What's New? CDC's STD Quality Clinical Services (QCS) and Treatment Guidelines

Webinar Transcript

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Caitlin Hungate:
Hi everyone and welcome to today's webinar on What's New? CDC's STD Quality Clinical Services and Treatment Guidelines. My name is Caitlin Hungate. My pronouns are she and her, and I'm a training and technical assistance provider with the New York State Family Planning Training Center. And I'm honored to be with you all for today's webinar. A couple of housekeeping items before we begin, this webinar is being recorded and will be posted to our website, NYSFPtraining.org, it's on the slide, in a few days along with the slides.

Everyone on today's webinar is muted given the large number of participants. I am joined by two of my colleagues on our team, Jennifer Kawatu and Angelique Higgins, and Angelique is our technology guru. So if you have any questions with the Zoom platform, she is your go-to support person. We do have time at the end for questions, and you can ask your questions at any time using the chat function. Due to our webinar settings, the chat is only visible to panelists, so we'll make sure to read out the questions so everyone can know those questions.

We do encourage you to participate as you're able to, and we welcome your questions and comments throughout the webinar. So let's dive into the learning objectives for today. So by the end of the webinar, we hope that you'll be able to describe at least three recommendations for providing quality STD services. We hope you'll also be able to identify or list at least two updated recommendations in the CDC treatment guide things, and to identify at least two updated screening recommendations from the taskforce. And last but not least to describe two strategies for providing high quality STD services. Without further ado, I'm going to turn it over to our speaker, Dr. Michael Policar. Dr. Policar?

Dr. Michael Policar:
Great. Thank you Caitlin and thank all of you for joining us this morning. So we're actually going to cover two different topics. The first is the CDC quality STD guidelines. And then I want to give you an update about some of the more recent guidelines from the CDC about treatment of sexually transmitted infections particularly in the last year or two.

I only have one disclosure and that is I was on an expert panel about contraceptive efficacy with Evofem Biosciences about a year ago and we won't be discussing that topic at all today. So here's an outline of the various things that we'll be discussing. When will we see the 2021 CDC STD treatment guidelines? And then much of our time will be spent on the CDC quality clinical services guidelines.

And the other topics listed below are the ones for which their recent guideline updates. But let me start with number one, because we've been waiting well over two years for the CDC to publish their CDC STD treatment guidelines. Of course, the last one was in 2015, I'll refer to them every now and then in this talk. We expected the next set of guidelines to be published in 2019. And then it got pushed to 2020.

It was all finished in early 2020, and then the pandemic came and what's happened is that there has been so much published in the morbidity and mortality weekly reports over the last year and a half,

about the whole COVID-19 pandemic, that it's pushed the publication of the CDC STI treatment guidelines back.

But the most recent fairly authoritative rumor I've heard is that they will be out by this summer. And by the way the name changed. So they will be called the 2021 CDC Sexually Transmitted Infection Treatment guidelines rather than the STD guidelines. I've seen an advanced copy, I had a webinar by the CDC on these new guidelines in December, and there are some fairly significant changes and we will be talking about at least a few of them in the various topics below.

Now, so this audience I don't need to spend much time on letting you know about the epidemiology of sexually transmitted infections because I'm sure you've heard through a variety of clinical sources as well as in the lay press about the fact that STD rates continue to increase year by year or sometimes at really surprising rates of increase.

Now, of course, that's slowed down to some degree during the pandemic but it was probably a reflection of the fact that people weren't coming in for testing. And in fact, there were actually problems of shortages of the reagents to be able to do STD tests. So we're probably seeing as many STDs as ever, but during the last year we haven't diagnosed them because of either people staying home or not having the right test kits.

But if you compare the time between 2013 and 2017, overall there was a 31% increase in all of the various categories of STDs and then CDC data compared intervals between 2014 and 2018. And what we saw during that phase was about a 20% increase in the rate of chlamydia, a 63% increase in the rate of gonorrhea, a 70% increase in syphilis and also a significant increase almost a tripling of the rate of syphilis among newborns with congenital syphilis. So those are the most recent figures we have, but as much as we're doing in terms of screening and testing, the problem continues to grow.

So let's start with the recommendations for providing quality STD clinical services that was published on January 3rd of 2020. So these are not quite a year and a half old. There was initially a fair amount of sort of publicity coming from the CDC about this, but quite honestly, it was varied because of all the information coming out starting in about February, relative to the pandemic. So lots of people really don't know very much about this guideline, just because of the fact that it never was able to penetrate the audience very well because of all the other things that were happening in our lives.

So this is the CDC webpage. It still looks like this about the recommendations for providing quality STD clinical services, and all of the content that I'm going to be discussing right now, you'll be able to get from the CDC website.

So let's start with kind of an overview of why Gail Bolan, who was chief of the STD branch at the CDC, and others that she works with wanted to be able to do this in the first place. And the reason is because they were aware of the success of the quality family planning guidelines. Now all of you know about the document called the QFP, delivering quality family planning services that was published in 2014, which was a collaboration between the office of population affairs and the center for disease control.

