, so let's talk about the oral PEP options. So you have TDF FTC trovata, or you have t f FTC to SCOBY. It's good. As you see what the picture the main difference is size. For some individual size doesn't matter for them the pill size, but for some in May. So let's talk about the difference the main differences between the two. So for Truvada, all people at risk through sex or injection use, can use Truvada. Some of the most common side effects of Truvada are headaches, abdominal pain, and weight loss. Now for the scoby. For it's for people at risk through sex, except for people assigned female at birth, who are at risk of getting HIV from vaginal sex. And the most common side effect is diarrhea for disobeying. So, question number two, a 44 year old cisgender woman who regularly injects heroin is seen in the clinic to discuss starting PrEP. She occasionally shares needles and injecting equipment, a proxy approximately four weeks ago, she had a negative HIV test. She has not been able to stop using heroin despite attending multiple addiction treatment programs. She intermittently has receptive vaginal sex with two cisgender male partners, which of the following would be recommended for use of HIV PrEP for this woman? You have a daily tenofovir, Allah fan of mine and she said Amin be daily tenofovir emtricitabine see on demand to go on dosing. What's enough a bear and to sit again after each injection episode or D long acting injectable kava tegu. There.

17:56
Okay, so 55% Say it is B. And you are correct. Remember, daily snarf ver interested in being with study for IV drug users. So it's important to when you are assessing a patient for PrEP to really do a thorough history because if they're if they are IV junkies, you know already off the bat is Tabata is the best option for them. Although there's other options for PrEP, which avato would be the best option for them. Now Shiva is a convert prefer regimen for our population proof because it's proven efficacy and safety and trials. And it's also available as a generic medication as equivalent to the branding Truvada. So the scoby is not available as a generic just to keep

that in mind as well, too. So I want to talk a little bit about the scoby. So for the scoby, they had a discoverer trial, which was the largest PEP clinical trial with over 5300 patients. So this was a randomized active control, double blinded trial. And in this study, they had men who have sex with men and transgender woman. So for over 96 weeks, on the scoby arm, you'll see that there was 2694 participant, and then on the bottom arm there was 2693 participant. So you'll see here that in the study population, a subset of 70% of the patients who were using Truvada at baseline, you'll see that 51% were randomized to Scobey and 49% was randomized to Tabata. So one of the big things that people talk about between Tabata In SCOBY, is that a lot of people, you know, to SCOBYs better on the kidneys. So and this graph just shows how long the long term impact markers or renal function over 96 weeks. So the blue line here is the scoby. And the gray line here is Chewbacca. So in this study, they showed that there was only 0.1 decrease for individuals using the scoby. And the Cretan levels compared to a 0.03. Decrease using a Travato. So those are the main differences in regards to Vada and the scoby in regards to renal data. Same again, with the scoby on the bone data, just in this study shows significantly less impact on the bone mineral density, and change in Siena, both arms continue through 96 weeks. So they show here with the graph is going up to a positive on the scoby arm, and a slight negative on the Travato arm. But you also gotta keep in mind too, with a bone density, this is something over time, it's something that's not immediate. So I don't want individuals to think that, oh, I can't prescribe Truvada for patients remember to borrow still the preferred regimen for individual on PrEP. So you see here 24 to 29% of patients this stuff said he had osteopenia or osteoporosis at baseline.

21:47
So I see a question here is PrEP conscience indicated at any stage of kid chronic kidney disease. I'm going to bring that up. So I'm going to talk about what are the what are the requirements for the scoby and PrEP in regards to your kidneys. And depending on your credit and clearance level, it may be contraindicated, and I'm going to explain that in a little bit for you.

