Implementing the CDC *STI Treatment Guidelines, 2021*: A Conversation for Family PACT Providers
September 8, 2021

Nicole Nguyen:

Hi everyone. Good afternoon and thank you for joining us today for our webinar titled Implementing the CDC *STI Treatment Guidelines, 2021*: A Conversation for Family PACT Providers. We hope you are all doing well and staying safe. My name is Nicole Nguyen, I'm the Program Manager of the Family Planning Program here at the California Prevention Training Center. The CAPTC, under contract with the California Department of Health Care Services' Office of Family Planning, is sponsoring today's event.

Nicole Nguyen:

And so, before we get started, I just want to go over some really quick housekeeping slides. So first please check to make sure your audio and your desired settings are correctly picked to either join through your computer audio or to call in through your phone. And if your internet connection is shaky, we highly recommend that you call in through your phone to get the best possible sound.

Nicole Nguyen:

And then second, please check that you're able to see the viewer screen with the slides on the left and the GoToWebinar control panel on the right. And just some quick buttons on the dashboard, this orange box with a white arrow, this is how you can hide or show your dashboard. You don't want to see it, or you accidentally click it, this is how you can make it reappear again. And then right under that is the audio tab where you can change your audio preference at any time. And then third, please submit all your comments and questions via the questions box.

Nicole Nguyen:

Today's webinar will take about 90 minutes and will include time at the end for the presenter to answer all your questions. So please send in your questions as you think of them throughout the webinar and our speakers will address them, as many as possible, at the very end. This webinar will be recorded and responses to questions not answered today by our presenters will be sent out to participants later with the recording and the slide deck. There is an evaluation at the end, so please fill it out because your feedback is extremely important to us and really help guide us in developing our future content.

Nicole Nguyen:

And then before I introduce our presenters, I just want to acknowledge that we are really excited to be working with the University of Nevada, Reno School of Medicine to provide CMEs for this event. This webinar qualifies for 1.5 CME credit, and is only available to those who watched the entire webinar live today. Unfortunately, those who watch the recording after it will not be eligible for the credits. And the link to access your certificate will be included in the follow-up email to all those who attended today, along with the recordings, the slides and the evaluation survey.

Nicole Nguyen:

And then, of course, for transparency's sake, we just want to say that all presenters and planners and their partners do not have any financial relationships with commercial interests related to the content of this activity.

Nicole Nguyen:

Okay, so now for the exciting part, I get to introduce our presenter. So we are really excited to get to have Dr. Ina Park and Dr. Michael Policar with us today. They're both two of our superstars here at CAPTC. So Dr. Ina Park is the Clinical Program Medical Director and Principal Investigators here at the California Prevention Training Center. She is a professor in the Department of Family and Community Medicine at the University of California, San Francisco School of Medicine, and a Medical Consultant in the Division of STD prevention at the Centers for Disease Control and Prevention. She's the co-author of the 2021 CDC *STI Treatment Guidelines* that we'll be hearing all about today, which is the country's premier resource for diagnosis and treatment of sexually transmitted infections. And she is also the author of the really awesome, newly released book, Strange Bedfellows: Adventures in the Science, History, and Surprising Secrets of STDS. It's awesome, I highly recommend it. And then, welcome Ina.

Dr. Ina Park:

Thank you so much, Nicole.

Nicole Nguyen:

And then next is someone we're always, always happy, and excited to have present for us, is Dr. Michael Policar. Dr. Policar serves as the Clinical Professor of Obstetrics, Gynecology and Reproductive Sciences here at UCSF School of Medicine. And from 2005 through 2014, he was also the Medical Director of Program Support and Evaluation for the Family PACT Program administered by the California Department of Health Care Services' Office of Family Planning. He currently serves as Professor Emeritus of Obstetrics, Gynecology, and Reproductive Sciences here at UCSF.

Nicole Nguyen:

And so, with that, Ina and Mike, the floor is yours.

Dr. Michael Policar:

Okay, no problem.

Nicole Nguyen:

Yes.

Dr. Michael Policar:

Thank you, thank you very much. Jumped the gun here. Hang on.

Dr. Michael Policar:

Okay, so thank you all for joining us.

Nicole Nguyen:

That's right, I need to make you presenters really quick.

Dr. Michael Policar:

Okay, good. Thank you.

Dr. Michael Policar:

And we'll do, oops, kind of jumped the gun here. Okay, do you have me as a presenter?

Nicole Nguyen:

Oh, yes. Sorry, let me just.

Nicole Nguyen:

Sorry. Let me make you a presenter. Yes.

Dr. Michael Policar:

Okay, show my screen. Here we are. Okay. So just a couple of introductory remarks and then we're going to jump into our content. So Ina and I spent a fair amount of time talking about how we wanted to do this, and we decided to pattern it after a discussion we did a couple of years ago that had to do with a clinical practice alert about gonorrhea and chlamydia that was published for the Family PACT Program. And rather than just to sort of go through a traditional presentation with lots of studies and lots of slides, we actually did it interview style. It worked out really well.

Dr. Michael Policar:

So, for the most part, I am going to be interviewing Ina, given the fact that she was part of the expert panel that wrote the 2021 CDC *STI Treatment Guidelines*. And most importantly, in addition to telling you about how the guidelines changed, what Ina's going to be doing is telling you about why they changed. And that's really important information because sometimes when you read the guidelines themselves, it isn't immediately clear, or it takes a lot of reading to get that figured out. So I'm delighted that Ina is going to be able to share that information with you.

Dr. Michael Policar:

Number two, what I wanted to remind you is since this is a Family PACT webinar for Family PACT providers, I know that you'll be curious about whether or not the Office of Family Planning has actually changed Family PACT benefits to include the new guidelines. And the answer is, is that that's in the works. They are being evaluated right now. The policies, procedures and billing instructions for Family PACT will be updated fairly quickly. But one of the things you'll learn as we go through the guidelines is the fact that many of the changes are changes in the preferred regimen and the alternative regimen, but it's with many of the antibiotics that you're used to using, all of which are already covered by Family PACT. So the point is, is that for the most part, you will not find any barriers or obstructions to using the new guidelines as you're treating Family PACT patients, because virtually all of the regiments that we'll

be talking about in fact are covered, and we'll be reminding you about that to some degree during the presentation itself.

Dr. Michael Policar:

So, let me go on from there. Okay, here are our learning objectives and I won't read them for you, but of course we have to tell you about those in advance because of the fact that we're offering CME credits for this talk.

Dr. Michael Policar:

Here is the cover of the guidelines that we've been waiting years and years for it seems.

Dr. Ina Park:

True.

Dr. Michael Policar:

A little bit about that history, but the point is, is that they were actually devised by the expert panel a few years ago, but given the pandemic coming when it did, it delayed the publication of the new guidelines, which started out actually as 2019 STI Treatment Guidelines and now have finally been published in July of 2021.

Dr. Michael Policar:

Now, one of the nice things that the CDC did is to not only make the guidelines available on their website, in fact that's the middle box where you can download the PDF of the entirety of the guidelines, they also have some very helpful things that you can use as well as job aids as you're taking care of patients clinically. One is a wall chart that hopefully you'll have available in your clinic and maybe in every one of the exam rooms just to make it easy for you. And the other is a really nice pocket guide that has all of the treatment regimens for STIs. And I use that one all the time as I'm writing lectures, it really saves you the time of having to weed through the guidelines themselves and getting straight to the recommended and alternative treatment regiments.

Dr. Michael Policar:

You may also notice at the bottom of the slide, what the CDC is telling us about the mobile app. Most of us have gotten very used to using the CDC STD Treatment Guidelines from 2015 in their mobile app. And now for the 2021 STI Treatment Guidelines, the mobile app is in process, but it's not yet available. So in the meantime, try to use the handy pocket guide as a way of reminding yourself about the regimens. And also, by the way, you can download something from this webinar. It's a handout that we've made available to you, which is a comparison of the 2015 CDC STD Treatment Guidelines and the 2021 STI Treatment Guidelines. So you can very quickly see in a comparative way how things have changed.

Dr. Michael Policar:

One last thing before we get into the questions is why did the name change from the STD Treatment Guidelines to the STI Treatment Guidelines? And Ina can expand on this a little more in a moment, but the way I understand it is that the idea is, is that sexually transmitted infections refers to basically

pathogens that cause infections through sexual contact. And many of those infections have not yet actually caused disease, that a person is newly infected with gonorrhea or chlamydia or syphilis, but they haven't actually developed a consequence, a sequela of that, which would be a sexually transmitted disease. So what the CDC was trying to tell us is rather than a focus on treating established diseases, that we have to think more expansively about treating infections, most of which are actually asymptomatic. And at that point, they are sexually transmitted infections rather than diseases. So that tells you a little bit about why the name has changed and why all of us should be working on trying to change the nomenclature that we use from using the term STD to using the term STI.

Dr. Michael Policar:

So, first question I'm going to ask Ina is when is multi-site sampling necessary? Of course, when we're talking about that is that we are, of course, used to taking genital samples from the vagina of females, from the penis and urethra of males, usually done in the case of chlamydia and gonorrhea through a urine sample in males, but there are those circumstances where we actually need to sample three different sites. And that's something which is quite clearly detailed in the new guidelines. So I am going to give Ina the permission to advance the slides.

Dr. Ina Park:

Okay.

Dr. Michael Policar:

Hang on, to Ina Park, just a second. And Ina's going to be able to advance for us. There we go, okay.