So the idea at the SB branch in the CDC was let's do a companion volume to that that has to do with providing services for sexually transmitted infections. And the way that they initially divided that up was what are the services that should be done in a primary care environment, as opposed to what should be done in places that specialize in STD care?

So the idea was as a compliment to the CDC STD treatment guidelines with emphasis on operations. This is a really important point to remember. This guideline looks at systems, the STD treatment guidelines looks at management of individuals. So for those of you on the call who are quality improvement directors, or medical directors or people who are responsible for looking at your overall system ability for ... I'm sorry, for screening, diagnosis, treatment of sexually transmitted infections, this guideline will be really helpful for you.

So the key questions that the CDC used as the starting point is which STD related services should be available to people who either have STDs or at risks, including asymptomatic people in primary care settings. I'll define those for you again in just a moment, but that's mainly community clinics, FQHCs, the officers of OB-GYN, family planning clinics, and then the private practices of course and primary care as well, internal medicine, family medicine and pediatrics.

And then the second question is in specialized STD care settings, what more should they be doing that goes beyond primary care? And then the third thing they did, which I thought was very helpful was what are the reasons, the indications for which primary care providers would send a patient to a specialist for more advanced care? What is the referral threshold is another way of being able to say that. So they were pretty clear about defining what the quality clinical services guideline should look like in terms of its scope and purpose.

So it is intended to define optimal STD care in a way that compliments the CDC STD treatment guidelines, and number two it's to help you assess your services that are available in your clinic from a system point of view. On the other hand, they're not intended to be a diagnosis or a treatment guideline that exists in the 2021 STI treatment guidelines. And it's important to point out that not every service is expected. So what you'll notice is the fact that there are certain things that are strongly recommended and other things that are considered to be shoulds, but not necessarily must.

So again they were very clear about what constituted the difference between the QCC and the STI treatment guidelines. And I won't read them for you other than to say that over on the blue side with QCS, that we're really talking about systems, issues and how to improve your systems. Over on the treatment guidelines side, it's more about the care of individual patients.

Now, the next thing is that they do have specific color conventions. And if you see it in purple, it's something which should be available. On the other hand if it's in blue, it is something that you could make available, but you don't have to in your clinic and it's considered to be a weaker recommendation. So, I sort of jumped the gun there. So let's talk a little bit about the kinds of services that are provided basically on the left side as basic STD care, as opposed to the ones that are considered to be specialized STD care over on the right side.

So basically basic STD care at the primary care level is recommended risk assessment, the best way to do that is to know about the five key mnemonic, which comes from the CDC about partners practices, past STDs and so on as what should be considered basic in a STD history. Screening and treatment of people who have asymptomatic infections and then treatment of common conditions. While in specialized STD services, it's going to include all of the things that are in basic STD care plus same day diagnostic and treatment services.

So there is an expectation at this higher level of specialized care that they're going to be able to do point of care testing and same day treatment, which may not be the case at the primary care level. Next is the kinds of settings where primary care settings, where STD services are being given as opposed to those specialized care settings. So I've mentioned already that the places that are considered to be primary care settings are let's say an adolescent health clinic, family medicine, or internal medicine providers, or family planning clinic, FQHCs, OB-GYN, in pediatric offices, school-based health centers, and other primary care clinics like an urgent care clinic, for example.

On the other hand, the two places for specialized STD services are in STD specialty clinic. Out here in the Bay Area, ours is called the city clinic in San Francisco where they specialize in STDs. I'm sure that you work with many clinics if you're not working in one already that primarily or exclusively does STD services. And they include sexual health clinics as well at that specialized level of care. And note that family planning is considered to be in the basic STD sort of primary care setting.

I think of family planning is kind of being a hybrid of the two because many family planning clinics are actually in some ways very specialized in doing STD services as well. So these are the various topics that are covered. Think of them as chapters that have to do with sexual history and physical exam, prevention, partner services, screening, evaluation of symptomatic conditions, laboratory tests, and offering treatments.

So first is about sexual history and physical examination. And thankfully, this one's very busy. Of course, I'm not going to read it to you, but I want to differentiate here the shoulds and the coulds. So the should in purple are the things that we should be doing as sort of a floor, basic level of care. So for example a physical exam for male and female patients with STD symptoms or concerns should be available at basic and specialized places. A pelvic exam for female patients should be available as a floor in both circumstances.

Now, if you look over on the left side where it says primary care settings, it says that you should be able to do a more detailed sort of sexual history and personal history, but that when you get into way more detail, that could be available. It says an anoscopy looking for evidence of pre-invasive regions of the anus, which are due to HPV could be available as a basic STD service in a family planning clinic.

So, on one hand, it's saying you don't have to do that, but on the other hand is permissive and saying that if you want to add an anoscopy in a primary care setting, or let's say in a family planning clinic, because that would be perfectly reasonable to do that. Now on the right side, where it says specialty care settings, we have to be able to do a much more detailed sort of specialized STD visit. We should be doing anoscopy. We should be doing colposcopy and high resolution anoscopy HRA as it's referred to for people who have abnormal anal cytology tests, sort of the correlate of what we do for colposcopy on the cervix and in the vagina could be available in this specialty STD setting.