22:23
Another interesting thing with the scoby for PrEP, they have a thing called the day tracker. So you know for some individuals, it may be hard to remember to take your on medication, and what the day tracker, it tells you each day. So pretty much it's easier. If you don't see that you your pill wasn't popped out. That means you didn't take it for that day. And so for some individual, it really helps them. You just have to keep in mind if you just do decide to use a day tracker, you have to put a note to the pharmacy, please dispense and day tracking, some pharmacies may not carry it, they may have to actually order it. Another cool thing with the day tracker, because you know, sometimes people don't want to carry their bottle. And when you see in this picture, you can actually tear off seven pills at a time and you can just travel with that. So for some patients, it may be convenient depending on you know, their lifestyle where they don't want individuals to be aware that they're on PrEP, this may be an option for them the day tracker. Okay, so here's another question. A 28 year old cisgender men who have sex with men presents for evaluation to start PrEP. He reports for cisgender male sex partners in the past six months. He typically has receptors rectal sex and does not use condoms. He's interested in

PrEP but does not believe he would reliably take a pill every day. He says that he typically knows when he's likely to have sex and says he could take pills before and after sets. Which one of the following is the recommended dosing schedule for on demand are 211 to not for their anticipating for HIV PrEP? A two tablets two to 24 hours before sex one tablet 24 hours after the first dose and one tablet 24 hours later. B to tablets one hour before sex than one tablet and one hour after sets? C one tablet two hours before sex than one tablet. One hour after sex or D one tablet two hours before sex and then one tablet one hour after sex than one tablet one day after sets

24:40
Okay, so 72% said it was a and you are absolutely correct. So let's talk a little bit on PrEP on demand. So, like the question said PrEP on demand, you have to take two tablets today. only four hours before sex, one tablet taken 24 hours after first dose, and then one tablet taken 40 hours after the first dose. If sex occurs again during the interval, continue daily dosing with one tablet and one tablet taken daily. And so 40 hours have passed since the last sexual counter. PrEP on demand is really good for individuals who scheduled sex on their calendar. I have had some patients who wanted to PrEP on demand. But I found that there have been using it more frequently. So if you have a patient if you if you dispense provide us a patient who is only 30 tablets in the bottom. And if the patient by the second week of the month is asking for a refill, it's probably better to just have them do Truvada or PrEP daily. Because remember, you're taking two tablets, two to 24 hours before, and then one after and one after. So if you're if you're constantly using PrEP on demand, almost like a daily use, it's better just to take one tablet once a day and maintain those drug levels. So it's also good to assess that I have had some patients that in the beginning it worked well for them. But then you know, they started having sex more frequently. And it's made more sense for you to just do daily PrEP instead. So when you have patients on PrEP on demand, it's important that you reassess the situation and make sure it's the best option for them at the moment.

26:39
Okay, so who is PrEP on demand not recommended for PrEP on demand is not recommended for individuals who engage in vaginal sex, transgender woman who take estrogen, individuals who use injection drugs, an individual with Hepatitis B virus. So if you if you're someone that Hepatitis B, you want to be adherent to the medication you need to take this daily because you do not want to have any flare ups. The two on one dosing was only study in adult MSN population. So you always have to keep that in mind. Make sure that PrEP on demand is for the appropriate patient.

27:23
PrEP in the transgender population. So daily adherence is especially important for transgender woman taking feminizing hormones. There's some studies that have shown high doses of feminizing hormones result in lowering of activated to not severe diphosphate levels and erectile tissue. So it's important that that's another reason why transgender women should not do PrEP on demand you want to make sure you maintain those drug levels. Seeing that some studies

have shown that sometimes feminizing hormones can decrease those levels so it's better to keep a daily use and regards to PrEP. Okay, so this question a 23 year old cisgender woman who has sex with men and woman is seen in the clinic to discuss potentially studying PrEP what medications are indicated as a potential options you have oral Tanaka there are feminized inch acidic being an oral it's enough a bear and consider being you have oral turn off of their elephant am I interested in being or it's not very interested in being an injectable kava Tiger beer, or it's enough that they're interested in being only or oral Tanaka they're interested in being an injectable cabinet type of bear.