Dr. Ina Park:

Okay, let me make try then. So Mike, just to, let me see if I can actually advance. Not yet.

Dr. Michael Policar:

Okay. I will try once more and if not, just tell me and I'll advance for you.

Dr. Ina Park:

Sounds good.

Nicole Nguyen:

Also, try just clicking on the slide Ina, and see if that just...

Dr. Ina Park:

Okay, let me see that.

Dr. Michael Policar:

Ina, you should be able to now. Give it a try.

Dr. Ina Park:

Okay.

Dr. Michael Policar:

There we go.

Dr. Ina Park:

Okay. So just to add one more comment to your sort of discussion about STI versus STD. I think the field of family planning had moved in this direction actually well before the field of STD had, and we actually tried to get the nomenclature changed for the 2015 guidelines, but it didn't stick. But I think there's an acknowledgement as well now that STI might be a less stigmatizing term. And I think while none of our patients want an STD or an STI, I think we're all for using less stigmatizing language whenever possible. So that's another sort of argument for STI versus STD.

Dr. Ina Park:

So, I wanted to talk a little bit about preferred specimens for GC/CT infection. So for cervical infection actually, a vaginal swab is the preferred specimen. And this has been around for a long time, this is not new. And by the way, when we talk about something new, we're typically going to highlight it in yellow to make it stand out for you. And we've known this for at least the past five to 10 years, that the sensitivity is at least as good as cervical swabs, and it's certainly better than urine. And the self-collection option has mostly been studied in cisgender females, but it has also been looked at for HPV and cervical cancer screening in trans men. And it seems to be acceptable for both trans men, as well as for cis females. And then there's less specimen processing required than with urine. And so of course though, you need to see what type of specimens your lab will accept and how they should be handled so you don't have a specimen returned and not tested.

Dr. Ina Park:

So, when we talked about who needs to get multi-site testing, well, for a long time, we knew that men who have sex with men needed to have multi-site GC and CT testing. So this is cisgender MSM. And that is because the majority of gonorrhea and chlamydia infections can be missed if you only screen people at the urogenital site. And most of these pharyngeal and rectal infections, as we know, are asymptomatic. So the CDC does recommend for folks who have insertive intercourse to test a urine NAAT for GC/CT, and then if you have receptive anal sex, do a rectal swab, and then if you're giving oral sex or having receptive oral sex, to do a pharyngeal gonorrhea nucleic acid swab.

Dr. Ina Park:

Now pharyngeal chlamydia testing is still not recommended because there's very low prevalence, even in higher prevalence populations like MSM. Many of us have these tests bundled and we can't separate them so it's fine. If you end up getting a positive pharyngeal chlamydia, go ahead and treat it. And one thing about offering testing and who you should offer it to is that you can offer testing to folks even if they don't acknowledge, for men who have sex with men, if they don't necessarily want to tell you all the types of sex that they're having, there is under reporting of behavior. And if you have any doubts, offering three site testing is completely reasonable.

Dr. Ina Park:

So now this is new, cisgender women and multi-site testing. So lots of folks have been saying, "Hey, we know women perform oral sex on men. We also know that women have anal sex. And so what about screening those sites in cisgender women?" And finally the CDC said this should be based on a shared clinical decision. They used to just say, "Don't do it or just really only focus this on men who have sex with men." And now everything is sort of loosening up a bit, and in particular adolescents, there is specific language around considering pharyngeal and rectal testing in that population in particular.

Dr. Ina Park:

And then finally, there's also a more fleshed out section on transgender and gender diverse people. And I wish that this was even more fleshed out, but we're just going to be taking baby steps. And for transgender or gender diverse people who are having sex with cisgender men, all of the studies seem to reflect that the risk for STIs is similar. So you're going to screen those populations similarly to cisgender MSM.

Dr. Ina Park:

Now, the CDC also said, "Okay, we know people are having gender confirming surgery. And so if you've had a vaginoplasty, then transgender women who've had a vaginoplasty should be screened at all sites of exposure." And they did not specify whether or not to use a urine test or a neo-vaginal swab. But I will say that if your neo-vagina is constructed completely of squamous epithelium, those cells cannot be infected by gonorrhea and chlamydia and so a urine test is reasonable in that situation. If you don't know what type of tissue is used to construct the neo-vagina, or if the person's surgery was done using colon mucosa, then it's a good idea to do a neo-vaginal swab.

Dr. Ina Park:

Now, for transgender men who've had a metoidioplasty, if the natal vagina is still present and the person is using the vagina or a front hole or however, they refer to it for sex, then you can use either a cervical or a vaginal swab.

Dr. Ina Park:

So, I'm trying to advance. Let's see. Uh-oh.

Dr. Michael Policar:

Try again, if not, I'll advance it for you.

Dr. Ina Park:

Yeah, I think if you move the cursor, then it takes mine, so if you could advance to the next slide, that'd be great.

Dr. Michael Policar:

Yeah.

Dr. Ina Park:

Yeah, so what about this question about how much rectal chlamydia and gonorrhea is there in cis women who are seen in sexual health clinics? And it depends on whether or not the person acknowledges a history of anal sex. So looking at a study by Chandra et al., in the UK, the overall positivity in the clinic was 6% for cisgender women. But if the woman reported having receptive anal sex, then obviously the percentage and prevalence went up, so almost 26%.

Dr. Ina Park:

So, it's a little bit different here because women who have a rectal infection are more likely to also have a cervical infection. So if you only screen the cervical site, you're going to miss only about 18 to 23% of those rectal infections also, which is different than in MSM where you have lots of folks who have rectal infections who don't have a urogenital infection.

Dr. Ina Park:

And then another study in 2016 also found a lower percentage overall of rectal GC and pharyngeal GC and a higher percentage in this particular STI clinic setting for rectal chlamydia, almost 9%. And again, pharyngeal chlamydia, very low prevalence in this population. So certainly we know that rectal chlamydia and gonorrhea certainly happens and is more likely to happen if people report history of anal sex.

Dr. Ina Park:

And then this study is actually from a large commercial laboratory and they took specimens from women that were paired. So they had a rectal specimen as well as another anatomical site. And if you have a rectal infection and that infection happens to be with chlamydia, your genital chlamydia infection is going to also be positive about 65% of the time and negative about a third of the time. It's a little bit less correlated for folks who have rectal GC. If you have rectal GC, the genital GC in this study was positive about 40% of the time. But one thing I wanted to point out, this is actually a study using Quest data, almost half of women actually had just a rectal infection and did not have an infection at another anatomical site. So again, all of these data came together and folks considered, we should probably loosen up the recommendations around rectal and pharyngeal testing for cis women.

Dr. Ina Park:

So, let's talk about technique for a second. And I think many of us pivoted to having patients self-collect during this time, but if we aren't doing the collecting, swabbing both tonsillar pillars like you would with a throat culture, and there was actually a study that said if you actually get the patient to gag, you're more likely to get a positive result if an infection is there. And for a rectal swab, it's all in the wrist, you want to put it in about three to four centimeters and twirl around. And again, I have to say, I think there's probably seven or eight studies that I can think of that show that patients can do quite a good job in terms of specimen collection.

Dr. Ina Park:

So, Mike, I think for a long time, folks were thinking that Family PACT did not cover multi-site sampling, but I hear you have some good news to share with folks on the call around this. And can you talk about the Family PACT benefit around extra genital screening?

Dr. Michael Policar:

Sure. Thank you. And just one quick thing to add to all the helpful information that you just gave, that particularly when it comes to females, as you heard a moment ago, where we stand on that is that there's an assumption that you are going to be taking a sexual history that asks the female patients you see about whether or not they're having anal receptive or oral receptive sex. And we are actually going to come to that later in the webinar when we talk about the new 5 Ps. That is to say sort of an advanced way of taking a sexual history, where you can find out that important information, which is going to drive some of your screening decisions.

Dr. Michael Policar:

So, the question is, does Family PACT cover multi-site screening? And the answer is yes, they do. And that's been the case as of September 2018, so for three years. So both Family PACT and Medi-Cal permit up to three gonorrhea, chlamydia nucleic acid amplification tests per recipient, per day, recognizing the fact that there are a significant number of both males and females who will need to be sampled at all three different sites. So the throat, the genitals site, and the anus.

Dr. Michael Policar:

Remember to use separate NAAT test kits, regardless of which of the three sites you're sampling. Because, of course, if only one is positive, you need to know which one which may have an effect on not only the treatment regimen that you use, but also the kind of follow-up you do, particularly in regard to test of cure. The CPT codes are the same whether you take that sample from the throat, from the genital tract or from the anus so be sure to label your samples clearly.

Dr. Michael Policar:

And remember that in Family PACT, whenever you send a screening test for an STI, like for gonorrhea and chlamydia with the NAAT test, that on the lab slip, you not only have to put the ICD 10 code for the method of contraception that the person is using, but in most circumstances, not all, but most, you also need to put an ICD 10 diagnosis for the reason that you're doing the gonorrhea, chlamydia test in the first place. And in the policy, procedures and benefit manual for Family PACT, policies, procedure, and billing instructions I should say, the PPBI, as well as the sample super bill or encounter form that you may be using from Family PACT. There's a whole listing of relevant ICD 10 diagnosis codes.

Dr. Michael Policar:

The only time you don't need to do that is when you're doing routine gonorrhea and chlamydia screening of a female who's 24 years of age or less. In that case, you only need to put what her method of contraception is. But if that younger person has more than one test per year, or on different dates of service, or if she's 25 or older, or if it's a male, you always need to include two ICD 10 codes on the lab slip, one being the family planning method, and then the other being that indication for doing the test. Okay.