So again, you don't have to, but you could. In my experience high resolution in anoscopy is usually done in either an HIV clinic or in a gastroenterology practice, but it could be done in a specialized STD clinic setting as well. So again the coulds, which are permissive and the shoulds which are a floor.

The next is about prevention. And basically what they say is that those in primary care settings and in STD settings, that we should be making at a minimum HPV vaccination and Hepatitis B vaccination available. And there are a lot of primary care sites, and I'm thinking here OB-GYN offices that don't make either HPV vaccinations or Hepatitis B vaccination series of three injections available.

And they're saying we should be able to do that in any setting that offers STD services. And then further down, basically it says that in primary care settings, other things that we might be doing for prevention are Hep A vaccination or providing PrEP or nPEP provision. I'll define nPEP a little later, but just to remind you it's non-occupational HIV exposure. The PEP of course refers to Post-Exposure Prophylaxis.

So, in other words if a patient comes in and says, "I had a very high risk sexual contact with someone who I suspect or know was HIV positive." Then that would be a person who is a candidate for Post-Exposure Prophylaxis, not because they had a needle stick injury, an occupational exposure but they had a non-occupational exposure. So that's what nPEP refers to.

On the other hand, on the right side so specialized STD care, the guidelines say that we should be doing Hep A vaccination in addition to HPV and Hep B vaccination, as well as high intensity STD behavioral counseling, which is defined as an intervention, which is a two hours or longer. Next is partner services, and for everyone, the recommendation is that expedited partner therapy, and it's now legal in virtually every state should be done at both the basic level and at the STD specialty level. And that additional interventions are in the primary care setting. We could be doing interactive counseling for partner notification, don't have to, but we could be doing that. And then over in the special care clinic side, then we should be doing that.

Now, just to remind you. Interactive counseling for partner notification means doing a role play with the patient about you've been tested positive for chlamydia or for gonorrhea or both. How are you going to tell your partner or your partners about that? Let's do a five minute or a three minute role play about how you're going to tell me, how are you going to tell the partner rather that you've been found to be positive for an STD, you're going to be treated, why the partner should be treated, how the partner should be treated. Let's practice that a little bit.

So now notice again, that expedited partner therapy is a basic should and that every primary care setting doing STD services should be able to do expedited partner therapy. Next is one of the things that we should be screening for in regards to sexually transmitted infections. So there lists both for primary care and specialized services are at a minimum we should be able to screen for gonorrhea, chlamydia, syphilis, Hep B, Hep C, HIV, and do cervical cancer screening. With HPV alone, with cytology alone, or a combination of HBV plus cytology which is go test it.

Then in addition, they say in primary care circumstances we could do trichomoniasis screening. And the CDC in 2015 did have a recommendation in the trichomoniasis chapter, which basically said that people who are at high risk of STDs should be routinely screened for Trich once a year and HIV positive people should be screened for trichomoniasis once a year as well. So that's a could in the primary care setting, it's a should in the specialized STD clinic.

And they go on to say down at the bottom, that screening and assessment could be available at the specialized STD care site for anal cancer as well. So in other words, STD clinics could be doing anal cytology, could be doing anoscopy, and if they wanted to could even be doing a high resolution anoscopy.

All, alright, next are what are those conditions that should be manageable at those of primary care and in STD specialty setting level. And again I won't read the whole list for you, but basically any genital ulcer disease, either in men or in women, I should say males or females. Male urethritis syndrome, vaginal

discharges, pelvic inflammatory disease in females, genital warts in either males or females, ectoparasitic infections and of course that refers to scabies or crabs, epididymitis in males, various genital skin conditions and proctitis. So all things that we should be able to evaluate in a primary care setting or an advance STD clinic setting.

Next choice is some guidance about what are the point of care tests that we should have available? So what they consider to be the bare minimum is a thermometer and pH paper. Most of us of course have far more than that available. So over on the primary care side including family planning clinics, what we could be able to do.

I think for many of these, we should be doing them anyway, are having a microscope or point of care tests to evaluate trichomoniasis, test for bacterial vaginosis, which can of course, either be done by microscopy or it can be done with a number of different point of care tests, test for vulvovaginal candidiasis, a urine dip, urinalysis with microscopy and test for HIV, which would include either point of care tests for HIV, or sending out a blood sample for an HIV serology or both.

On the other hand, that complete list and a few more things, for example like syphilis testing are on the should be side of what should be done in specialty care settings. You'll notice at the bottom that certain tests could be available for example dark field microscopy for syphilis. But I understand from [the book] that there are probably about five or six places in the whole country that still have dark-field microscopy available for syphilis. So you can do it, but there's no expectation that you have to.

All right, next are all the different tests that you should be able to send to a laboratory. So that first list applies both to primary care and STD settings. And basically it's the things you're already sending to a clinical lab for gonorrhea, chlamydia, syphilis, herpes simplex, hepatitis A, B and C, and of course pregnancy testing.