28:46

Okay, so 62% said that it was see but that is incorrect. So for cisgender women, the PrEP options for them are either or it's enough if they're interested in being an injectable cabinet tag of bears. So let's talk about the newest option for PrEP, which is after two injectable PrEP. So what happened to you can have an oral Leedon dosing may be used approximately one month to assess tolerability it's a single dose of 600 milligrams given one month apart for two consecutive months and then monthly after that. It's approved for gluteal injection intramuscular injections only you cannot use it in your arm. It's not approved for your thigh only in the buttocks. So here I want to talk about a little bit about the study. So this study was HP tn 083 and the HP tn zero a three study that study You will study with men who have sex with men and transgender woman, you will see that there was a 69% lower incidence what aptitude was used. And HIV infections occurred three times less often on the injectable Capitec. Advair. So in a clinical study after to deliver a superior efficacy was significantly lower incidence of HIV infection versus a daily oral PrEP. So I want to talk about a little bit of the study design. So for this study, you have to be HIV negative as at no greater, and at high risk of sexually acquiring HIV infection, some of the exclusion for the study was active or recent, illicit intravenous drug use. So keep in mind, if you're a patient, that IV drug use, you already know, only serratus, option, chronic current or chronic history of liver disease and surgically placed or injected buttocks implants or fillers. That was really important. So during my experience with the HPT, and zero a free trial, it was really important that we did assess for those who had any fillers or butt implants. So as a provider, you want to ask all your patients those questions, and you don't want to assume who would have and who doesn't have it. For my experience during the trial, there was a host of different individuals that use butt implants or fillers. So it's important that you ask that question, even if you may think they may not have it, but you need to make sure that you are clear on that. Because if you are injecting this medication, and it goes into an implant, who knows what the results would be with this medication, just been storing implants. So it's very important that unfortunately, for individuals who have but implants or fillers, they are not, it's not recommended for them to use aptitude. So that's not an option for them. So I just want you to keep that in mind that that's a very important question to ask when you're trying to assess to see if aptitude is a good option for your patient. So in this chart design, you'll see we had a randomization. Individuals either randomized to the Truvada arm or or a cabinet tag there. So they had oral leading up to five weeks. And during the study, we're just simply testing to see their tolerability. And after the fifth week, they would transition into the injections. So even though there were an injection phase, so if you were in the cabinet tag of her arm, you would

have got the cabinet tech of your injection plus placebo pill. Or if you were in the Tabata arm, you got the actual act of Shabbat of drug and then the placebo injection. So in the HP tn 03 study, here is a chart about the resistant profile. So let's show that there's some resistance mutations under aptitude. So an incident infections under aptitude was 12, but under Tabata was 39 and then the sum of only four participants had mutations. That was NC associated mutations, compared to DiVita. They had four participants with NRTI associated mutations.

33:44
So everyone wants to talk about how's it with injection? What are some of the patient's reaction? So here is a chart about the safety profile establishing over 2000 participants. So under aptitude injection site reaction, of course, was the highest adverse reaction, then followed by diarrhea which is 4% under aptitude compared to five percentage, but sort of pretty much really close similar side effects headache 4%, antibiotic 3% fatigue 4% But then Travato was 2% Sleep Disorders pretty much even nausea 3% under attitude compared to 5%, which about a dizziness 2% And after two or 3% Winterbottom flatulence was pretty much the same and abdominal pain. So I want to talk a little bit about injection site reaction. So it's really important if if you have not done injections a lot to really review injections before you decide to get a patient opportune. Either if the nurse at the clinic is doing or the provider is doing it. It's important about the location so don't On a child, we have found that more patients had more painful experience, depending if the injection wasn't done at a proper site. So it's important to review locations of the look at the structure of the buttocks and the muscles way to do injections. You never want to do injection to close and work to the buttocks, you want to do somewhere where it's mostly muscle. And you also have to keep in mind the gauge of the needle. So what's important is if you had a BMI greater than 3030, you will need to use a needle as two inch compared to someone would it be in my lesson 30 needs to use a needle that's 1.5 inch. So typically understudy those who had injection site reaction, usually between the first a second shot a little bit discomfort. And by the third shot, participants were usually used to injection and really didn't have any issues or very few patients in the study that actually had like a grade three reaction. But it's mostly important to know where that injection site where it was done is done in the wrong location. That is not good. Some patients have experienced where they did an injection and for some reason the injection pooled in one error the medication, so you hit a wrong spot as well, we noticed that you did an injection or the drug is just pulling looks like a knot. You didn't hit the right spot. So it's really important to review injection sites and how to properly do the injection because the cab attack of beer the APA to medication is a fixed solution. So that's important to keep that in mind reviewing that and make sure that you're doing the injections properly.

