

HIV Prevention, Screening, and Treatment Transcript

DEMYSTIFYING HIV/STI TESTING, TREATMENT, AND PREVENTION WEBINAR SERIES

Hi everyone, welcome. We will give it about another minute or so for folks to join. I have 12:02, so I think I'm going to get us started. We have a lot to cover today, so good afternoon, everyone. I'm Beth Gyllstrom from Minnesota Department of Health and I'm pleased to welcome you to the second in our three-part series "Demystifying HIV, STI Testing, Treatment and Prevention," which we are hosting in collaboration with the Minnesota Medical Association.

So, a few quick housekeeping items. We are recording this session. Also, please hold your questions until the end or you can put your questions in the Q&A and we can address them during the session. We will post the evaluation link towards the end of the presentation, but we will also send it out via e-mail to participants. We're compiling questions, and if we don't get to them, we're actually going to post all of them with the recorded sessions on our website after the series is complete. So, with no further ado, it's my pleasure to introduce our speaker today, Dr. Nick Lehnertz. Dr. Lehnertz is a physician and medical epidemiologist specializing in infectious disease epidemiology prevention and control at the Minnesota Department of Health. His work includes responding to novel and emerging infectious outbreaks such as SARS-CoV-2 and mpox, creating strategies to reduce the risk of acquiring syphilis and HIV, and understanding the drivers and barriers to healthcare utilization, especially among disproportionately impacted populations. So, with no further ado, Nick, I will turn it over to you.

Thanks, I'm going to shut my camera off and then go ahead and get started here. Everybody can see the slides. For today's talk, we're going to talk about HIV. OK, real quick, I have no disclosures. Opinions expressed during this are our own and don't necessarily represent MDH. And I just want to acknowledge that a lot of this work is being done through MATEC and CDC and the national HIV curriculum and things like that. So just acknowledging all the wonderful resources and people that are out there.

OK, so I want to talk about HIV today. We're going to do an overview of HIV, talk about the EPI, especially in Minnesota. I want to talk about screening and testing, and then of course, prevention and treatment, and then hopefully we'll have some time for questions at the end.

I'm going to start with key takeaways though, and here are the few things we can take away.

Number one, there are people living with HIV in every single county in Minnesota. Throughout the entire state, we got folks living with HIV. Everyone age 13 to 64 years should be screened for HIV at least once as part of routine care, and more often if they have one of several risk factors and I'm going to highlight that again. Everyone, I don't care what's going on, 13 or 64 - more than once, if they have risk factors. Nationally, right around 13% of individuals with HIV are unaware that they are living with HIV, and that goes back to this routine screening of everyone, right? And that's similar in Minnesota, just unaware that they have HIV. Population

level screening is imperative to identify these folks. I want to talk about HIV PrEP, our pre-exposure prophylaxis. It should be offered to everyone who's at risk for HIV. And then, of course, rapid initiation of antiretroviral therapy is critical to reduce the transmission and to reduce individual clinical sequelae in those individuals infected with HIV. We'll touch on each of these.

So, let's start with HIV, a real brief overview.

The illness that was subsequently dubbed AIDS was first identified in 1981 in this MMWR here, and then HIV was identified as the virus causing AIDS in 1983. Since the identification we've had 91.4 million cases and 44 million deaths globally. Those numbers were astronomical. It's an envelope virus of the Retroviridae family. It targets primarily CD4T lymphocyte helper cells. So we all know this, and it basically leads to the continued loss of CD4T cells and extreme immunosuppression. It significantly weakens the immune system, and what happens is that if it's untreated, it will eventually progress to AIDS and subsequent death due to these various opportunistic infections.

I'm going to blow through this real quick because I got a lot to cover, but I just want to remind everybody that HIV particles, you got a lipid membrane surrounding a protein capsid. You got these envelope glycoproteins on the surface gp120 and gp41. They're the things that attach and help fuse to the host cell. The RNA is inside the HIV capsid. You have two copies of RNA, along with protease integrase and reverse transcriptase proteins. And this is critical, and I'm going to get to it. Identifying the HIV structure is critical for understanding the clinical presentation and the development of therapeutics.

The HIV virus fuses to that host cell expressing CD4 and then along with the co-receptors. This is T helper cells, but also dendritic cells, monocytes, anything that has CD4 expressed. The HIV RNA and enzymes enter the cell right and then the viral DNA is formed through that process of reverse transcription right. Of keynote, this process is prone to errors leading to the development of new HIV genotypes.

So, we have attachment/fusion, we have reverse transcription, and then we have the viral DNA is integrated into the genome of the host cell. So, it's actually put right into the genome of the host cell and from there you have transcription of the HIV DNA into multiple copies then of the new HIV RNA.

It was integrated in the DNA and now becomes back to viral RNA. That new viral RNA and the associated proteins go to the cell surface, where a new immature HIV forms. And then the virus is subsequently released from the cell and the HIV protein called protease cleaves that into create a new mature infectious virus. We got integrase, protease, reverse transcription all that kind of stuff.