And then at the bottom are other lab tests which could be sent to a lab optional. So for example, a gonorrhea culture, if you're worried about antibiotic resistance, let's say in addition to or in addition to a nucleic acid amplification test. Someone tests positive with a NAAT test for GC, and you're part of a surveillance network that's looking for resistance to antibiotics. Then you would have the availability of sending off the culture as well for susceptibility testing. And that is considered to be a minimum for STD specialty clinics as well.

Next is a list of all the various conditions that we should be able to treat. So on the left side are the various STD conditions that primary care clinics can choose to treat. You don't have to treat all of them, but if you don't treat each of those conditions and you have to have a referral pathway to be able to send a person to treatment.

So for example, in your family clinic, and you don't treat people for proctitis or epididymitis, you at least have to be able to refer people to a source of where they can be treated for that. On the other hand, on the right side is a long list of diagnoses that patients have where it's expected that people will be treated for all of those various conditions in an STD clinic.

Next has to do with what are the circumstances where you should be available ... I mean, where you should be able to treat people with various antibiotics, either by dispensing onsite in your clinic or by prescription. This is a pretty straightforward list. So it says as a minimum, you have to have treatments available in the primary care setting for vaginal candidiasis, BV, urinary tract infections, prescribing

patient applied regimens for treating genital warts like nickel warts for example, ectoparasitic infections, and an expectation that you make PrEP available to your patients, either in the primary care, cetera.

In addition things where you should be able to treat it are anti-virals for herpes, metronidazole for trichomoniasis, emergency contraception and again non occupationally related post-exposure prophylaxis. And then on the STD side of all of those things as well. Now, the last of the various lists that are included in the CDC quality STI guidelines are what are the circumstances when you should be referring a patient to a specialist? And this might be a infectious disease specialist. It might be to an OB-GYN infectious disease specialist, or an internal medicine infectious disease specialist, or a pediatric infectious disease specialist.

But these are the kinds of circumstances where they're basically saying we don't expect you to handle this at a primary care level or even an STD specialty level, but you do need to have a referral pathway where you can consult with a local or regional specialist in this circumstance.

So what they list are various circumstances of complex gonorrhea cases, complex chlamydia cases, complex cervicitis and epididymitis cases, complex PID for example, when a person's like say resistant to ... I shouldn't say resistant, when they have allergies to various types of typical antibiotics that are used to treat PID, or let's say a person who's got such a bad case of PID that she has a tubo-ovarian abscess and needs to be admitted.

So we need to have relationships with specialists who will be able to manage that. Next are referrals for females who have complex vaginal discharge, trichomoniasis, vaginal candidiasis, where you treated the person on a couple of occasions and they're just not getting better. And therefore you may need special diagnostic capability, and so on. And in that circumstance, had to refer to a specialist, in this case in vulvovaginal conditions.

Next are complex syphilis cases. That's mainly tertiary syphilis and people who have penicillin allergy. Next to that are complex cases of herpes and followed by complex cases of warts. And by the way when external genital warts are up in the anal canal and very difficult to get to, or when you have just a huge broom of warts on the vulva or in the vagina, or on the cervix, those are really tough to treat. And oftentimes will take an infectious disease specialist to be able to do that.

Complex ectoparasitic infections and a person may ... Especially if they've got HIV, they need to see a dermatologist for that. And then there are a number of things that are listed in regard to sexual assault. So that reviews the entirety of the guidelines. Surely you'll get a chance to read them. And now in our next 20 minutes or so before we take questions, what I want to do is to give you an update about where we are with screening and treatment of various conditions based on newer recommendations from the CDC.

So we'll start with just a quick reminder about the list of STI screening for cis women that come namely from CDC STD treatment guidelines, as well as the US Task Force. It's a little inaccurate to say 2015, because some of these have been updated, but sort of the high level view is that for sexually active adolescents and adults who are 24 years of age or younger, we still do gonorrhea and chlamydia screening annually. We screen for other, and that's irrespective of a person's sexual behaviors.

We screen for other STDs based on risk. And we screen for HIV at least once between the ages of 13 and 64 years of age, of course, more often in the circumstance of people who have higher risk behaviors for

the acquisition of HIV. For women 25 and older, again STD and HIV testing is based on risk. We'll talk more about that in just a moment and then is a longer list of circumstances for screening females who are HIV positive.

I need you to excuse me for about 10 seconds. There's some sign going on in the background. I just need to close the door. So hang on for just a sec. I'm back. All right. So now to talk about a little bit more about each of those circumstances. So I already mentioned what the US preventative services task force guidelines is, and that is we screen sexually active non-pregnant females who are 24 years of age or younger every year. From in, there is no recommendation. So routine screen.

So basically we screen males on the basis of their risk factors rather than routinely every year. Now, one of the things I wanted to add is that in the guidelines from the California STD control branch, there are a couple of other guidelines that we use in California that now are used elsewhere. And that is that if in your practice, what's referred to as practice site prevalence, if the rate of people seen in your clinics for chlamydia is 3% or higher, or the rate of gonorrhea is 1% or higher, then you would do routine screening.