36:58
So I want to talk about the HP tn zero a four study design. So HP tn 04 was studied in Justin cisgender woman ages 18 to 45. woman had to be HIV negative at screening and at high risk of sexually acquiring HIV. excluded in the study was history of liver disease or being pregnant currently breastfeeding. So the study design was completely identical to hp 10 03 and only different it was particularly only for cisgender woman. Also here in HVTN, zero a four study 90%

lower incidence for APA to HIV infections occurred 12 times less often when on aptitude. Same here with the resistant profile on aptitude they had three incidents of infection, zero incidents of resistance compared to 36 individuals on the Tabata arm were one participant at the M one a for mutation. Okay, so recommended dose and schedule for oral lead in for PrEP in adults and adolescents weighing at least 35 kilograms. So the oral leanings at least 28 days will give the oral Cabot's habit bear 30 to 30 milligram tablet once a day for 20 days. And then you transition into the intramuscular injection at month two and at month three. And then you the continuation of injections will be at month five and every two months going after. So you should administer on the last day of oral leading or within three days thereafter. Now if you decide to do the aptitude without doing the oral lead, and here's the schedule. So you will do an inter muscular injection at month one and month two, and then the continuation month floor four and every two months after individual may be given aptitude up into seven days before or after the date of the individual scheduled to receive injections. So what do you do if you have missed injections? If it's less than one month since the Miss target injection date, you can resume injections on the final day of oral cavity could be or within three days and then continue with every two month dosing schedule. If the one if it's greater than one month, since you missed injection, you have to repeat initiation injections, two injections one month apart on the final table oral cavity Agador or within three days and then you continue with every two month dosing after. Okay, so here's for another question. A 34 year old cisgender man with a history of condomless sex with multiple cisgender male partners expresses interest in injectable long acting Cavatappi or for HIV Pre-Exposure Prophylaxis. Which of the following is true regarding long acting injectable cavitation verify HIV for PrEP. The recommended dosing is 600 milligrams into Muskogee once repeat in one month, then repeat it every two months a 28 day period taking oral cabotegravir As a leading as required before receiving the intramuscular form of formulation, the intramuscular dose should be increased from 600 milligrams to 800 milligrams is a person body mass index is greater than 30 or optional sites to give the intramuscular injection include the deltoid or gluteal region. Okay, so 75% said a and 21% said b. So, yes you are correct a the recommended dosing is 600 milligrams into mescaline once repeat in one month and then repeat it every two months. So, let's talk about some contra indications. So, any individual who is HIV and invisible HIV cannot have PrEP. If you have a confirmed creatinine clearance of less than 60 should not be prescribed Truvada if you have a creatinine clearance less than 30 should not be prescribed to SCOBY an app or to cannot be called administer with anti coalescence. So the answer that question before if someone has kidney disease or any stage, if you have a chronic claim is less than 30, you really should not be on PrEP, once it's less than 30. So PrEP is really not a good option for them. Unless they're current and Clarence starts to improve and you get it over 30 You can put them on Discovery.