Keep that in mind because understanding HIV structure in the lifecycle provides an opportunity to link this pathophys to both transmission and a clinical course, and here's the kicker, the understanding of potential therapeutic targets.

And we go later on, we're going to talk about prevention and PrEP and treatment – we're going to deal with a lot of this kind of stuff and how we can sort of block these processes to stop the HIV replication.

Enough of that. Let's talk about HIV transmission. It requires contact with bodily fluids that contain the HIV virions or infected cells. That includes blood, semen, vaginal secretions, breast milk, wounds, mucosal lesions. Routes of transmission includes sex, right? So direct transmission through sexual activity, needle or instrument related. So sharing contaminated needles or maybe needle stick injuries in an occupational setting.

You can have vertical transmission from an infected mother to the child during pregnancy or childbirth or through the breast milk, and then you can have transfusion or transplant related. And that's quite rare.

Transmission risk is highest in early and also advanced HIV when the HIV virus concentration is the highest. As a simple summary, right, when we have undiagnosed or untreated HIV infection, it leads to elevated HIV viral load, which results in decreased CD4T cells, which results in an immunocompromised state in the individual. We have increased risk of transmission to other individuals, and then we have an increased risk of individual clinical sequelae, including that progression to AIDS and subsequent death.

What are we trying to do here, right? I'm always I'm an objective focused person. I always like to think about what's the point. What am I trying to achieve and what we're really trying to achieve I think are four different things. We're trying to prevent individuals from acquiring HIV, right? We want to identify individuals already infected with HIV. We want to prevent subsequent transmission of HIV. And then of course, we want to treat HIV infections because we want to prevent those sequelae in the in the subsequent opportunistic infections seen in those that are untreated ends up.

Let's look at where we are. Let's check out the epi and see how are we doing here in Minnesota.

Let's start with identifying people living with diagnosed HIV in Minnesota. As of December 31st, 2024, there was nearly 10,000 people assume live and living in Minnesota with HIV/AIDS. This includes 5,715 living with HIV and another 4,111 living with AIDS.

This does not include an estimated 1,100 undiagnosed individuals living with HIV infection, and why this is critical is because ... they're responsible for nearly 40% of the new infections that happen, it's those individuals that are unaware of their HIV status. Now the majority of people living with HIV reside in the metro. Nearly 20% of the individuals reside in Greater Minnesota and again, as we mentioned before, there's eight people living with HIV in every county in the state and here you can see why we have the highest number of people, right kind of concentrated in the metro region. We can see every single county has them all.

Now real quick, this is just sort of like a quick breakdown. What we see here is we see in the suburban there's the most individuals living with HIV in the suburban region and in obviously Minneapolis. But in greater Minnesota, again, 20% of people living with HIV are out there.

Let's talk about the impacts like who are the individuals living with HIV in Minnesota, and you can see here on the bottom, I've circled the population of Minnesota in total, right?

And we can see that nearly 80% identify as white, and then there's much smaller proportions of individuals of other racial and ethnic groups, and yet you can see here that the distribution of people living with HIV is much different than the general population. Some of the numbers like 15% of males living with HIV, identify as Hispanic and 20% identify as Black, African American right, while in females you can see 41% identify as Black, African born and 22% black African American.

This is again an example of a disproportionate impact in historically marginalized populations that are currently living with HIV, and this will be a theme that will continue on as we move forward here. And so in summary, right there are people, again and I keep repeating myself, living with HIV in all counties in the state.

OK, the majority are in the metro, but 20% of people living with HIV reside in Greater Minnesota.

HIV infection continues to have a disproportional impact on BIPOC communities and other historically marginalized communities, and I will continue to repeat that as well.

It is currently estimated that at least 1,100 individuals are currently unaware that they are infected with HIV, and this is the point I got to earlier. It's estimated that 40% of new HIV infections are transmitted by individuals who are unaware of their HIV status. The idea of identifying individuals that are unaware of their HIV status is in its absolute imperative to stop transmission.

These are people living with HIV. What about new HIV diagnosis? So, let's look at new HIV diagnosis by year. And you can see here in 2024, we had 311 cases identified. These are newly reported HIV or AIDS diagnosis. This is pretty high. I mean in the 2015 to 2020 or so, we were hanging right around between like 295 and 222. So 311 – I hate to say this, but the trend line from 2020 to 2024, it's up. And so that always concerns me a little bit. If we look at new HIV diagnosis by sex, there's many more males than females. 250 to about 65.

So that's always a concern. And just as a side note – Are we capturing everybody that's at risk? Are we screening everybody appropriately? Do we understand their risk factors? All that kind of stuff. Are we under-diagnosing females? I don't know, it's just hypothesis generating. So just a thought.

So, let's look at new HIV diagnosis by county of residence in 2024. And here you can see similar to prevalence for people living with HIV. New HIV diagnosis occurred throughout Minnesota, right? In Greater Minnesota, it made up 22% of the cases and you can see here, while the majority are seen in the metro region, we again have new diagnosis throughout the state. And then a highlight, of course the 22%.