So let's say in your clinic, you find that the rate of chlamydia in females between 30 and 35 is 5%. Then what you might want to do is screen all females between 30 and 35, because of the fact that you're above that 3% threshold. So just the thought about knowing how to tailor routine screening in your practice based on the patients in your practice, and by the way how do you find out what the practice site-specific prevalence is in your situation?

You basically ask the laboratory that you send your test to, to run a positivity rate for the last few years. So in girls that are between 30 and 50 for example, we want to know by five-year intervals what is the positivity rate. Within a week or two, they should be able to give you that information for your clinic. All right, next is this issue of for females 25 and older, what are the risk factors that should trigger gonorrhea and chlamydia screening? Because we don't screen them routinely automatically. We screen them based on their risk factors.

So it all depends on who you ask. US Task Force says that if a person has had a previous sexually transmitted infection, or has a current sexually transmitted infection, newer multiple sexual partners, and they don't define unfortunately multiple sex partners, a sex partner who has other partners, a sex partner with an STD, people who inconsistently use condoms, people who exchange sex for money, drugs, safety, or housing, are all circumstances where we should be screening people that are 25 and older for gonorrhea and chlamydia.

The problem I have is that even though those are reasonable, they're not very specific. So what do they mean by multiple sexual partners for example? So again, I'm just going to tell you a little bit about what I think are more helpful guidelines about who gets targeted chlamydia and gonorrhea screening based on their risk factors and again, these come from the California Department of Public Health.

So there are seven, a history of gonorrhea, chlamydia, or PID within the last two years. So now we have a timeframe, more than one sexual partner in the last 12 months, a new sexual partner within the last 90 days. Number four, I think is really important qualifying. That is rather than just to say is your partner having sex with someone else? What you'll ask instead is do you have reason to believe that your sex partner has had other partners within the last year?

And that's not just a flowery way of saying it. That's actually a validated question. It's associated with the chlamydia rate of 6% or more. So it's not does your partner have other partners, instead, do you have reason to believe that your partner is having sex with someone else? That will give you more accuracy in knowing that there's a greater likelihood that your patient actually does have chlamydia that way.

Next is exchanging sex for drugs and money within the last year. African-American women up to age 30 maybe in increased risk. And again, that depends entirely on your population in your setting and then other factors that are identified locally including the prevalence of gonorrhea and chlamydia both in your community. And again, specifically in the site where you work.

I worked in the county hospital for 30 years at San Francisco general. And our rate of gonorrhea in our women's health clinic was under 1%. And that being the case, we did targeted springing rather than doing working screening. Of course for non-pregnant women. Pregnant women have always got gonorrhea screening. Next is just a reminder of where you get your samples for gonorrhea and chlamydia. And basically what this says is for females that a vaginal swab is preferred and many clinics in fact are doing a self administered, a vaginal swab rather than forcing the patient to have the speculum exam or a kind of physical exam where the vaginal swab is obtained.

Patient can go into the bathroom, collect the swab, drop into a container and then it's an offer for testing. And as a matter of fact during the pandemic, now many times those collection kits are actually being delivered curbside to a patient who then takes the collection container home, or to another place. Gets the specimen sample from her vagina, drops it into the collection container and then drops it off at the clinic.

Now another important question, and I'll only briefly mention this is what about multi-site screen? And by that what we're referring to is in females not only taking the sample from the vagina, but what about an oral pharyngeal sample, or what about erectile sample? So CDC guidelines are quite clear and have been since 2015 that for men having sex with men, you should really sample all three sites, throat, genital, and anus.

But in females that has never been very clear. So what we do basically is to screen on the basis of sexual history, have you had oral sex or do you have anal receptive sex and then separately testing those sites if it comes up positive. And there is some data about how likely it is that the throat or the rectum are going to be positive in females. So the first study was done in the UK, but it was strictly done in STD clinics.

Basically what they found was that rectal chlamydia positivity in females was about 6%. If a person reported anal receptive sex, it was 26% that you would have chlamydia, and significant number of rectal infections would have been missed if you only do the vaginal sample. The lower study was done in the United States, and there are lower rates of oral pharyngeal and rectal gonorrhea in females, but roughly about 2% and for chlamydia pharyngeal gonorrhea ... I'm sorry, rectal chlamydia is about 1.9%. Pharyngeal chlamydia is about 2% just to give you an idea in a high prevalence population, in an STD clinic about how common those are, and I'll skip that slide.

So basically at least for a female patient who says that they do have oral sex, or they have anal receptive sex, it is appropriate to sample not only the vagina but the throat and the anus as well with separate swabs. For the throat, be sure to sample the tonsillar pillars. Patient will usually gag but hopefully you can get a good sample before that. And for the rectal swab, that can be inserted three to four

centimeters into the rectum, twirl the wrist all the way around, 360 degrees and then put it into the specimen container.

All right. Next is what about new treatment recommendations for gonorrhea and chlamydia? And of course, this is a reminder of when we're going to be treating people for GC and Ct, those who have positive test, those who have a partner with a positive test, females who have mucopurulent cervicitis, or a male who has a prelim urethritis, and then females who have pelvic inflammatory disease.