Dr. Ina Park:

And Mike?

Dr. Michael Policar:

Yes.

Dr. Ina Park:

Can I ask a quick question about that? And if you have a person, regardless of gender, who has a new exposure, who you feel may need to be tested again, and let's say that person comes in three weeks later, is there a limit in the number of multi-site tests per month, for example, that Family PACT would cover?

Dr. Michael Policar:

Yeah, thanks for asking. And the answer is, is that three tests per day is per 30 day interval.

Dr. Ina Park:

Thank you.

Dr. Michael Policar:

Yes.

Dr. Michael Policar:

So, I'm going to ask, while we're on the subject of gonorrhea and chlamydia, one of the things that stands out in the new guidelines is a change in the recommendation about treatment of chlamydia infections. So we've switched from azithromycin, which used to be the preferred choice, back to using doxycycline yet again. So why did that happen and are there any circumstances left when you would use azithromycin?

Dr. Ina Park:

This is such a great question, Mike. And I remember when this was proposed and I got lots of emails from my folks who do adolescent medicine, for example, or folks who work in urgent cares and just a collective groan saying, "What do you mean seven days of doxycycline compared to single dose azithro?" I'm going to give you some rationale, and I'm going to tell you the circumstances in which you might want to consider using azithro over doxy and when you really want to push the client or patient to try to get them on board with doxycycline. Next slide.

Dr. Michael Policar:

Let's see if you can do it. Can you advance it?

Dr. Ina Park:

There you go. Oh, great.

Dr. Michael Policar:

Go back one.

Dr. Ina Park:

Oh sorry, back one.

Dr. Michael Policar:

There you go.

Dr. Ina Park:

So, this includes both observational studies and randomized controlled trials of looking at the efficacy of doxycycline versus azithro for urogenital infections. And the doxy is in dark blue, the azithro is in a lighter blue. And in fact, there was actually a systematic review of all of the studies and found very similar results to the Geisler study or the Kong study where there was a 3% difference in efficacy. So I want you to put that in your brains, about 3% difference for urogenital infection between doxy and azithro.

Dr. Ina Park:

So big deal, right? I mean we knew this and so why would we make a switch to every site of infection just for a 3% difference? Well, we wouldn't, but what really raised concern, and these are observational studies looking at doxycycline versus azithro for rectal chlamydia. You can see that it's significantly worse, right? And we're seeing now more like an 8% difference, sometimes a 20% difference. And so this was concerning obviously for treatment failure at the rectal site.

Dr. Ina Park:

And so there have been two randomized controlled trials. I'm just going to present one of them to you because the other one, it found very similar results, looking at doxy versus azithro for rectal chlamydia.

Dr. Ina Park:

And this slide versus azithro for rectal chlamydia. And this slide is from Julia Dombrowski, and so I'm sorry, there's a little formatting issue. But this is how it was sent to me and I can't fix it. But I just wanted to show that in her study, that if we look at folks on the left side of bars, which is a complete case. Meaning that they had chlamydia at baseline and they showed up for at least one of the follow-up visits, where they got a test-of-cure. The difference in efficacy was 100% versus 74%. So it's even worse than what we saw in the observational studies. So obviously this is very concerning in terms of failure. Just of note, by the way, 20% of the participants when they came to their initial study visit, had cleared their chlamydia on their own.

Dr. Ina Park:

And so, which I think is an interesting sort of factoid from this study. But for those who had chlamydia at baseline, you'll see a huge difference, and a similar study published in the new England Journal by the Australians just earlier this year. So that just really cemented the idea that we really should use Doxy instead of azithro for rectal chlamydia. So there was a change in the 2021 guidelines. Anyone who's not pregnant should get Doxy. Their alternative regimen is azithro is still there as well as the Fluoroquinolone regimen if needed. And certainly I have used a fluoroquinolone regimen when we've had azithro treatment failure in the past. Doxy treatment failure is rare, but does happen, and you can

use fluoroquinolone in those cases as well. There is a delayed release doxy that you can take once a day. It is more expensive. It's supposed to have less GI side effects. So in pregnancy, the recommended regimen is still single dose azithro. And a test-of-cure is recommended in pregnancy at three to four weeks. And then amoxicillin is still the old standby alternative regimen.

Dr. Michael Policar:

And I just [crosstalk 00:30:05] want to make a quick comment about your training, chlamydia in pregnancy for Family PACT patients. And of course, remember that that once a person is known to be pregnant, then they are no longer eligible for Family PACT. But I know that certainly there are those circumstances where it's just not entirely clear whether or not a person's pregnant. For example, they didn't have a negative pregnancy test, but given their history of when they had intercourse relative to their last menstrual period and so on. There might be a question of pregnancy. And in that circumstance, you could go in the direction of using azithromycin.

Dr. Ina Park:

Yeah.

Dr. Michael Policar:

But again, I just want to remind you that while this is really important information for you to see, because of course we don't want to use a doxycycline and a person who's known to be pregnant and who's planning on continuing their pregnancy. I didn't want to give the impression that somehow Family PACT now, covering services for pregnant women. But we certainly acknowledge the fact that sometimes it's unclear and that you still have to treat a person who might be pregnant as if they are.

Dr. Ina Park:

Yeah. And Mike, I think, your second question of this little segment was really about when would we use azithro. And I think, when I've been doing the shared decision making sort of process with patients sometimes. Because especially folks who are used to taking a single doses chlamydia and now they're being told that they have to take doxy are sometimes questioning that. And I've explained, especially if I think a rectal infection is likely. The difference in efficacy, really with doxy versus azithro. If a rectal infection is highly unlikely then really, if especially if they say, "There's no way I'm going to remember this. You know, can you just give me the single dose?" I have very little qualms about giving that if I think a rectal infection is unlikely.

Dr. Ina Park:

My patients who are doing adolescent medicine... I mean, sorry, my colleagues are doing adolescent medicine. Many of them are still using azithro because they are really concerned. I just had a teen patient who said, "you know, I want to take the single dose therapy because I'm too afraid that a bottle is going to be discovered with pills in it, by my parents". So those are real concerns.

Dr. Michael Policar:

Absolutely. That's really good advice. Okay. Well, let's switch from chlamydia now over to gonorrhea infections. So there were some significant changes about treatment of gonorrhea, which actually were first published back then in December 2020, but fully intermitted into the new recommendation. So why

the switch from dual therapy to ceftriaxone monotherapy? And is there still a role for dual therapy? And if so, with what?

Dr. Ina Park:

I know, Mike, I feel like we're having whiplash. You know what I mean? Like we just got used to dual therapy now we're going back to monotherapy. So I've been in the field long enough that we've had a back and forth, you know what I mean, between mono and dual therapy. So I'm just going to go into it a little bit and provide some rationale.

Dr. Ina Park:

So, here's the problem. The baseline problem is that we have, and that we've had is that half of gonorrhea isolates in this country are resistant to at least one antibiotic. If we look back to 2009, you'll see that in the dark green, three fourths of isolates were actually susceptible to everything. Then now in 2019, you'll see that we're down to less than half that are susceptible to all drugs. Then you'll see in different colors, those that are resistant to just fluoroquinolone versus, two antibiotics or just doxycycline.

Dr. Ina Park:

So, let's start with that at baseline. Then this is one of the primary drivers for the change in dropping azithromycin. So the percent of GC isolates in the national surveillance program at CDC that have reduced susceptibility to azithro, went almost to 5% in 2019 and is probably going to be worse for 2020. Therefore they felt like it was probably time to pull that. Not because, that's not terribly high, right? Fluoroquinolones resistance is over 20-25%, but azithro, as you guys know, is used for so many other infections in the community, respiratory infections, as well as Shigella and other GI infections sometimes. So the idea of sort of preserving it for use and not putting pressure on the bugs that are circulating by having more azithro circulating around. So the decision was made to really just drop it and double the dose ceftriaxone. Which again, as Mike said, came out in December, so 500 milligrams IM, if you weigh under 150 kilos, and if you're heavier than that, then it's going to be a full gram ceftriaxone.

Dr. Ina Park:

If you're empirically treating someone for what you think is gonorrhea and you haven't yet ruled out chlamydia again, the seven days of doxy that we talked about and if you have concerns, obviously you can give, azithro to co-treat possible chlamydia. But in general, if you know that you're treating just gonorrhea and chlamydia has been ruled out, you're just giving monotherapy with ceftriaxone. And the CDC came out with this kind of controversial recommendation to do a test-of-cure if you're treating pharyngeal gonorrhea. They say 7-14 days. I will say, do yourself a favor if your clinic is going to implement this wait 14 days, because there are new data that are not yet published, but lots of folks are still persistently positive at seven days. I think seven days is just too soon. So I think please, err on the longer side of doing your test-of-cure, if you're going to do test-of-cure pharyngeal GC.

Dr. Michael Policar:

So, can I ask you a quick question then before we go back. So let's say you do a test-of-cure after treating someone ceftriaxone on. You do a test-of-cure for a person with pharyngeal gonorrhea and what if that test-of-cure even two weeks later it was still positive?

Dr. Ina Park:

Right.

Dr. Michael Policar:

So, did they get retreated with, with ceftriaxone or with something else?