New HIV diagnosis by sex and race ethnicity in 2024, and you can see here again. I've highlighted sort of the overall population demographics, and we see again this disproportionate impact that it's having on historically marginalized communities, 26% of males with a new HIV diagnosis identified as Hispanic right, 11% of females identified as Hispanic. 9% of new HIV

diagnosis in 2024 in females identified as American Indian. Alright, they make up 1% of the population. Like you can see, obviously Black, African-born and Black, African American as well are completely disproportionately impacted by new HIV diagnosis. I will continue to hammer that home.

And so here's another key thing. And I, and I think this again is sort of like hypothesis generating, but here's the percent of cases by years. You can see that the graph here is 2015 to 2024. The percent of cases that either have a diagnosis of AIDS or progression to AIDS within one year of initial HIV diagnosis, and you can see that it's it kind of goes between 20.

And 30% are either at AIDS or at AIDS within one year of all new HIV diagnosis. And from a hypothesis, we're not catching people soon enough, right? Risk of progression to AIDS is about 1 to 2% per year and then about 5 to 6% after the first three years. These folks are being are going to AIDS either at diagnosis or shortly thereafter, about 20 to 30%, and so we need to screen more. We need to identify these people earlier. Keep that in mind.

If you saw earlier in the key takeaways, I talked about screening everybody starting at age 13. Why do we screen so early? Well, that's because we're seeing HIV diagnosis among adolescents and young adults. From 2015 to 2024, you can see here that there are between, I would say about 40 to 60 or even 70 cases of HIV diagnosed in 13 to 24 year old every year. And so in 2024, as you can see, we had 48 cases who identified as male, and nine cases identified as female in individuals aged 13 to 24. And so, one of the reasons that we screen so early is to catch these individuals. And then you can see here again in adolescence in young adults by sex, race, ethnicity – we have a disproportionate impact in the BIPOC populations. So where do we go from here?

OK, we know HIV transmission is happening throughout Minnesota. It affects both men and women, including adolescents and young adults, and a disproportionate impact on BIPOC and historically marginalized communities. So, what are we going to do, right?

Well, we're going to identify individuals with HIV. We're going to screen and we're going to test symptomatic individuals. We're going to prevent transmission through PrEP and PEP, and we're going to treat HIV infection. And we're going to rapidly initiate antiretroviral therapy. We're going go through that as well, but all of this is key again to the objectives. We want to identify, we want to stop or prevent, and we want to treat.

So, let's talk about screening and testing. But before I get there, I want to talk about how to talk about sex. Obviously one of the major roots of transmission is through sex, and often times in a clinical setting it's difficult, especially maybe we don't have a relationship or a trusted relationship or it's a new relationship. How do we talk about sex and how do we talk about it openly? And there's lots of frameworks and all that kind of stuff.

And I'm you probably all heard about the five Ps where you ask about partners and practices and past history and all that kind of jazz. And I guess my point is that you can pick whatever framework you like.

I personally like the goals framework and I've outlined it here, and one of the reasons I like it is because there's findings that suggest that patients want health care providers to talk to them

about sexual health, right? They want it. They may not initiate the conversation, but they want this. And so, I think the overall point is You have to take the time. It's not something that's easy to do, especially if we don't do it often. Pick the time to have open, authentic, nonjudgmental conversations with patients about sex. It's just sex. Everybody has it. And so I think it's incredibly important to do this, especially when we're talking about HIV and other STIs to have that conversation.

Let's talk about HIV screening.

It is recommended that everyone between the ages of 13 to 64 are tested for HIV at least once using an opt-out approach. And so, you're just going to test them, unless they specifically say no, I do not want to know my HIV status. People with certain risk factors should get tested more often, right?

You should get tested at least once a year if you are identified as MSM, if you've had sex with somebody with HIV, if you've had more than one sex party since your last HIV test, you shared needles and syringes exchanged. There's a number of risk factors and stuff. When in doubt, test if the patient requests it. You should test if you have any clinical suspicion. The more we normalize testing, the more normal it becomes.

Now in addition to this routine, opt-out screening for HIV, clinicians in every setting, but primarily primary care, urgent care, ED settings – you should order HIV testing when a person is diagnosed with another STI. You should also do when a person presents with symptoms of acute HIV infection.

The question is, what is a typical presentation of acute HIV infection? I'm going to go through it. And to be honest with you, and I'll be frank, it's probably not that helpful. You just have to have it on your radar. You have to think acute HIV.

So acute retroviral syndrome is a symptomatic illness that develops in many people. Not everybody, but many during the acute HIV infection phase. It can be asymptomatic, or a mild nonspecific illness. I generally think of mononucleosis. Usually occurs within the first 28 days after infection and here you can see sort of like the days following HIV acquisition acute HIV happens right in sort of like that 10-to-25-day range after acquisition. It can last three to 14 days, can be longer, right?

It can be mistaken for mono or other nonspecific viral syndromes. And common symptoms, obviously, it's just sort of like this general viral presentation, fever, malaise, joint pain, muscle pain. You can have this morbilliform rash – and I put a picture of that up on here – as well often presents.