So first is going to be the treatment for chlamydia. And this is what will be in the 2021 CDC STD treatment guidelines. Remember for, gosh, at least the last 10 years, our treatment of choice has been azithromycin one gram to treat lower genital tract chlamydia. Then 2021 guidelines will change that. And they're going to change it back to using doxycycline 100 milligrams twice a day for seven days, or doxycycline delayed release 200 milligrams once a day for seven days.

Now, why did they do that? Primarily because they're starting to see some strings of chlamydia that are azithromycin resistant, but they are not resistant to that longer seven day course of doxy. And so you remember that back, jeez, in the late '90s or early 2000s, we used a week of doxycycline and before we went to azithromycin, now we're back to using doxycycline for seven days. The alternative regimen is azithromycin one gram orally directly observed. So hopefully we can hand it to the patient in the clinic and watch them take their medication. And it is still the first line treatment in pregnancy because we'd rather avoid using tetracycline white drug in a person who's pregnant.

So hopefully you've made that switch where now doxy for a week is your preferred regimen for chlamydia. Although you still can azithro, it's just again a concern about resistance. Now, how about gonorrhea? That has changed quite dramatically. And it's based on something that was published in the MMWR on December 18th of 2020. So this is about what? About four or five months old, basically. And again, there's significant concern about gonorrhea resistance.

So the new recommended regimen for treatment of gonorrhea in females or males, and this is both anogenital infections and oral pharyngeal gonorrhea is ceftriaxone now 500 milligrams IM in a person who weighs less than 330 pounds or ceftriaxone a full gram IM in a person who weighs more than 330 pounds. So basically the drug we're used to using for treating gonorrhea, but now in a significantly higher dose. 500 milligrams for most people and then a full gram of ceftriaxone for people who weigh more than 150 kilograms.

Now, do we ever use dual therapy where we use a combination of ceftriaxone and azithro or ceftriaxone and doxycycline? And basically what it says is that if chlamydia has not been excluded with a negative test result, then go ahead and treat that possibility of coinfection with chlamydia with doxycycline 100 milligrams for a week, or in pregnancy use azithro one gram PO. So just to clarify this a little bit, basically it says if you're screening someone for gonorrhea and chlamydia, the gonorrhea part comes back positive, the chlamydia part comes back negative.

Then you don't have to treat the chlamydia, you can treat the gonorrhea with ceftriaxone at a higher dose by itself. On the other hand, if you're treating syndromic, because it's a partner, or if it's someone who has mucopus coming from their cervix, for example, and you don't know yet whether it's gonorrhea, chlamydia or both, and you're going to treat empirically. And the point is you still treat with a combination of the higher dose of ceftriaxone plus doxycycline for a week.

So again, this explains why basically increasing concern for antimicrobial stewardship. In other words, we don't want to like overdo or overuse azithro for example, and get even more chlamydia resistance to it. Number two is if ceftriaxone continues to work quite well, but the higher doses just to make sure again, that resistance to a higher dose ceftriaxone doesn't occur. And the reason for the switch from azithromycin back to doxycycline is because of the increased incidents of azithromycin resistance.

Now there are of course situations in which you don't have injectable ceftriaxone. What you need to do is to prescribe or dispense to patients oral medications. And we still use Cefixime, but again at a much higher dose. So for uncomplicated urogenital and rectal gonorrhea infections, now the recommendation is Cefixime, you may know that by it's trade name of Suprax, but there are many generic routine.

So Cefixime 800 milligrams once, or for people who are allergic to cephalosporins or penicillin to use gentamicin IM plus azithromycin orally as a way of treating those infections. So again you can treat with only pills. This is particularly good for expedited partner therapy. So if you're a patient with gonorrhea, she is going to take medication to her partner to have the partner treated. Then the way you would do that is with Cefixime 800 milligrams as a single oral dose.

All right, now, just a couple of other quick reminders, so we can get to our Q and A and that is for the most part, we don't do tests of cures after treatment of gonorrhea or chlamydia. This is a list of those circumstances where you would want to do a test of cure, probably the most important of which is in pregnancy, we still routinely do a test of cure.

And then the last topic I'm going to cover, there are a few other things that are in the handout, but again I want to be able to get you to the questions is to say a word about mycoplasma genitalium. There are lots of questions about this. There's a new test for which there are lots of marketing things going on out there. And this definitely will be covered in the 2021 CDC STD treatment guidelines.

So mycoplasma genitalium was mentioned in earlier CDC guidelines, but primarily for males and not for females. So the prevalence of M genitalium infections is around 2% in both males and females. In a high risk population it's higher, about 15%. And in females, there is a association about a doubling of risk of cervical infection, PID, preterm birth, spontaneous miscarriage, and infertility in women who have mycoplasma genitalium.

The thing is though that there has not been a proven cause and effect relationship. So in other words, just having the infection is not necessarily the cause of the PID or the preterm birth. It could be that other factors, other sexual behaviors, other pathogens are the cause of the breach on birth or the PID. And everyone's waiting for studies that show that if you treat mycoplasma genitalium, that actually improves fertility, or that it reduces preterm birth or spontaneous abortion, we don't have that yet in females.