Dr. Ina Park:

You know what? I actually have the document up and I will try to figure out how to put it in the chat a little bit later in the Q&A, but the state of California and the California Prevention Training Center actually came up with treatment failure guidelines about what to do in this scenario. If you really think there isn't a re-infection situation happening Mike, because that often is the case. But if it's not a re-infection and you truly think it's a treatment failure, then we should be getting a gonorrhea culture and essentially going to double the dose and give a gram of ceftriaxone, and actually give two grams of azithromycin. So actually, give dual therapy with double the dose of azithro as well as with, with the gram of ceftriaxone. That's just in a nutshell. It goes into more detail, but I will try to put that in the chat.

Dr. Michael Policar:

That'll be really helpful. Hopefully we won't see many of this treatment failures, but it's sure helpful to have advice about what to do. Thanks.

Dr. Ina Park:

Should we move on Mike?

Dr. Michael Policar:

Yeah, go ahead sure.

Dr. Ina Park:

So, I think if ceftriaxone is not available, the dose of Cefixime was doubled to 800 milligrams. And again, just as monotherapy. If you haven't ruled out chlamydia, try to treat the doxy and if you can't use doxy or the patient is not going to be compliant or adherent then try azithro. So for true cephalosporin allergy, the recommendation has not changed from the last iteration, which was a gentamicin 240 milligrams plus azithromycin 2 grams. One pearl is that, the concentration of gentamicin requires it's about six milliliters that have to be injected. So you usually have to divide the dose. The issue is, is that gentamicin does not work very well for pharyngeal gonorrhea. So, in all possible if you have pharyngeal infection, please try to use ceftriaxone whenever possible.

Dr. Michael Policar:

Great.

Dr. Ina Park:

Yeah.

Dr. Michael Policar:

Okay. So again, staying on the topic of gonorrhea and chlamydia, was there any update in the guidelines regarding patient delivered partner therapy?

Dr. Ina Park:

Yes. And thank goodness. I think one of the things... I've been wanting to see this for a while. Mike. You know, they did their specific language around...Our job as providers is not over when we just treat the patient. It's important to discuss partner treatment and that is specifically called out. One of the things that we banter around in California is this idea of bring your own partner or BYOP. Which would be, essentially notifying a patient that they have chlamydia and saying, "Hey, if you have a main partner, bring them with you and we can treat both of you at the same time." That is actually an approach that was studied in the state of California and seems to work well.

Dr. Ina Park:

Now patient delivered partner therapy is a form of expedited partner therapy. Where the patient often gives medication directly to the partner or some states also allow a prescription to be written. Right? For the patient's name and then an extra dose for the partner. can be written in there, or writing a prescription in the name of the partner. So ideally, and here in the state of California, there's a program through essential access health, which provides free medication for this, where you give also written instructions for the partners. So they don't take a medication that they're allergic to for example. The state of California, actually in 2001 set up a whole sort of reporting hotline and email when they first approved this to see if they would get reports of adverse events and there was nothing reported. So I think that's encouraging. I think more when I first started in the field Family PACT did not cover on patient delivered partner therapy, but I'd love for you to update folks on what the benefit is right now.

Dr. Michael Policar:

Okay. I'm going to do that in just a second. I want to go back. You just talked about, cause I want to mention something about the first bolt. And that is the fact that, I really appreciate the fact that in the new CDC, STI treatment guidelines, that they explicitly said that the responsibility for discussing partner treatment rest with the diagnosing part provider and the patient. Because of course in the past, there was always a little bit of confusion about, well, is the health department going to track down the partners? Shouldn’t the system for contact tracing actually take care of that?

Dr. Michael Policar:

And the reality is that since the pandemic county health departments or state health departments are just so overwhelmed with work that has to do with, the COVID-19 pandemic, that they just don't really have the time or the staff to be able to track down partners. Particularly if we're talking about something like gonorrhea, chlamydia, trichomoniasis, and so on. They maybe in some circumstances might be doing that with HIV or even syphilis, but they're not doing it with gonorrhea and chlamydia. So we are really responsible for it. And they, like I said, they're quite explicit about the fact that it's the provider that made the diagnosis, working with the patient who is responsible for, for these interventions that have to do with getting a partner screened. So the question-

Dr. Ina Park:

Can I just add one more thing?

Dr. Michael Policar:

Yeah.

Dr. Ina Park:

Is one more thing, Mike, is that finally, they also removed this specifier that they used to have, where they would say it's really only for cisgender heterosexual folks.

Dr. Michael Policar:

Uh-huhh (affirmative).

Dr. Ina Park:

We've expanded it to say... And I just think that that is a reasonable, it's just unreasonable to say, we can only use this in heterosexual people. I mean, I think it's a harm reduction strategy. It's obviously ideal to get people in, especially if they're at risk for HIV. To do all the other testing that they should have. Right? But I think that the CDC has finally just sort of expanded and removed this sort of cis-gender hetero terminology or restriction on the practice. I would love for you to talk now about what's going on with Family PACT and its benefit around PDPT.

Dr. Michael Policar:

Okay but, I have to compliment you first about the chapter in your book that has to do with the history of contact tracing.

Dr. Ina Park:

Oh right.

Dr. Michael Policar:

Absolutely fascinating.

Dr. Ina Park:

Oh Mike.

Dr. Michael Policar:

Yeah.

Dr. Ina Park:

But no one has time to do it anymore, except for COVID and HIV and some syphilis. Lots of health departments. I have had to deprioritize some of their syphilis as well. So no one's going to help anyone do contact racing for STI is right now. It's just really on the patients and the providers to help.

Dr. Michael Policar:

Right? So as you were saying, the good news is that the Family PACT, and for that matter, Medi-Cal changed their policy in August 2020. So a little over a year ago now, and here, I'm going to quote directly what the policies, procedures and billing instructions say. And that is if a Family PACT client is diagnosed with gonorrhea, chlamydia or trichomoniasis and expedited partner therapy is medically necessary to prevent reinfection of the patient. The provider can either dispense medication directly to the client, to provide to his or her partners. As I was saying, there are many clinics that actually have partner pacts all ready to go to give to the patient, to take to her partner or his partners, or to provide the client with a prescription. And this is important in the client's name, not in the partner's name, for medications, have a sufficient quantity and sufficient duration to treat in acute infections in both the client and the partner.

Dr. Michael Policar:

So, what it's saying is that you can basically double or even more, double the prescription to treat both the patient and the part and very obvious question. I'm sure it's not, I apologize. This uncovered slide is, but what if the person discloses that they have more than one or two partners? And the answer is, that at least Family PACT will cover that all the way up to five partners. So, if the patient discloses that she or he has that many partners and you're providing multiple partner pacts, then all the way up to five on the same date of service will be covered by Family PACT for antibiotic therapy.

Dr. Ina Park:

And Mike?

Dr. Michael Policar:

Yeah.

Dr. Ina Park:

Yeah. And Mike, you know there've been studies now, both in California, as well as in Missouri that have looked at which of these approaches is most likely to get a partner treated and absolutely giving medication directly to the client. If that's at all possible is better than providing a prescription because some of those prescriptions do not get filled. And then some studies, a quarter of those prescriptions don't get filled. So in terms of making sure that the partners get treated, if you can possibly give pre-packaged medications, that is certainly the way to go.

Dr. Michael Policar:

Agreed. Okay. So, the next question is, what about PID? Given the fact that we've talked about gonorrhea and chlamydia, which are the most common causes of pelvic inflammatory disease in females, how would the treatment guidelines change there? And I'm going to answer that one, but I would also love to have the insider's view from Ina once I finished. So the guidelines have changed about the outpatient treatment for pelvic inflammatory disease. And again, when you've been doing this for a long time, as, as many of us in the audience, we've seen these, these regimens change over time. They've changed yet again, and it's primarily because of this randomized control trial. Where females with PID were treated with ceftriaxone 250 milligrams IM, plus doxycycline for 14 days. In the past, the

addition of metronidazole was optional. So you could do it if the person also had BV, if you wanted to improve anaerobic coverage, but you didn't have to.

Dr. Michael Policar:

So, what this study basically did was to treat people with ceftriaxone and doxy. Then they were randomized to getting a third drug, which has metronidazole 500 milligrams twice a day for two weeks, or they got a placebo twice a day for 14 days. So it was really intended to answer this question in an RCT about whether or not using metronidazole in addition to ceftriaxone and doxy actually change outcomes. So the primary outcome was whether or not a person improved clinically in three days, but additional outcomes were anaerobic organisms present in the endometrium at 30 days. They would find that out by doing an endometrial biopsy and then sending that material for culture, for anaerobic organisms, as well as looking at outcomes, fever, reduction, and reduction in cervical motion tenderness. What they found was that clinical improvement at three days was similar in the two groups.

Dr. Michael Policar:

So, whether or not metronidazole was used, or placebo was used in the short term, the outcomes were the same, but in the longer term, adding metronidazole made a difference. It reduced anaerobes in the endometrium, when that was checked by black culture, 30 days late. It reduced the likelihood of *Mycoplasma genitalium* in cervix all the way down to 4%, in the people who were treated with three drugs versus 14%, in people who were treated the two drugs and also reduce cervical motion, tenderness and pelvic tenderness down to 9% in people who got all three drugs in comparison to 20% of people who were only treated with two drugs. So the conclusion from that well done randomized control trial was that metronidazole should be routinely added for the outpatient treatment of pelvic inflammatory disease rather than optionally as it was in the past. So now the guidelines say we have two options for treating PID in females.