So, when in doubt, I remember a couple weeks ago, I said think syphilis, think HIV. Somebody comes in and perhaps you think that maybe HIV is under differential. When in doubt test.

Here's the benefits in screening. If you offer HIV screening to everybody all the time, like I said, when you normalize something, it becomes normal. You reduce the stigma associated with HIV testing and it creates opportunities to talk about sex, talks about sexual health, the ability to negotiate healthy sexual relationships. Incredibly key, right?

And then it helps develop that patient provider relationship. You know that trust that we're always looking for anyway, it's highly effective. I think the most important tone here is it's cost effective, right? And obviously it fosters early diagnosis and treatment. Those are huge things, but that conversation is so key.

So really quick, we'll talk about HIV testing. And HIV testing, it can be confusing if you don't do it regularly. But really simply, there are generally three types of HIV tests available. You have your nucleic acid test. HIV 1 RNA test, they're designed to detect actual viral RNA. Then you have these HIV 1/2 antigen antibody tests which are always known as 4th generation HIV test, and these are great because they detect both antibodies, IgM and IgG, along with the viral P24 antigen. So those are really good. And then you have HIV antibody tests which only detect the IgM and IgG antibodies.

Each test has its own testing window, right?

And the nucleic acid tests are actually capable of detecting HIV the earliest. And then, of course, there are rapid tests and self-tests. I'm not going to get into those but be aware that they are available out there as well.

About the testing window period after infection. The window period is the time after infection and before seroconversion. So before the antibodies rise to a detectable level. And so if you test during the window period, you're not going to identify HIV, right?

Here's that thing again where it shows the blue line shows the HIV RNA right. And so starting about at day 10, that sort of starts to become detectable.

And then you can see here I read around day 17 or so you see the HIV P24 antigen that's part of that 4th generation test that starts becoming detectable. And then the purple line is the HIV antibodies. And you can see that's more delayed.

We're talking more like 25 to 30 days before that's identifiable. And so, all tests have a window period. It varies by test and type of specimen. If you get fingerprint blood that has a longer window period than a plasma specimen.

And there's lots of resources on this as well. You can look it up, but if you're testing during a window period and the result is negative, get tested again right until you've gone past that window period.

Here's the lab based HIV testing algorithm. And real quickly, I don't want to spend a whole lot of time with it, but you start with that 4th generation antigen antibody test. If it's negative, then it's negative, right? However, and I'm going to get to this later on, if you have a high clinical suspicion for acute HIV infection, remember there's that window period. Don't hesitate to test again. And don't hesitate to test with HIV Nat, which has a shorter window, period.

Now if it's positive, you follow that up with that with a HIV one, HIV two antibody differentiation, amino acid, right.

And that will either be positive for HIV, 1 positive for HIV, 2 positive for both, or it will be negative for both, or indeterminate. If that is the case, right then, you'll want to follow up with an HIV Nat and see if that's positive or negative.

It's all about window periods and what's turning positive or negative, and so if you follow this algorithm it's pretty straightforward.

And again, I just want to note that if there is a strong clinical suspicion of acute HIV infection, but initial testing with the 4th generation antigen antibody test is negative, you need to follow up with an HIV one nucleic acid test.

So you've tested, you've screened this individual, you've tested them, and now you want to deliver the test result, and I'm going to talk about the status neutral approach. Irrespective of the result, it's an opportunity, right? If the test is positive, it's an opportunity for treatment engagement. We're going to initiate rapid art. We're going to educate on prevention of HIV transmission. We're going to link you up other support services. If it's negative, it's an opportunity for prevention, right? We're going to talk about continued testing and PrEP and doxypep and education on prevention. It's an awesome opportunity.

Let's pretend it's negative, OK? So, let's test this person and they're negative. What are we going to do? We're going to prevent and I want to talk about HIV pre exposure prophylaxis or HIV PrEP, and I'm going to spend some time on this. Right off the bat I just want to note that HIV PrEP is a grade A recommendation from the USPSTF, right. All of these organizations endorse discussion of PrEP for the prevention of HIV and it's everybody, right? It's a wonderful tool.

Grade A recommendation. Let's talk about what it is, right? HIV PrEP medications that can be delivered either orally or it has intramuscular or sub Q formulations. You can do daily dosing with the orals. You can do injections every two months or you can do it now injections every six months. I'm sure you've heard about that.

The daily oral medications include Truvada or or descovy and these will get into all the little letters and all that kind of jazz. I put the brand names in because that's what most people know from us and so I don't promote one over any of them, but there's a couple of different oral options. And then you can have on demand Truvada, we'll get into that. It's otherwise known as 2-1-1 HIV PrEP. Long acting injectables include intramuscular cabotegravir, which is known as Apretude, and that's every two months. Or you can have every six months. And this just came out this year, with SQ lenacapavir, otherwise known as Yeztugo.

And so lots of different options, OK.