41:55

So, just discontinue after two. You have to keep in mind Kabataan levels wane over many months when discontinue during the tell phase cabotegravir will fall below protective levels and patients at risk for HIV exposure should be offered an alternative PEP option. So this graph here just talks about PrEP and the HIV resistance. So we have this on a resistance risk when you know after two starts to drop. So some some things to keep in mind. CDF and tap are Fe FDA

approved for the treatment of Hepatitis B virus. So when taken daily, Truvada are discovered may be used as PrEP and concomitant Hepatitis B virus treatment. So discontinuation of Truvada are discovered in patients with chronic Hepatitis B requires close monitoring for rebound Hepatitis B virus viremia servoz PEP may be continued during pregnancy and breastfeeding if risk of HIV acquisition is ongoing, and the scope is not approved for use as PrEP if a patient is pregnant or attempted to conceive. And de SCOBYs preferred for cisgender men who have sex with men and change and a woman with osteoporosis. And another question a 30 year old cisgendered men who have sex with men presents the clinic discuss options for PrEP reports condomless. Sex with male partners he has repeatedly tested negative for HIV, and it's estimated creatinine clearance was 95. On a recent test, he's open to both oral injectable medication for PrEP but is particularly concerned about side effects. Which of the following statements is true regarding side effects of PrEP medication. tenofovir, our fallen might interested have been frequently induces ICP osteopenia or osteoporosis and requires really monitoring with dual X ray DEXA bone scan, renal side effects of Sonoff if you're interested in being a common end result in medication discontinuation and approximately 30% of persons over one year or injection site reactions are the most common side effects with long acting injectable cabotegravir But infrequently to discontinuation of the medication

44:16

okay 94% was see so you are correct injection site reaction are most common side effect, while long acting injectable kava tech, but and frequently leads to discontinuation on the medication. So keep in mind injections may be something new for your patient. The first one first first two, you have to get used to it but most patients continue with it unless they have a really bad adverse reaction. So let's talk about some good clinical practice, pre prescription counseling and assessment. To assess for health literacy literacy, obtain a thorough sexual history and jug jug use history We that's important because you didn't, you'll know what option will be best for your patient. make clear that PrEP efficacy is highly dependent on adherence, it only works if you take it as prescribed. Also, with monitoring, you want to monitor for side effects. Within two weeks of having someone from your team verify the patient fill their prescription. Adherence intention and care explored address potential barriers to ongoing use of an adherence to PrEP provide adherence counseling, and avoid discontinuing PEP or withholding it from a patient at risk of acquiring HIV. You always want to meet your patient where where they're at. So you stop in for their prescription because they didn't show up for an appointment. That's not a good practice, you want to ensure that their patients are safe. And this meet your patients where you're at and come up with an agreement when you can, you know, get to see your patient and follow with them. Risk Reduction offer condoms refer for substance use treatment and mental health support as appropriate. Okay, so let's talk about the future of PrEP. So as you can see, the long acting injectable PrEP has already been approved. Right now in development, you still have preventative vaccines, daily, monthly or PrEP in development, or combo or PEP possible dual pill to market buy was ready 2022. So that's still in development. You also have long acting implants, multipurpose vaginal rings, broadly neutralizing antibodies, patches and search are long acting magical rings or enemas are still in development in preclinical and clinical stages. Want to talk a little bit about the tobacco Ring Ring trials. So the this is a flexible silicone brain

that a woman can insert in the vagina for monthly protection against HIV. So this is still pending and FDA approval. If this was approved, there'll be another option available for women. And this is just some of the studies that were done. In regards to the rain and their effectiveness. I just want to talk a little bit about HPV vaccine trials, we talk about feature PrEP, a lot of times you talk about other treatment options. And a lot of times we don't talk about HIV vaccine trials ACV I had an experience of working on several different HIV vaccine trials and you have to keep in mind if we are able to find an effective HIV vaccine, then you will be no need for taking medication for crap. If you can find a vaccine that can prevent individuals from getting HIV, that will be a huge step. So there are a couple of vaccines in the pipeline and preclinical and phase one and phase two. And phase two B and three Comstock trials, I just want to bring up the most recent one from Maderna. So as a as with the mRNA tech use for COVID-19 vaccine, this HIV MRA vaccine work by delivering a piece of genetic material that instructs the body to make a protein fragment of the target pathogen, the immune system will make a response against the pathogen become a prepare for future exposure. The vaccine is designed to present that spike protein on the surface of HIV that facilitates entry to the human cells. None of these vaccines can cause HIV. That's really important. A lot of people think that oh, if it's an HIV vaccine, it has to act the virus in which it does not. But these two particular trials I want to bring up because this was just launched recently in January of 2022. And then another one in March of 2020 through 22. So as you know, some certain, particularly with the HIV vaccine, since it's so complex, they have been studying HPV vaccines for years now. And even two years ago, they had a phase three trial but didn't have the result that we're looking for. And they're still vigorously trying to find effective vaccine because once that's found, that's a huge step in helping to stop the spread of HIV. We have a vaccine that can protect you against it. Okay, so for questions I know are some questions in the chat box.