Dr. Michael Policar:

One is again, ceftriaxone 500 milligrams IM, plus doxycycline, a hundred milligrams orally twice a day for two weeks with metronidazole 500 milligrams twice a day for two weeks or cefoxitin 2 grams IM with probenecid. Probenecid basically causes the blood levels of cefoxitin to be much higher, which is more effective in killing off the gonorrhea. But again, followed by doxycycline for 14 days with metronidazole given for 14 days. So, one question that I'm sure you all have and something which is included in the guidelines has sort of a variant on what was in the 2015 guidelines is what, if you work in a clinic where you're seeing a patient with PID and you just don't have the ability to use either of these injectable cephalosporins. You sure like to. They have the best evidence to support them, but there are those circumstances where you might have, might not have the ability to do an injection.

Dr. Michael Policar:

So, in the narrative, they do list an alternative regimen. Although they specifically say it's for people who have an allergy to cephalosporins. So they say, if you have a cephalosporin allergy, it's the community prevalence in individual risks for gonorrhea that is low and follow up is likely. You can use the regimen that had been listed previously for oral treatment PID, which is legal, ofloxacin, 500 milligrams a day for two weeks, plus metronidazole twice a day for two weeks or moxifloxacin, and metronidazole given for 14 days, but they also make it very clear that you have to do a gonorrhea NAAT test on the same day that you do that oral treatment. If the gonorrhea NAAT test is positive, then what you've just treated

with... The legal ofloxacin and metronidazole or that moxifloxacin and metronidazole isn't enough, and the person needs to come back. And if they have the cephalosporin allergy and can't use one of these regimens, then the guidelines basically say, talk to an infectious disease specialist about that. Because you'll have to figure out a way of getting the PID manage in a circumstance where you can't use cephalosporin.

Dr. Ina Park:

now.

Dr. Michael Policar:

So that's where we stand-

Dr. Ina Park:

Yeah, and you might end up using gentamicin in that circumstance. I would definitely sort of seek out counsel and I'll actually mention, we have the consult service as well, where we can have people send to those questions if they end up coming up.

Dr. Michael Policar:

Okay, well, we're going to switch gears a little bit and now talk about a greatly expanded section that has to do with *Mycoplasma genitalium*. As of a few years ago, there is an FDA cleared test for *Mycoplasma genitalium* and nucleic acid amplification test. So, the questions are who should be screened for *Mycoplasma genitalium* and when? And a separate question is apart from screening asymptomatic people, when should it be used as a diagnostic test?

Dr. Ina Park:

Okay. So before even going into the slide, I'm just going to say, we should not be screening anybody for *Mycoplasma genitalium,* and you can talk about that as well in the Family PACT benefits. So please don't screen asymptomatic folks for *Mycoplasma genitalium*. I'm going to talk about this bug. Really. It scares me a little bit. It's so common, and it's got such high levels of antibiotic resistance that it, is certainly a concern. And one bug that I want you guys to keep your eye on. Now that we do have an FDA approved, very sensitive and specific nucleic acid test. So, I want you to think about *Mycoplasma genitalium* sort of in between, it's not as common as chlamydia, but it is actually in most studies a little bit more common than gonorrhea. Prevalence in national studies of cis-gender men and women is 1-3%.

Dr. Ina Park:

But if we look at sort of high-risk populations, it can be as high as 11 to 16%. So there is an association and It's not as slam dunk as, HPV and cervical cancer, for example, but there is an association with cervicitis, PID, and bad birth outcomes like pre-term birth and spontaneous abortion as well as infertility. So the strength of the association is not as high as it is with chlamydia and gonorrhea. We are looking also for longer term studies that show that preventing Mycoplasma might prevent these negative outcomes, and then that might lead to screening recommendations, but we're not there yet.

Dr. Ina Park:

Oops. I entered the field in 2007 and we were just hoping and praying for *Mycoplasma genitalium* FDA approved test, and it took 12 years, but it did come out in 2019 and there are actually now Aptima was the first and, there's another manufacturer Roche that has one now approved for a urine penile meatal. So just, swabbing the outside of the urethra. Urethral swabs endocervical and vaginal samples and many large commercial laboratories had their own what I call home brewed PCR tests that they'd never published performance data for, but for the most part, the technology being used was probably pretty good. And it is recommended, for use of diagnosing non-gonococcal urethritis in males, and can also be used for recalcitrant or recurrent cervicitis.

Dr. Ina Park:

But the issue with this bug is that in most of the studies, and most recently the Magnum study over 50% of these *Mycoplasma genitalium* had a resistance mutation to azithromycin. Azithromycin which we were using, a lot for NGU and cervicitis is really not effective against this bug. So Mike, this probably brings you to your next question,

Dr. Michael Policar:

Right. So, there is a new recommendation for how to, how to treat *Mycoplasma genitalium*, particularly in the context of the recurrent non gynecological urethritis or recurrent cervicitis, so that instead of using medications simultaneously, you use them sequentially. So tell us a little bit more about that one.

Dr. Ina Park:

Yeah, sure. So again, don't screen people who are asymptomatic. We don't really have data that, that actually prevents negative outcomes and don't use it for the initial diagnostic test for cervicitis, urethritis, PID, or infertility. Now, now that we have an FDA approved test, I want to acknowledge that there are lots of folks just using it from the get-go, for folks who are presenting with symptoms, but just...

Dr. Ina Park:

Not for folks who are presenting with symptoms, but just, the party line from CDC is to not use it at first. But if you do detect *Mycoplasma genitalium* because somebody fails initial treatment. The recommendation for treatment regardless of gender, is to use doxy cycling, a hundred BID for seven days, and then follow it up with moxifloxacin 400 milligrams for seven days. So, I will tell you some of my patients have been really crestfallen when you tell them that they have to be on antibiotics for two weeks, but that's really, I think what is needed to ensure complete eradication. The doxy does not cure Mycoplasma, but it does reduce the organism load.

Dr. Ina Park:

And then hopefully that will do that to the extent that moxifloxacin can actually come in and eradicate it. There is moxifloxacin resistance developing. It is not as bad as azithro. There was a study in Seattle that showed over 80%. How does it throw mice and resistance similar in San Francisco right now? So, if you look at the guidelines, it'll tell you the specific scenarios in which to use the *Mycoplasma genitalium* test, but it's primarily in cases of folks who fail initial treatment for urethritis and cervicitis.

Dr. Michael Policar:

Right.

Dr. Ina Park:

So, No. Mike, did you have any more sort of conversation or questions around that before we talk about family matters?

Dr. Michael Policar:

I think you covered it well. And so, an obvious question is, does a family pack cover the *Mycoplasma genitalium* NAAT test and how about the sequential antibiotic therapy? And so, the answer is that as of a couple of years ago, family pack actually did, had the antibiotics that you just heard about a minute ago for treating presumed Mycoplasma genitalium. Now family pack does not cover for the test yet. That is under discussion about whether or not to cover it. And of course it has nothing to do with how good of a test it is or where that sort of thing, it has to do with the utility of a test like this one in what is fundamentally a family planning program. But what the PPBI currently says is that for people who have persistent or recurrent cervicitis in females, also nongonococcal urethritis that hasn't responded to treatment with doxycycline or azithromycin, family pack does cover Doxycycline for a week, and then Moxifloxacin once daily for seven days.

Dr. Michael Policar:

Now, the way that that's listed in the PPBI right now is based on the old guideline, which is using those two drugs simultaneously. And of course, the way it's been changed is to use them sequentially. But the point is they're both still covered by Family PACT. But a little caveat is the fact that the Moxifloxacin is only for pharmacy dispensing and it requires a tar or a treatment authorization request. So, if you're going to be using this particular combination to treat recurrent cervicitis or recurrent nongonococcal urethritis, the doxy you probably have available in your clinic, or it's easy to prescribe with a moxifloxacin, and you could do an online tar, explain why you're treating the person with moxifloxacin and you shouldn't have any problem getting that approved by the MediCal pharmacy tar office. And if you need a reference for specifically that coverage, it's in the benefit grid on page 22. So, to be continued about the test, but at least in terms of these recurrent syndromes, that it is available for you to use.

Dr. Ina Park:

Yeah. And then coming soon to a clinic near you, hopefully will be an FDA approved test looking for resistance mutations. Because when we do have that, if the Mycoplasma is susceptible to azithromycin, there is an option also to use an extended dose of azithromycin as well. But we're not talking about it here because I think for the most part, we don't have that test yet. So, we're just going to need to do sequential therapy as we talked about.

Dr. Michael Policar:

Okay, well, we're going to switch gears yet again and speak a little bit about syphilis, which of course has been a very hot topic over the last four or five years, both because of an increase in the incidents of syphilis, as well as our concerns about congenital syphilis. So, how are the guidelines for syphilis screening changed since the 2015 CDC guidance?

Dr. Ina Park:

So, yes, Mike, there's been an acknowledgement, the first box here is in pregnancy, and then there's just been an acknowledgement about the epidemic increase in congenital syphilis cases and the number of congenital syphilis cases, which was over 1300, surpassed the peak of mother to child transmission of HIV, even at the height of the AIDs epidemic. So, that's the sort of level of problem that we're dealing with. The syphilis guidelines though, for pregnancy didn't change much on a national level. They say everyone gets screened at the first prenatal visit. And then again at 28 weeks and at delivery, if at high risk or residing in an area of high morbidity. But one thing that did happen was what is high risk was better defined here. And that includes for example, transactional sex and a history of incarceration and the patient or the partner, et cetera, et cetera.