I just want to mention that right now, approximately 25% of individuals with an indication for HIV PrEP have received a prescription. 25%. I mean, to be honest with you, if we want to stop transmission, we need to get that much higher. And here you can see here this is PrEP coverage over time from 2017 to 2022, and Truvada has been around since 2012 and yet we've only got approximately 25% of individuals with PrEP. That has to change.

Indications for HIV PrEP include all sexually active adults and adolescents who are having sex in the past six months and any of the following. Sex partner with HIV. OK, obviously right. If they've had a bacterial sexually transmitted infection within the past six months or if they have a history of inconsistent or no condom use with sexual partners. And I'll be blunt. I think that puts a lot of people into the indication for HIV PrEP. Also, persons who inject drugs should be

assessed for the sexual risk of HIV, including injecting partner who has HIV. Sharing injection equipment or a sexual risk for acquiring HIV.

So let's go over it. These are the oral regimens, as I mentioned before, Truvada and Descovy. They're combination NRTIs, which stands for nucleoside reverse transcriptase inhibitors. And so this prevents sort of like that reverse transcription of the viral RNA into DNA. So you take these daily. And then you can also take Truvada at on demand and we'll get into that. TDF reaches maximum tissue concentration in replication at about seven days and the reason why I want to mention this is that this is important to start this and maybe have some dialogue about waiting until effective dose before having sexual relations. However, there's a lot unknown about this. We don't really know the number of days to effective tissue concentration to prevent acquisition of HIV. So just something to think about there.

Studies demonstrate that the overall effectiveness of oral prep directly relates to compliance measured by tenofovir levels in the blood. And so, this comes from a paper here that demonstrates basically, if we measure tenofovir and it's high, you have a better chance of preventing HIV. So, compliance is always an issue with oral regimens. Very specifically for Truvada. It was approved back in 2012. You have to have a negative HIV test prior to the initiation of HIV pre-exposure prophylaxis. It's not recommended to individuals with kidney function of an estimated glomerular filtration rate and clearance of less than 60 mLs per minute. This is the regimen that is used with on demand prep. We'll get to it. And then there's been multiple randomized clinical trials that have demonstrated safety and effectiveness for both MSM, heterosexual men, and women, serodiscordant couples.

And then Truvada alone was shown to be safe and effective as HIV prep for persons who inject drugs. And so if you can see here, Truvada is actually indicated for everyone, including individuals with the risk of injection drug use.

Now we're going to go to Descovy, which is the other oral regimen. That, again, is a nucleoside reverse transcriptase inhibitor combination. It was approved in 2019. It is not indicated in individuals at risk of HIV from receptive vaginal sex. Now studies are ongoing so hopefully, look for that. But this one is in gay and bisexual men and trans women.

It's also not indicated for those at risk from injection drugs, and it's not for on demand PrEP – that 2-1-1, and it's not recommended for individuals with pretty severe kidney disease with estimated creatinine clearance of less than 30.

And so I mentioned before about on demand PrEP. So let's talk about this a little bit. The 2-1-1 dosing strategy has been studied with Truvada. All right, this, that's the older one, and it's been shown to be effective in preventing HIV transmission among individuals who identify as MSM.

So the idea is, is that you take two tablets within 24 hours. Or two to 24 hours prior to the initiation of sex, right? Then after, that you take one every 24 hours And you have no sex for 48 hours. OK, so you can see here in the diagram. I don't if I explained it very well. But you take two pills two to 24 hours prior to sex. So if you know you're going to have sex in the evening, you take your pills two to 24 hours prior, and then you take one pill every 24 hours afterwards until there's two full days, 48 hours without sex.

And so you can see here on the top diagram – initiation of sex. They took the two pills within at least two hours prior and then they had sex and then 24 hours. They took another pill and then 24 hours they took another pill. And that's the 2-1-1.

So prior to initiation, obviously, we're going to need HIV testing. We're going to look at serum creatinine, hep B, and then STI labs as well.

Let's move on to injectable regimens. This has been a game changer for a lot of folks because of that issue with oral medications and compliance. PrEP for HIV. There are two different injectable regimens. There's a two-month and a six month, and so Cabotegravir is the two-month regimen and the Lenacapavir is the six month every six months. Cabotegravir is actually known as an integrase strand transfer inhibitor. OK. And then Lenacapavir is a capsid inhibitor, so it blocks the formation of that of that viral capsid.

Both have data demonstrating high levels of efficacy for preventing HIV. They're well tolerated. Counseling on adherence is important and we're going to get to that with Cabotegravir.

You know we are constantly looking at long term efficacy and tolerability. Here's the kicker. It's expensive, right? So we're looking at maybe \$25,000-50,000 per year per person. Cabotegravir is generally covered by insurance, Medicaid can require prior auth. But I'm not a treating physician and so I don't know about all the, you know, some of the issues that have gone into that. I've just heard that it can be very difficult and Lenacapavir as well and we're working on ways of getting this to individuals, but it's a work in progress. Let's first talk about Cabotegravir again. It's an integrated strand transfer inhibitor, right? You can see here you get an injection followed by a second injection one month later and then an injection every two months. It was first approved in 2021 for all populations of sexually acquired HIV. You can see here that there's a 69 to 90% risk reduction of HIV compared to those individuals who took Truvada. So it's even on top of that. No renal restrictions, but here's the kicker. Taking this may lead to an increased risk of integrase strand transfer inhibitor resistance, so INSTI resistance, and that's important and we'll get to treatment later on among those who have had acute HIV infection at initiation or become infected. That's why it's critical to have a negative HIV prior to initiation and repeat HIV testing at time of each injection.