Tara 49:23
We have one that we can go. Okay, you and I. So the chat box one says what is the concern with estrogen and on demand dosing?

49:32
So the concern of estrogen on demand dosing is with the studies that they've shown that if you use when you're on to Tanaka Vir and with estrogen, it can decrease the turnoff of your levels. So the concern is if you don't on demand where you're not constantly taking the drug where you have a maintain drug level, if you're using on demand, there consensus, it can probably potentially decrease a little bit Get lower because you don't have a lot of drug levels you system. So you're only taking a few drugs you're taking to two to 24 hours before and then one after one after. So if you're on the feminizing hormones, the concern is that it can drop it low enough, we're not really getting that protection compared to you, if you're maintaining that drug level, you have higher levels in your body already. Were, if there was a slight decline, you still have that enough protection. So they haven't really studied it and transgender woman on feminizing hormones to definitively say that it's safe for them to do it in that option. So to err on caution, it's better that they stay doing it daily instead.

Tara 50:41
Um, I don't know if you can see the q&a pop up here with all the questions. Dr. Brooms Kennicott. But our we have a question here, the new guidelines do not mention sexual partners of injection drug users. Any thoughts

50:58
on that? So my thoughts on that is if you do have a partner who is injecting drug use, one way to prevent you from getting HIV or another safeguard for yourself is to go on PrEP. Because you know, you can't control the situation of your partner, your partner could be using clean needles now, and something may change where they may end up using needles, someone else needs a needle and it can increase their risks. She always gotta keep in mind that you, you're going to control what you can do and not what someone else does. So if you do have a partner that is injectable use injectable, injectable drugs, I would recommend that you do go on PEP just to protect yourself.

Tara 51:44
I'm just gonna randomly go around here. Would you suggest that homeless patients be prescribed PEP?

51:52
Yes, I suppose. So PrEP are suggests PrEP for anyone that's at risk for getting HIV no matter if they're homeless or not. So with someone who's homeless, it's important to know their situation. For example, I know for I have some had some patients that live in homeless shelters and their concerns with pills. So someone who's homeless, in general PEP might be a better option for them. So there's different options now. But if you're homeless, and you're at risk for HIV, absolutely, I recommend you to have PrEP. Great.

Tara 52:25
We have another question. How would you address misinformation that states once you start PrEP and stop it, it would make it easier to get HIV?

52:36
Okay, I'm not sure why someone would think that it will make it easier for you to get HIV. I think it if someone stops using PrEP, it could be for multiple reasons. Depending on what their lifestyle is, it can be that they're no longer having sex, so they don't want to use PrEP or they're in a committed relationship and don't feel that they need to use PrEP doesn't necessarily mean that it's easier for you to get HIV, you really have to look into why they stopped PrEP and what their current situation is. Because you know, you could be on PrEP. And that one time they decided to miss four or five, six doses in a row, and then you end up getting HIV, you still can be at risk if you're not completely adherent to that medication as well. So that kind of really does debunk that stigma. If you stop it, you can be on it and still have it I have had patients that Sara

convert to HIV because something was going on in their personal life. And they decided to stop taking PrEP for a short period of time and during that time, the acquired HIV. Okay,

Tara 53:40
we have a few more questions here. Dr. Kennicott. Can you see these in the chat or in the q&a?