Dr. Ina Park:

But I just want to point out that all of us are here in the state of California, that the state of California did come out with their own guidelines to say, we should really be screening everybody at 28 weeks. And then delivery screening is sort of on in as needed basis based on risk. So, for MSM it's just more specific than all MSM, including those on prep should be screened at three to six months. And a new thing highlighted here is that there should be universal opt-out screening for anyone entering correctional facilities. And unless of course, that you're in an area that has no syphilis, but for the most part, that area, that really doesn't happen in the United States anymore. There's no change for folks living with HIV and for STI clinic patients, for the most part, folks that are coming in should be screened for syphilis. And certainly if another STI is diagnosed.

Dr. Michael Policar:

Right. Now, before we leave syphilis, I'm going to go back and ask you one other very quick question. Although I'm sure it's not a quick answer but we need to talk about. So, one of the things that's in the syphilis chapter of the new guidelines has to do with various alternatives of screening for syphilis. And so, they kind of outlined what the traditional algorithm is of starting with a non-Treponemal tests, like a VDRL or an RPR, and then using treponemal test as a way of confirming that a person actually had syphilis.

Dr. Michael Policar:

They also discuss something which is called the reverse sequence algorithm, where you actually start with a treponemal test, like an EIA or a CIA. We can define those later if anybody's interested or an FTA abs or image ATP. Those are tests specifically for the treponema. And then if any of those are positive, then to use a non-treponemal test like an RPR or VDRL in this alternative sequence. So, the first question I know people are going to ask is, oh does Family PACT cover the alternative [inaudible 01:03:37]? The answer to that is not yet, but the RP is having a look at it. But number two, Ina can you tell us a little bit more about what you've been seeing in terms of the number of labs that have switched over to that alternative of starting with a treponemal test first? Is this something that we should be anticipating or preferably doing?

Dr. Ina Park:

Yes, so most of the large commercial laboratories have switched over to using the reverse sequence algorithm and lots of public health departments have resisted that, especially because those

Treponemal tests stay positive for life. So, they're not as useful when you have a population. If you have a lot of population, you're screen a lot of folks that are HIV positive or MSM where you have very high sort of history, Pert zero prevalence rates for a treponemal antibody. So, but many commercial laboratories have switched. Kaiser switched in 2007 in both Northern and Southern California. So, it's sort of the wave. It's been a wave that's been happening now for the past 15 years. And there are certainly folks that are holding out and still using a non-treponemal test or an RPR. And now there are a few automated RPRs because the whole drive to use the reverse algorithm was based on the fact that those tests are automated.

Dr. Ina Park:

So, you can do 200 tests in an hour. And every RPR actually has to be manually pipetted. So it takes more time. And so, there's a lot of forces driving the change. It's a headache and there are actually syphilis lab guidelines that are going to be coming out. I'm working on them actually right now. And so, hopefully, in the next year we will see those and hopefully they will provide more clarity on how to interpret all of these things. And they provide some guidance for labs as to which algorithm they should choose, but primarily it's driven by finances and the fact that things can be automated. So, they're less expensive in the long run for the lab.

Dr. Michael Policar:

Right. Okay, great. And I'm really glad you're working on those guidelines and one of the other things to say about it for our audience, as you read the chapter on syphilis treatment and syphilis screening, is the fact that number one, it's really going through a significant amount of changes for all the right reasons. But number two is the fact that it was very clear to me that syphilis diagnosis is not based strictly on a laboratory test anymore. They really also have to pay attention to what you find on physical exam, to look for shankers or kind of alone lotta, or a rash that goes along with syphilis, because when you're using these tests, they are also tempered by what physical findings are in terms of whether or not the person has primary syphilis, secondary syphilis, latent syphilis, and so on. So the lab test of course are hugely helpful, but you can't rely on them alone. You also have to be able to do a physical exam as well.

Dr. Ina Park:

That is so important. Yes.

Dr. Michael Policar:

Yep. Okay. Well, let's talk briefly about herpes, the screening. They have the infection on herpes, they do described screening for herpes type two antibody, and they talk about two step serologic testing. What is that? And how should it be used? Patients are still asking questions about herpes and can you test me for it? And have I been infected in the past? And so, where are we now with the two steps and why?

Dr. Ina Park:

Yeah, so the general takeaway I want to sort of set the stage with is that CDC is really only recommending serology testing in a couple of circumstances. And that's whether if the person has been given a clinical diagnosis, but has never actually had any official lab confirmation. And if somebody reports genital symptoms, past history or recurrent genital symptoms, and they don't have a diagnosis, or if there's a serodiscordant partnership where the person comes in and says, my partner is living with HSV. And I'd like to know if I also have it. The issue with these tests, which I'm going to actually go to the

next slide is that their predictive value, especially when you have these values that they give you, call them index value. And anything over one is considered positive, but if you have a low positive result between one and 3.5, the predictive value of that test being a true positive is actually about 50%.

Dr. Ina Park:

So, these data were presented to the U.S.S Preventative services task force, and they said that there is too much harm with these tests that give false positive results, especially when they're low positives, that they gave it a great D recommendation. And so, right now we don't have a lot of other backup options though for these serology tests. So, CDC said, okay, if you're going to use these serology tests, we should have a two-step process and get a confirmatory test. And so there are two confirmatory tests that are mentioned. One is called the bio kit, and the second one is the Western blot. The Western blot, as far as I know, is only being done at one laboratory in the country, which is University of Washington. And I have ordered that test for patients multiple times when they've had a low positive serology, it's a pain in the butt, and it costs $200 out of pocket.

Dr. Ina Park:

So, but it is very accurate. And then the bio kit again, is just not widely available. So, I think the hope is that by recommending two-step testing, that the CDC is going to hopefully drive some more demand for the confirmatory tests to be offered through commercial laboratories. But again, really it's not recommended for screening the general population unless someone has some good reason, you know what I mean, to be screened, like they report some sort of symptoms or have a serodiscordant partnership. And really, almost nothing changed with treatment.

Dr. Ina Park:

And so, I just wanted to point out that they did remove two regimens related to Acyclovir. One that was five times a day for the primary outbreak and one that was 400 milligrams for recurrent outbreaks, more frequently. So, everything pretty much stayed the same. And Mike actually made the slide and highlighted very nicely for us, the shortest courses and the lowest frequency of treatment for primary recurrent and suppressive treatment. Because I think all of our patients are looking for that. So, I just wanted to point that out here, we won't go over all of it, but just to say that there was very little change, unfortunately, and no new drugs.

Dr. Michael Policar:

Right. Okay. And then the quick point that I would make is Family PACT only covers Acyclovir and not Famciclovir or Valacyclovir. That's something that could change in the future, but at least for now, the regimens you saw in the first column that had to do with Acyclovir are available through Family PACT. So, the next question, I know our time is getting shorter, but we're doing fine. This is important information. The guidelines regarding the treatment of vaginal trichomoniasis change both for who gets screened, for trichomoniasis, as well as the treatments that we use. So, can you say a little bit more about that?

Dr. Ina Park:

Yeah. And the major change I wanted to point out was that for folks, cis women living with HIV, there was no change. And this also would include transgender men living with HIV, so annual screening. But now they actually mentioned, they don't mention trans men. They do mention cis women in corrections

that opt out screening should be performed. And if someone is at risk, so multiple partners, a history of STI, inconsistent condom use, sex work or injection drug use. And at least for me, this is most of my patients. So, there's I think more liberal kind of expansion of who should be screening for trichomonas. And then the assays, we do have an excellent trichomonas NAAT. And then there are also rapid antigen tests as well. And just like with gonorrhea and chlamydia after treatment, everyone should get retested at three months, which Mike points out is actually a Family PACT benefit the NAAT, as well as the rapid antigen test.

Dr. Michael Policar:

Correct.

Dr. Ina Park:

Yeah. But one of the things that you mentioned was how treatment has changed. And I just wanted to point out the rationale for that. There was a randomized controlled trial that looked at seven days versus a single two gram dose in folks that were not living with HIV, 623 cisgender women. And they actually did a culture as the test of cure, six to 12 days after they got treated. Because at that time, a nucleic acid test would still be positive, just because of residual sort of genetic material hanging around. So, you'll see, excuse me, that first of all the cure rate overall was not even 90%, but it was better for seven day treatment versus single dose treatment. And this is what led to the recommendation. Now pregnancy treatment is not specifically mentioned, but Mike and I have discussed and discussed with the CDC that it probably makes sense if you have someone who's pregnant to use the seven day treatment, regardless of pregnancy status.

Dr. Ina Park:

But one thing I do want to point out is Metronidazole and alcohol there's been for the past 50 years, we've said don't drink when you're taking Metronidazole. And the worry was that you would have an disulfiram like reaction because Metronidazole might inhibit acetaldehyde dehydrogenase, which makes folks like me flush when we drink alcohol and get very yell. And there was actually a Norwegian study that did a very comprehensive review of the evidence, and they actually translated it from Norwegian to English for this lit review and found that there have been no studies that actually show sort of a negative or synergistic effect of Metronidazole and alcohol. So, now the guidelines are changed to say, you don't have to stop drinking alcohol, but we know that Metronidazole does cause GI distress and can cause nausea. And so can alcohol. So again, if it's not bothering folks, then if they want to have a drink, no big deal.