Of course, the last one we'll talk about is Lenacapavir. It's a capsid inhibitor. It's a subcutaneous injection and it's every six months. And so that was just approved here in 2025. It's, again, highly effective. A couple of trials have demonstrated 100% effectiveness in young, cisgender women in Africa and then also in gay and bisexual and gender diverse people in the US and in six other countries. It's injectable. Antivirals encourage better adherence and so it's easier. You have to take that daily pill. That can be very difficult. Studies have shown that injections are safe, well tolerated. There's no renal restrictions on this, but again, the question becomes who's paying for it. And so people are working on that. I'm not going to go too much in depth on this and stuff, but oral prep and injectable prep. You need to have follow up monitoring.

So I'll just highlight a couple of things really quick. On initiation, they have to have a negative HIV test and a negative 4th generation antigen antibody test. We got to look at their creatine clearance. We have to look for lipid panels for those that are taking the Truvada. And then hepatitis B, hepatitis C.

And then at three months, we again want to test for HIV using both the 4th generation test and the HIV RNA test. And then SGI testing and then so on and so forth. So it's pretty much continual STI testing. We need to check that creatin clearance, especially if there is moderate kidney disease. Pregnancy women of childbearing age should be screened for pregnancy at least every three months.

Ends up if there's acquisition of HIV during this time, we need to get people started on treatment and then STI screening. Obviously, if they're coming in, they should be screened for bacterial STIs as well every three to six months. And there's different, based upon the population, regimens. But if they're coming in every three to six months, they should be tested for bacterial STI's, and then heterosexual women and men should be screened for syphilis and gonorrhea at six months and chlamydia every 12 months.

And then similarly with injectable prep, follow up monitoring for both of these at initiation. You have to have that 4th generation HIV test and an HIV one. The nucleic acid test at one month for the Cabotegravir you need to have that those two HIV tests again and then every two months you have to have that 4th generation HIV test and an HIV 1A nucleic acid test as well.

And then also they say STI testing at least every four months.

A side note is that Cabotegravir is contraindicated with drugs that induce UGT1A1, and so just because it can reduce the effectiveness. Then of the Cabotegravir. These drugs include carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin and rifapentine, and so just as a side note for that. And then Lenacapavir, very similar on stuff you want to test every three to six months at initiation, every three to six months for antigen antibody HIV, that 4th gen test and also the nucleic acid HIV one test.

Same thing with pregnancy. Women of childbearing age should be screened for pregnancy at least every three months, and very similar for the STI screening as well, three to six months, and then chlamydia every 12 months in heterosexual men and women, along with gonorrhea and syphilis every six months. Sorry, I'm going so fast, but I'm watching the time as I do this.

So, HIV post exposure prophylaxis, the non-occupational exposure PEP was just updated in the May of 2025 and there's both non occupational exposure and then occupational exposure. Post exposure prophylaxis is indicated in individuals with a potential HIV exposure to nonintact skin or mucous membranes. That presents a substantial risk for HIV transmission. And so obviously in the occupational setting, that's needle stick injuries. In non-occupational, we're looking at sexual intercourse, drug use. Other things like that. Initiate PEP as soon as possible after exposure but within 72 hours. You should do a rapid HIV test or a fourth gen test before starting PEP. You should do PEP for 28 days and the treatment regimens for both occupational and non-occupational pep are the same. The recommended regimens, and we probably all heard of Biktarvy, right? And so it's biktarvy. It's kind of like the treatment regimen as well that we start folks on. And so you can start biktarvy or you can start dolutegravir plus one of the tenofovir, plus another NRTI and so 28 days and started as soon as possible.

Pregnancy and breastfeeding is not a contraindication for PEP. And then when in doubt you can always get an ID or HIV medicine consult.

But don't wait to initiate PEP. That's the big. That's the big kicker, OK? That's prevention.

Let's talk about our status neutral approach and what happens when the test returns back positive. So let's talk about initiation of rapid ART. And I remember, and I'm older. And so I remember back when a positive HIV was an automatic ID consult. And it was, you know, it was something that was not handled through primary care.

That's all changed, I think. And I think that diagnosing a new infection and initiating treatment, I think it's there's a lot of data that suggests that it should be done in a primary care setting, and it can be done in the primary care setting that will help get more people into treatment sooner.

So, OK, diagnosing a new infection, as I mentioned, individuals who test positive HIV rapid initiation of treatment and linkage to care is a critical early step in successful treatment, and then it just talks about the benefits.