53:47
I see. I would like to know about Kevin Nuva. I went over Kevin Nuva. For me aptitude for practice Kevin Lewis for HIV treatments. Sorry, I went over that already by my service a particular question in regards to aptitude for PrEP. Given u equals u would you still use PrEP in a person trying to conceive if their partner is violent virologic li suppressed for greater than six months? Great question. So for this greater than six months, I mean, I guess how greater than six months, I guess it really depends on the comfort of the patient to if they're greater than six months, and you know, studies have shown that, you know, partners may they do not get HIV, but I think it depends on the comfort of that patient. You know, you provide them with the information, you know, this is what research have shown. These are your options and, you know, see what works best for them. There's patients who don't feel it needs to be on it, knowing that their partner have been virally suppressed for so long. And then some that, you know, they still don't really understand you completely, and they feel more comfortable going on PrEP when trying to conceive so depends on the patient. I think what's most important is that you provide your patients all the information necessary for them to make an informed decision that works best for them. Okay, how soon after stopping injectable? Can you switch to oral PrEP Truvada or just SCOBY. So remember, injectable PrEP is a long acting medication. So what I show that the graph before how it wanes down, I think it's important to just let patients know if they decide not to restart right away. You know, once they stopped PrEP, so they got an injection today. And they decided to stop PrEP, injectable PEP, maybe about a month or so after. From now, it's safe to say that you can restart the oral pill as soon as possible. If you want to get them on oral regimen right away, you can do that. The next question? I know that transgender female to male individual are at high risk and notice graphs and demographics didn't include trans people without How do we know that 2% of new infections were trans and do you think that's accurate? Okay,

Tara 56:33
Dr. Penny, they meant male to female, just as a correction to that they meant male to female, okay. Yeah.

56:42
Okay. Okay. Okay. So that information I actually got from the CDC. And I can check back on that website, they do break it down a little bit further for you, whether it's male to female or female to male. And that's why they were able to get that percentage of the 2%. So there's actually more a little bit more information if you go on the CDC website in regards to different population and their risks, where you can get a little bit more information in detail about that.

Tara 57:18
Okay, and we have one more question in the q&a. Maribel says, Hello, the updates include the need of VL, who covers the test?

57:31
When he said who covers it says, do you mean by provider like the insurance company?

Tara 57:38
Yeah, I think they might need me in that in terms of monetary covering of the test. But Maribel you could write in a few.

57:47
I mean, most insurance company do cover viral test. I've never heard of them not covering viral load test. That'd be really weird. Especially if you have a patient you think may have acute HIV, and you're in your documentation, you're putting why you're doing this testing, it should be covered. If there's displaying acute symptoms of HIV, which will verify why you're doing this test.

Tara 58:15
Okay, and Maribel also said a government health plan question mark. So maybe that's more on the route of the

58:22
question. Yeah, that test is cover I've never experienced not having a viral not covered. That'd be actually really weird. But yes, that is covered. Okay, great.

Tara 58:34
And then we have one more question in the chat, and then we can close out. So what do you advise if I'm thinking they meant someone misses a Truvada dose?

58:48
So what do I advise? Yeah,

Tara 58:50
if someone misses a dose of Truvada,

58:52
alright, so what I what I do advise is don't, you don't need to double dose continue the next day. What's important to patients are humans, sometimes patients will beat up on yourself, you want to be positive with them and let them know it's okay that you miss a dose. But you also want to stress too, like if you're missing four or five doses consecutively in a row, I highly recommend that you use condoms until you will rebuild up that drug level in your body. So it's important not

to double dose continue the next day with your daily PrEP. And as always remember once you are least three to four days consecutive in a row for your next you know sexual encounter is recommended that you do use HIV until you know you're more consistent. You do use condoms and see a little bit more consistent with the medication just to protect yourself. Because once the levels drop below the need for protection than your you are at risk at that point. And always remember, as a provider, you always want to be sex positive and you always want to create a space for your patients. Be comfortable because you're you only can best help your patient if they're open with you. So you want to meet your patients where they're at. Always remember it's a collaborative agreement, not you telling them this is what best for you want to give them all the information and you guys work together figure out what plan works best for them.

Tara 1:00:20
Great, thank you so much. Dr. Broomes-Pennicott, a call that's great.

[End Transcript]