Dr. Ina Park:

And that's the best news of the entire treatment guidelines I have to say. So, everybody who has vaginal trichomoniasis seven days for male partners, two gram dose is still what's recommended. And then the alternative therapies would be Tinidazole two grams. And ACOG also changed their guidelines to match. So, I'm going to actually transition it over to you, Mike, because not in the actual document, but a separate companion document was a revamping of the Sexual History taking. And if you could describe a little bit the new 5Ps and the new CDC guidelines, I would love that.

Dr. Michael Policar:

Sure. I will do that. And in fact, there are two different places where you can find out more about this in detail. One is this brochure, which has been recently updated by the CDC called a guide to taking a Sexual History. And it gives you the newer version of how to do this. And they're actually in some of the initial chapters of the new CDC guidelines referenced to this as well. And many of you know, Patty Cason, who has been a frequent speaker at Family PACT webinars in the past, she was a part of the group that developed this. And hopefully we'll have a webinar on this topic in future. So, remember that there are five Ps to taking a Sexual History, partners practices, protection from SDIs, a past history of SDIs. And in the old version, there was one about pregnancy protection, but that assumed that everybody wanted to be protected against pregnancy, which is certainly not the case.

Dr. Michael Policar:

And the way that that one has been revamped is to talk about pregnancy intention rather than pregnancy prevention. There's also a six P in fact, there are a number of additional Ps, but there was a lot of discussion about whether we should be asking questions about pleasure. And that is to say, asking our patients that, once we've talked about these questions that relate to sexually transmitted infections, then ask a question about, "Are you happy with the sexual relationship that you have with your partners or partners?" So it's not there yet. That's more aspirational than it is concrete, but hopefully in the future we will see that as the six P, and then always when we take a Sexual History, then we ask about those five or six categories, then we'll ask patients afterwards, not, "Do you have any questions?" But instead we ask, "What questions do you have?" Assuming that people will have questions.

Dr. Michael Policar:

So, I'm just going to mention the ones that change the most. And the first has to do with the first P, that has to do with your number of partners. So, the old question was, "Do you have sex with men, women, or both?" The new questions are different. "Are you currently having sex with any type, oral, vaginal or anal with anyone?" Or you can shorten that just by asking the question, "Are you having sex?" If the answer to that is "No, not currently." "Have you ever had sex with another person in recent months? How many sex partners have you had? What are the genders of your sexual partners and do you or your partners currently have other sexual partners?" So, all of which are important in deciding in particular who needs to undergo targeted screening. That routine screening that we do for everyone like gonorrhea and chlamydia for females that are 24 and under, but for older females, for males, and so on, we want to know about partners that have to do with who needs to be screened or not.

Dr. Michael Policar:

So, that was the first P. Second P is again about practices. "What kinds of sexual contact do you have or have you had?" And they gave us very good language to use vaginal sex, penis in the vagina, anal sex, penis in the rectal marinas, oral sex, and so on. "Do you meet your partners online or through apps? Do you or your partners use drugs? Have you exchanged sex for your needs, like money, housing and drugs?" "The third P is what do you do to protect yourself from STI?" I won't read that but one that's important at the bottom is, "Are you aware of prep, a medicine that can prevent HIV? And have you ever used prep or have you considered using?" Because so many people may know about it from television commercials, but they really don't know what prep is and whether or not that's something that might be the right choice for them.

Dr. Michael Policar:

The fourth P is about a past history of sexually transmitted infections. This basically, is the usual questions of, "Have you been tested for STI and HIV? If so, when, what were the results, have you been diagnosed with sexually transmitted infection in the last couple of years? And were you treated, have you or your partners injected drugs? Have you and your partners been diagnosed or treated for an STI, and do you know your partner's HIV status?" And then the last P is this change from pregnancy prevention to pregnancy intention, and they specifically mentioned, what many of you have been trained and called the PATH questions. And P is an acronym for pregnancy attitude training, and how important is it for you to prevent pregnancy and Delvin? So, the first question is, "Do you think you'd like to have children at some point, or if you have kids now, would you like to have more?"

Dr. Michael Policar:

Second one is about timing. "When do you think that might be?" The third is, "How important is it for you to prevent pregnancy until then?" And so, one of the things that I've included for you is an algorithm that Patty Cason developed that helps you with counseling based on the answers to those three questions. Do you think you might like to have more children and the answer might be yes or no, or you're not sure then that leads to the second tier of when do you think that might be and how important is it for you to prevent pregnancy until then? And then basically what the outcomes are at the bottom, sorry for clicking through this so quickly, but basically is for people who are thinking about becoming pregnant or open to becoming pregnant, would you like advice about how to actually become pregnant or how to prepare yourself for a healthy pregnancy?

Dr. Michael Policar:

On the other hand, for people who are not planning on preventing pregnancy, whether that's not important or important where they don't want to become pregnant, "Would you like to talk about your birth control options? What's the most important thing to you about your choice of method?" So, these are all questions that should really be routinely covered with the female patients that we see. And this is kind of the most sort of well-developed approach we have to answering those questions, what used to be called reproductive life plan. And now it's much more appropriate to approach this through PATH questions. So, we're going to wind up, but I'm going to hand the microphone back to Iona to tell us about going forward. If you have questions, we have a couple of really wonderful resources for you. So will you tell us a little bit about the clinical consultation network?

Dr. Ina Park:

Yeah, we were just talking about that convoluted PID scenario, where you're using a fluoroquinolone and then you have gonorrhea, and the person has an allergy. These complicated questions, please shoot us a consult. This is an online consult service. It's answered by myself and our clinicians. We staff it five days a week, Monday through Friday. And you can say how quickly you want your response, depending on the urgency of your consult. And then I also wanted to point out the national STD curriculum for those of you who are STI junkies, who want more information, if you can go back one slide, Mike.

Dr. Michael Policar:

Oh, I'm sorry.

Dr. Ina Park:

No, it’s okay.

Dr. Michael Policar:

Hang on. Here we go. To the national curriculum?

Dr. Ina Park:

Yeah, the national curriculum it's hosted by the University of Washington and there is free continuing education credit. And especially if you have learners or you're doing any teaching, this is a great resource for folks to get up to speed. And then finally, our last slide is, please stay in touch with us on social media, through California PTC. And I also as well, if you want to stay in touch, here are our emails as well as my Instagram and Twitter.

Dr. Michael Policar:

Okay. Well, Nicole, we're back to you to make some time to answer a few questions.

Nicole Nguyen:

Yes. And I did tell in the chat that you are all, since we have so many questions going in, you'll stay an extra 50 minutes. So, for those who have to leave at exactly 1:30, don't worry about, you'll still get your full CME credits. But if you're able to stay an extra 50 minutes, our speakers will be staying on as well to answer the questions. So, I've assigned you questions. I think you just opened the questions tab and see it. And I don't know if you want to do rapid fire lightning round. Try to get as many as you can because there are some that you've answered in the presentation. So, you might not have to repeat to answer that again.

Dr. Ina Park:

Okay. I am having over-consumer questions. So, I just expand that little box.

Nicole Nguyen:

Yes.

Dr. Ina Park:

Okay. All right, Mike, do you see yours?

Dr. Ina Park:

Okay. All right. Mike, do you see yours?

Dr. Michael Policar:

Yeah, a little difficult, but I'm getting there.

Dr. Ina Park:

Okay.

Dr. Michael Policar:

I can see one. Any update on Family PACT to cover metabolic panel and Hep B and Hep C screening to facilitate... Hang on. Tell us a faster PrEP Okay. Oh, there we go. Faster PrEP initiation. Okay. The answer is, as far as Family PACT goes is that Family PACT does not cover PrEP at this point. There are many, many other opportunities for people to initiate PrEP with various programs through Medi-Cal, through commercial insurance, Ryan White funds. I mean, there are a number of different ways for people to be able to actually access PrEP And then of course, all of the different tests that go along with both initiating PrEP and then being able to monitor whether or not there were any sort of metabolic side effects or other adverse effects that are related to PrEP use.

Dr. Michael Policar:

So, Family PACT hasn't added those at this point, either the medications for PrEP or the various metabolic tests that surround it. Simply as I said, because there are many other opportunities for people to get it. And at least so far, the Office of Family Planning considers it to be sort of outside of the boundaries of what should be considered to be benefits within a state family planning program. So stay tuned. That may change at some point in the future. But at least for now, there are many other opportunities for people to get both counseling, as well as access to PrEP medications, and the various tests that go into a monitoring person as using them.

Dr. Ina Park:

So, I'll answer a couple. One is about patient delivered partner therapy. If the partner's pregnancy status is unknown and there's someone who could become pregnant, should you use azithromycin over doxy? And I'll tell you that that's not specified very well in the treatment guidelines, but I actually think that that's a reasonable approach if you don't know the pregnancy status of the partner and the partner is someone who could become pregnant. Especially if you think a rectal infection is not likely, then that would be a circumstance, which I think it would be reasonable to use azithro.

Dr. Ina Park:

Same question for someone who was sexually assaulted, where the assault did not include anal sex and you think that it's most likely then a cervical infection. Would that be a good opportunity to use azithro? And I do think that that's another reasonable situation as well. Obviously, if there was anal penetration, than I would err on the side of trying to use doxy. Folks are so traumatized that sometimes it's better just to give all the treatments single dose and directly observed and have it be done, but that would be a shared decision making thing I would do. And if the likelihood for rectal infection is low, I think azithromycin would be reasonable there as well. Mike, did you have another question you wanted to answer?