ART in patients with acute and recent HIV infection, you're going to have accelerated resolution of symptomatic acute retroviral syndrome, minimized immunologic damage. You're going to have diminished the size of the late HIV reservoir pool and prevention of HIV, right? And this urgency is greater if the individual is pregnant, has acute HIV infection, is over 50, or obviously they have advanced disease.

This idea of a direct linkage to care – a warm hand off, and we'll talk more about that is more effective than a passive approach.

And so I remember, like, you know, you get a diagnosis of HIV and you send them a referral to ID or HIV medicine or something like that. That's not what we would want to do. That's not optimized care right. You know, especially when the individual that you've recently diagnosed with HIV infection has multiple risk factors and there are things such as like use or lack of insurance or lack of access to primary care. Remember, 20 plus percent of new HIV diagnosis are happening in Greater Minnesota. You know where is their access to care, right? Residents in high poverty areas, housing and security, you can just go on and on, right? The key message is don't let individuals with new HIV diagnosis fall through the cracks.

It's this idea of a warm hand off and initiation of therapy.

Let's talk about this initiation of rapid antiretroviral therapy. And there are tons of resources out there.

I will have a list of these at the end, but to start with, a multidisciplinary approach works best to cover various aspects of treatment initiation, and I will say this, this is kind of pie in the sky stuff. This is if we had sort of unlimited resources of money to do this, but I do think having a multidisciplinary team is the best way to do this.

Having a dedicated social worker or case management to assist with insurance and other social needs, whether it be housing or transportation or things like this, and identification of barriers to HIV treatment, that's critical. We've seen here that is absolutely critical.

We need clinical staff to provide HIV, current and up-to-date HIV and other clinical education. We need to obtain the history to determine the correct HIV regimen. We need consents and a plan for follow up and all that kind of stuff. It takes a team to do this.

And then of course, when you diagnose someone with HIV, you need to get some labs. And I will right then, because they're already in the office and you need confirmatory HIV testing, that includes the HIV nucleic acid and the CD 4 cell count you can send out for HIV genotyping, including integrase resistance testing. And that comes from that concern over use of Cabotegravir for injectable prep. You can look at certain genotyping factors such as HLA B 5701. You need to get a comprehensive medical panel, metabolic panel, Hep A through C, you can do STI testing at all sites of exposure, TB, pregnancy test, all that kind of stuff.

But this is not outside the realm of what is normally done in primary care, I would argue. And then you can consider lipids, G6PD if they are from a certain part of the world. Toxic plasma IgG.

And then initiation of rapid ART. This is where we've come a long way since the early days of HIV, is that these regimens now are sort of standardized and incredibly well tolerated and very safe. And you know, gone are a lot of the side effects and contraindications and interactions and things that we used to have to deal with. To start, an integrase strand transfer inhibitor or the INSTI or the insti based regimen, and then specifically either bictegravir which is the the component in biktavry or dolutegravir is recommended for initial therapy in most people in most people because of the efficacy, the high barrier to resistance, the tolerability, low drug, drug interactions, convenience and better adverse effects profile, these are really well tolerated regimens.

So in summary, for people who do not have a history of using Cabotegravir as PrEP, and that's that every two-month injection, one of the following initial regimens is recommended.

You can either do biktavry all right, which is that integrase strand transfer inhibitor. That's the BIC, along with a couple of nucleoside reverse transcriptase inhibitors. That's the TAF or FTC. Or the dolutegravir plus the other 2 NRTIs.

Or you can do a two drug regimen which is dolutegravir along with lamivudine but you don't use that in folks that have RNA levels greater than 500,000 or HPV co-infection or you know or in whom ART is going to be sort .. before the results of the genotypic resistance testing. So save this one for folks. Normally it's biktavry or dolutegravir plus the other two NRTIs.

Now, for people who do have a history of Cabotegravir and when things get kind of complicated like this, as an aside, it's usually a call to your ID, professional colleague or something like this. Don't feel like you're stranded on an island if you have some like this. Pick up the phone. There's lots of help out there, so I'm going through this, but just as a side. We do have that.

You need to have that insti genotype resistance testing performed before starting ART, but if you're going to start ART right, use a protease inhibitor-based regimen. So boosted dolutegravir, right? And so it can be boosted, you know, with ritonavir or cobicistat, and then plus a couple of the nrtis you can you can do that as well. But again, I would recommend an ID consult for that.

So the key is initiate the ART. Don't lose them. Don't let them walk away and not have a plan in place for follow up and case management and social services and all that kind of stuff.

So OK, real quick, I want to talk about perinatal transmission and HIV during pregnancy. Pregnant patients should be tested for HIV during each pregnancy. Repeat testing is absolutely recommended for individuals who you have concern. If they have, you know recurrent STIs, substance use, housing instability. Any of those risk factors, repeat testing during pregnancy is absolutely recommended.

Without treatment, 25 to 30% of babies born to a mother with HIV will get HIV. If mothers are aware of their status and properly treated along with the infants, the chance the infant getting HIV is less than 2%.