What you probably have heard though, is that there are some new tests available to look for mycoplasma genitalium. FDA approved one called the Aptima M genitalium assay in 2019. It can be used both for females and for males. I've listed the sites that you can sample for you. There are some commercial labs that do in-house PCR tests for mycoplasma genitalium, but we don't know much about their accuracy. We know that the Aptima test approved by the FDA, or I should say cleared by the FDA does have a relatively high accuracy.

And the only indication so far for using this test is in the diagnosis of Non-Gonococcal Urethritis in males. So if you've got a male who's had burning on urination, maybe a urethral discharge, you've looked for gonorrhea and chlamydia and you can't find it, or maybe you've treated them and they're not getting better, then in that circumstance, it's recommended to use the mycoplasma genitalium assay.

There are no guidelines for using a mycoplasma genitalium screening test in females, or as a diagnostic test for cervical infections, urethritis, PID or infertility. So hopefully that will actually be included in the new CDC STI treatment guidelines. Also, as a reminder, the way that that infection is treated is with moxifloxacin 400 milligrams daily for somewhere between seven and 14 days. Unfortunately they don't do a very good description of when you use seven days and when you use two weeks.

And the reason for that is both doxycycline and azithromycin resistance is starting to emerge in the case of mycoplasma genitalium. So when we see the new CDC STD treatment guidelines in the summer, hopefully it will have even more information about both who to screen and how to treat mycoplasma genitalium in females.

Just lastly, a heads up about some of the other things that I've included in the slide task is let's say for your typical patient, they come in and say, "I had a new partner three or four weeks ago. I just met him or her. We didn't have a condom available and I'm concerned that I picked up an STD. I want you to screen these for everything." So what's everything? Gonorrhea, chlamydia, syphilis, and HIV should be routine for a high risk sexual contact.

Maybe an herpes type 2 serology, but only if that person is willing to change their sexual behaviors based on whether the test is positive or negative. And we don't do contact testing with a herpes culture, with an HPV test and with each hepatitis C or hepatitis B screening. And just again, to remind you about what's in the remaining slides for hepatitis B, the idea is everybody should leave vaccinated. Tried to find cases, we try to vaccinate.

In the case of Hep C, the US Task Force did come out with a new recommendation about a year ago, saying that every adult between 18 and 79 should have a once in a lifetime Hep C test. And then periodically, if your continued risk of acquiring Hep C. PWID stands for people who inject drugs. Then other than that, I've included that 2019 guidelines for who gets screened for HIV. I'm sure you know that already, but one of the important that they mentioned is that we should be using a test that is called a fourth generation HIV test serology, but there's also a point of care tests for fourth generation as well.

And that tests both for HIV-1 and HIV-2 antibodies. And in addition for the p24 antigen. And when you look for the actual antigen of HIV, it moves up by about four weeks your ability to make a diagnosis. So it's not a more accurate test, but it's a test which will turn positive earlier than the third generation test. And then finally just a few things about syphilis epidemiology that I'll just skip over. You can read them when you have time and what I want to close with and then we'll take a couple of questions is some resources.

So this is a list of CDC surveillance reports, treatment guidelines and so on. If you have a tough case, submit that case to the STD Clinical Consultation Network and here's their URL. And then the National Network of Prevention Training Centers can also be quite helpful in terms of answering patients about specific ... I'm sorry, answering questions about specific patients or about the STD program in your clinic. So with that, I'm going to wrap up and hand the microphone back to either Jennifer or Caitlin who's going to moderate our questions.

Jennifer Kawatu:
Great. Thank you so much Dr. Policar. We do have some questions here that have come in through the chat. So the first one is, should, or must providers wait for the official publication and release of the new guidelines in order to implement changes?

Dr. Michael Policar:
No, I don't think so. Number one, with the recommendations that I mentioned for gonorrhea, those have already been published, they were published in December. So absolutely you should start that. The only one that I kind of gave you a preview about was ... That will be published in the guidelines is the treatment for chlamydia with doxycycline instead of azithromycin. And the CDC has said enough about that, but I think it's perfectly reasonable to switch over to that.

And remember, of course doxycycline was already listed as an alternative treatment. So all that happened was just the switching of doxy to be the preferred treatment and azithro to be the alternative. So perfectly fine to do that.

Jennifer Kawatu:
Well, I'm going to ask a follow-up on that, because one of the questions that was asked is and I think you've clarified the first part of the question, but the second is, can you explain if and why ... I think you've gone over this, but I'm just going to give you a chance to clarify. If and why the committee of treatment recommendations, i.e doxy versus azithromycin, is different depending on whether or not gonorrhea is also present.

Dr. Michael Policar:
No. So the point is that if the person is diagnosed with gonorrhea and you don't have the result of a chlamydia test, then you haven't ruled out chlamydia. So you're going to treat both. So in that circumstance, the answer is you use the high dose ceftriaxone as a treatment for gonorrhea and the treatment for the chlamydial part is doxycycline for a week.

So azithro is considered an alternative, but the preference is to use doxycycline for a full week. So whether it's chlamydia by itself or whether it's gonorrhea plus chlamydia, now the recommendation for treatment of chlamydia is doxycyline for a week.

Jennifer Kawatu:
Great. Thank you. The next question is what is the STI prevalence in women who have sex with women and what screening is recommended for that population?

Dr. Michael Policar:
So prevalence of ... Often first all depends on which pathogen you're talking about, but the prevalence of gonorrhea and chlamydia is relatively low for women who exclusively have female sexual partners but it's certainly not zero. So it's really interesting that at least in the CDC guidelines, there's very little mention of women having sex with women. There's a lot of mention of men having sex with men, but not so much of women having sex with women.

But when you look at other sources, basically what it says is that within an exclusive female with female relationship, that the best thing to do in that circumstance is to evaluate the various STI risk factors that I just mentioned, and then offer screening based on that. Or recommend screening based on new

partners, more than one partner in the last year, a new partner in the last 90 days and some of the other things that are on the list and then let that individual patient make the decision about that.

The thing that can be difficult in some circumstances is that a person can disclose that they mainly have female partners, but that they may not exclusively have female partners. So periodically there might be a male partner involved, which would increase the likelihood of horizontal transmission.

So I think that's one of the reasons why there aren't very many specific recommendations about screening of females who are exclusively in relationships with other females, just because of the fact that number one, they're not really big studies and number two, because of the content of being effective, the occasional male partner that might occur.

Jennifer Kawatu:
Great. I think that we have time for one last question, and that is what can you tell us about the mail order test kits and prescriptions, and is there any data on the impact on health outcomes?

Dr. Michael Policar:
So part two is no, I don't know about studies about outcomes. There might be, but I haven't come across it. So I'm so glad that that question was asked because it's very confusing. So there's a difference between self sampling at home as opposed to what was referred to in the question, which is a mail order testing.

So what many clinics are doing is providing to a patient a test kit, which might be a formerly packaged test kit. It might be a brown paper bag with a test tube with sealing and a couple of swabs. So you can sample your vaginal discharge. You take that home, you sample yourself based on the instructions you get, you drop that off at the clinic. And then the clinic sends that to the lab that they usually use.

The beauty of that is the fact that you don't have to actually go into the clinic. If that test is paid for normally by your clinic, it will still be paid for by your clinic. Now, the other possibility is that you're using an at-home test service. So an example of that is you go to a commercial pharmacy, a Walgreens or CVS, or you can even do this online at Amazon.

You buy a test kit, and by the way, the price of those are based on how many pathogens are being looked at. So they're anywhere between $50 and $150. That kit is sent to your home, you follow the instructions for a urine sample, a vaginal sample, it might even be a spot blood sample. That is then sent back to the company that makes the test. They then send that to a clinical lab where the test is run, and then a clinician is available to give you your results.

Now that works reasonably well, but the trouble is that it's very rarely paid for by either health plans or by let's say a Title X clinic, for example. So the person's going to have to pay out of pocket for the test kit. And then number two is that they usually do not include the price of running the test itself. So you might pay let's say $100 for a kit that includes gonorrhea, chlamydia, syphilis, maybe even HIV, maybe even Hep B, but for all those tests, a laboratory is going to bill you separately for running the test.

When you bought the kit, you just basically paid for mailing and the availability of a clinician to give you the results. So the reality is that it works, it's accurate, but it can be quite expensive when in fact your regular clinic can make that available to you for free. So be very judicious about differentiating between

picking up this test sampling kit at your own clinic, where it will be covered as opposed by a commercial one which will work just fine. But if it's going to cost a lot out of pocket.

Caitlin Hungate:
Thank you, Dr. Policar so much and Jennifer, thank you so much for facilitating these great Q and A. If you haven't already, please subscribe to our e-news, we've chatted that link out in the chat and thank you everyone for joining today. I hope you join me in thanking Dr. Policar. We are so grateful for your expertise and guidance.

The next slide has additional resources in addition to what Dr. Policar shared and are hyperlinked in the PDF for you. Please as a reminder, the materials from today's webinar will be available in the next few days on our website. Our final ask is to please complete an evaluation. We have chatted that link out in the chat. We really appreciate your input and guidance and how we can improve future events. Thank you for joining today, this concludes our webinar.

Dr. Michael Policar:
Caitlin before we break, can I just add one more quick resource?

Caitlin Hungate:
Sure.

Dr. Michael Policar:
Obviously giving you guys a shout out and that is let me go back a slide, to the Reproductive Health National Training Center because they have developed so many really helpful resources about STD services by telemedicine and particularly this idea that I was just talking about in regard to curbside pickup of testing kits there are very, very helpful specific resources for you at the RHNTC website about how to do that. So take advantage of it.

Caitlin Hungate:
Wonderful. Thank you, Dr. Policar. So this officially concludes our webinar. Have a wonderful day, and we'll see you next time. Thanks so much.