So we need to screen and we need to treat to prevent transmission if we have an individual that's pregnant. If there's an individual that's HIV positive and they need care, reach out to Minnesota's Children's Perinatal and Pediatric HIV program. They are fantastic. And you'll have all this information I believe at the end, but they provide expert consultation to medical providers on the care and treatment of HIV infected pregnant persons and HIV exposed and infected children and youth up to 24 years of age. They provide care and prevention services to these folks and they collaborate with providers throughout Minnesota regardless of health system or where you are, all that stuff.

So bookmark that because that's a keyword. I'm again going to talk about the importance of linkage to care and social services when you diagnose them with HIV. We need to link them to the appropriate care and social services, and that team approach is critical, right?

A warm hand off, as we all know, is way more effective than a passive approach. Handing somebody a referral or giving them a phone number or something like that is not it. It just doesn't work. We have to have a warm hand off approach and here's a little clinician guide, but again there are tons of these sort of recommendations all over the place. Warm hand offs are great.

Other potentially effective strategies have been used, including shorten the wait time for new clinic visits, expanding the hours of your clinic, having like evening or weekend, or using telemedicine or other technological advances, conducting outreach to persons who no-show. If they no-show, reach out to them. Bring them in. Often times it's a difficult time for them. It's stigmatizing. They don't know what to do. They're afraid. Reach out to these individuals.

Conduct case management for new clients prior to their HIV medical provider visit and I would say do it all at the same time if they have the ability to stay there, get everything done as much as you can while the person is right there in front of you.

And with that, here are a few of the resources that I think are really great.

If you have questions about HIV right, you can call the National Clinical Consultation Center. I call them. I think they're fantastic. They focus on clinical HIV. They are brilliant. And so here's the number. You can always call them. Obviously if you have perinatal or pediatric concerns, you can always reach out to Minnesota Children's program. There there's the link there. I always like starting people on meds to use the Liverpool Drug interaction checker. There's a million of them out there, but I just happen to think that one's a really good one. And then you

can always call one of us here at MDH. There's our numbers down below. It's that 5414 number, 651-201-5414 and we can always link you up and discuss whatever you might need.

And so with that, I got a couple minutes left. I just want to go over the key takeaways one more time. There are people living with HIV in every county in Minnesota. These are individuals that you will see, right? Everyone, I capitalize that not because I'm shouting. It's because I want to emphasize everyone aged 13 to 64, and that seems young, should be screened for HIV at least once as part of routine care. And I would say more often if they have one of several risk factors. And I would say remember, early on we talked about who's eligible for PrEP. And it was individuals who have inconsistent or no condom use. That's, you know, I rarely say all or everyone, but I would guess that is a fairly high proportion of individuals, especially those individuals that may be at elevated risk with other factors.

Nationally, about 13% of individuals, and I think Minnesota is right in that ballpark, with HIV are unaware that they are living with HIV. They don't know their status and when you don't know your status, that's when you're at risk, not only for individuals with but transmission to other individuals, right? And then they won't know that that they're at risk for infection because they don't know your status.

Population level screening because of this is imperative to identify undiagnosed HIV. When in doubt, test. It's out there.

HIV PrEP should be offered to everyone at risk for HIV. And this is not just individuals who report multiple anonymous sexual partners and are very, you know, sort of like you have that everyone at risk. And again, I'm gonna go back to that if you had sex with somebody and maybe you have inconsistent or no condom use, you're at risk for acquisition of HIV.

You need to discuss with them the benefits of HIV PrEP. Not everybody but 25% right now are offered PrEP or taking PrEP that should be taking PrEP. Talk to people about it. Have a conversation about sex.

Rapid antiretroviral therapy is critical to reduce transmission and reduce losing that patient. We need to discuss positive results and initiate antiretro therapy. at that visit, or soon after with those warm hand offs, and follow up with that patient. Don't let these folks fall through the crack. And with that, I will hand it back over to Beth. I think I left enough time for a question or two. Thanks.

Thank you, Nick. Yeah, I think we do. We have about three minutes left. I'm looking in the Q&A. I'm not seeing any questions there. Thank you, Nick. That was very comprehensive. Appreciate you getting through all of that.

Does anyone have a question that you would want to unmute your cell phone and come off to ask? Or put in the chat in the Q&A.

And of course, we don't want to put anybody on the spot. You know you can always reach out to us if you have questions later on or you know, we'll be compiling a Q&A document after the conclusion of these MMA webinars that hopefully will answer a bunch of questions that you have so. You can always, if you don't want to now, we're happy to take questions later on as well.

Thanks, Nick for that clarification. All right. Well, you must have covered everything so well, Nick, that nobody has any questions at this time.

Yeah. Well, I don't know about that, but we'll see. So.

Excellent. Well, thank you again, Nick for a very, very nice presentation and thank you to everybody who joined us. As we mentioned earlier, once we are through this series, we will be posting these recordings.

And you will be getting the evaluation via e-mail. That evaluation does need to be completed to get your CME certification.

So with that, thank you for joining us and hope to see you next week for the for the last part of this series.

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