Dr. Michael Policar:

I do. So another Family PACT benefit question. Does Family PACT cover hepatitis screening? So let's break that down into Hepatitis B and Hep C. So in the case of Hep B, the national strategy that's outlined by the CDC is not by case finding of doing Hepatitis B screening tests. It's getting people vaccinated for

Hepatitis B. So in the CDC STD treatment guidelines, there's a fair amount of detail about how to get Hepatitis B vaccination done. And in that context, when you would or would not do Hepatitis B screening tests. So, the point is that it is not a Family PACT benefit because it's considered to be more of a primary care issue. And of course, Hepatitis B can be transmitted sexually, but it more often is transmitted by IV needle use and other ways of being spread by blood. And that being the case, what Family PACT would recommend basically is asking the question of, have you been vaccinated for Hepatitis B? And if not, then you need to see your county health department, your FQHC, your primary care provider, and actually become vaccinated for Hep B.

Dr. Michael Policar:

Now, when it comes to Hep C, the new recommendation of the U.S. Preventative Services Task Force is that everyone should have a once in a lifetime Hepatitis C screening test. And the reason for that is now there are a number of treatments available that will actually cure Hepatitis C, and therefore, even for low risk people, a once in a lifetime test. And then if you have risky behaviors, which again, are primarily around needle use, then you would need subsequent Hepatitis C screening as well. But the same is true for Family PACT, and that is that Hep C screening, while clinically indicated based on the guideline that I just mentioned, is considered to be more of a primary care problem than it is to be a family planning issue. So therefore, Hep C screening would be done at your local community clinic at an FQHC through your primary care provider, rather than through the Family PACT program.

Dr. Ina Park:

I have a question around folks who are using home brew *Mycoplasma genitalium* tests. Some folks are not going to be using the FDA approved test or lab is using a home-brew test. So, this question comes from a colleague who says that they're also testing for things such as Ureaplasma and Mycoplasma hominis, and both Ureaplasma Mycoplasma hominis can be colonizing bacteria that are commensal organisms that don't actually cause any problem. So sometimes people have come to me with a lab test from a different laboratory where someone's screened them for Mycoplasma and Ureaplasma. And if they have Mycoplasma hominis and Ureaplasma and they're completely asymptomatic because many people can be colonized, I actually ignore those results. Now, if they do have *Mycoplasma genitalium*, sometimes you're sort of stuck. For the most part, if they do have *Mycoplasma genitalium* and they came from a different laboratory, I will treat them, but we do not recommend screening for any Mycoplasma species or Ureaplasma at this time.

Dr. Michael Policar:

Okay. Well, I'll do a couple of rapid fire that are similar. Does Family PACT cover testing and treatment for *Mycoplasma genitalium*? I mentioned that earlier, and the answer is that Family PACT does not cover the screening test at this point, but Family PACT does cover treatment in the case of females with recurrent cervicitis and males with recurrent non-gonococcal urethritis.

Dr. Michael Policar:

Next question is. Family PACT doesn't cover the TPPA, which is a treponemal test for syphilis. That's what our lab does. No, Family PACT does cover that. What I was trying to say is that Family PACT covers the traditional algorithm, which is to start with a non-company multitask, like a VDRL or an RPR. If that's positive, then you do a confirmatory test, which would be a TPPA or an MHA-TP or an FEAVS. Family PACT does cover those confirmatory tests. What Family PACT doesn't cover yet is the reverse algorithm

that starts with the treponemal test, particularly an enzyme immunoassay or a chemiluminescence assay. That's the CIA. Those are much newer tests that directly test for evidence of treponemes. And those are not yet covered by Family PACT. But Family PACT definitely does cover the TPPA, although it does in the context of the traditional syphilis screening algorithm.

Dr. Ina Park:

Question around herpes serology confirmation. Do you know which labs are actually using the BioKit, which is one of the recommended tests by CDC. LabCorp, which is a large commercial lab, does a supplemental test after the HSV-2 antibody is positive. And is this the BioKit test? It is not. It's a different assay, which I believe it's the similar to Quest, which it's called the Inhibition assay. It is not recommended because it uses some of the same antigens as the initial serology test. Although it's supposed to help sort out false positives, it's not as good as the other confirmatory tests such as the Western Blot or the BioKit. So I don't know which large commercial labs are doing it, but I will check and we will put it in the written responses to the Q and A if I can figure that out.

Dr. Ina Park:

The other question is that if you have a couple where one person is diagnosed with an STI and does not want to disclose status to the partner, what do you do? As the provider, you really can't force someone to disclose. And even the health department, this person mentioned that in the past, they might've gotten the health department involved, the health department, to do contact tracing, still has to get the consent of the patient. So if the patient doesn't consent to notification of their partners, you really don't have a lot of leeway as a provider to actually do that on your own.

Dr. Michael Policar:

Okay. I'm sorry. Were you done, Ina?

Dr. Ina Park:

Yes, that's fine. I'm just scrolling down.

Dr. Michael Policar:

Okay. All right. Good. So is Family PACT considering ever covering vaginitis panels? I can't quite read the rest of the question, but the answer is no. So what this has to do with is that there are a number of products out there that will basically screen for a number of different pathogens that cause vaginitis. And basically, there are some older versions that are actually point of care tests that you would do that screen for trich, bacterial vaginosis and for candida. And then there were some newer versions of that as well.

Dr. Michael Policar:

But the point is that there are no national guidelines about routinely screening anyone with a vaginitis panel and they have a tendency to be really overused. So the point is that Family PACT does cover specific tests specifically for the diagnosis of vaginitis, and we've already discussed what some of those tests are already. For example, the Nucleic Acid Amplification Test for trich, for example, and I've mentioned some of the others. Of course, Family PACT covers microscopy. But Family PACT does not cover the vaginitis panels primarily because for the most part, there is no guideline that recommends

their use. When it comes to diagnosis of a person who has a vaginal discharge, there are tests for each of the main pathogens, which will cause that that are benefits for Family PACT already.

Dr. Michael Policar:

Next is for LGBT patients for whom contraception is not a concern or doesn't apply. How should we document an ICD-10 code? This is something that comes up really commonly. Remember that the main criteria for eligibility for Family PACT, number one, you have to be a resident of California. Number two is that you have to meet income requirements and those are listed in the PPBI in terms of specifically what the income levels are that would make you eligible or not for Family PACT. The third is for the most part, you don't have any other insurance that covers contraception, especially including Medi-Cal. If you have Medi-Cal already, there's no reason to have Family PACT. The exception to that, being that in certain circumstances, people are really worried about confidentiality and disclosure. And in that case, particularly for adolescents, if you have other coverage, then you may qualify for Family PACT. Also very well-described in the PPBI.

Dr. Michael Policar:

What the question is really asking is what about people... Let's say a man having sex with other men who doesn't have a female partner where there is no risk of pregnancy. So what the requirement is in Family PACT is that it has to be a male who's capable of causing pregnancy or a female who's capable of becoming pregnant. It doesn't mean that you're necessarily having a hetero partner that you're going to cause pregnancy or that you're a female who's necessarily going to become pregnant, but you have to have the capability of doing so. And so if it's a male who's had a successful vasectomy, if it's a female who's had a successful tubal ligation or hysterectomy, then there is no risk of pregnancy and therefore you would not be eligible for Family PACT. Okay. I know it's a real source of confusion, but again, the thing to remember. A male was capable of causing pregnancy, a female who's capable of becoming pregnant is one of those four criteria that has to be met.

Nicole Nguyen:

You can just continue on. Ina is trying to come back in, so she'll join us when she can.

Dr. Michael Policar:

Okay. Let me just run through some of the other questions quickly. All right. Okay. So, one question is the most recent update to the benefits grid from September of 2020 or where can the most recent update be found? I'm so glad you asked you. The answer to that is that Family PACT has an incredibly good website that is actually maintained by Nicole and other people at the California Prevention Training Center. It's familypact.org. If you go to that website, the third drop down menu over is for providers. Hit that menu, and then drop down to the section on PPBI, which is Policies, Procedures, and Billing Instructions. Once you open that, then you will go to a benefit grid, to a formulary, to all of the chapters of the PPBI that I've been mentioning that you can read directly and it's incredibly transparent and clear about what's a Family PACT benefit or not a Family PACT benefit.

Dr. Michael Policar:

And by the way, yeah, there have been lots of changes since September of 2020. Every time there's a change rather, the page and the PPBI is updated. It tells you specifically the date. Another thing that you'll look for in the FamilyPACT.org website in the provider section is you can click on Family PACT and

Medi-Cal bulletins. So they come out once a month and they explain what Family PACT benefits have been added, deleted, advice that comes from Medi-Cal and so on. As a clinician, it's really worthwhile to have look at that every month or two, particularly the Family PACT bulletins because it'll give you very specific issues about additions and deletions and changes to the Family PACT PPBI.

Dr. Michael Policar:

I guess while we're still waiting for Ina to come back while we have a little more time. Is gonorrhea culture not inept for pharyngeal gonorrhea testing post-treatment coverage available? The answer is not yet, but I know that the Office of Family Planning is looking at how to do that. The Nucleic Acid Amplification Tests are so incredibly accurate that when the decision was made about coverage of GC culture, that was back in the days when people were using chocolate agar, Thayer-Martin media in a candle jar. And of course that was completely out of date.

Dr. Michael Policar:

Nowadays, gonorrhea culture has come up as an issue again. Because when a person has a positive NAAT test, there are those circumstances where you need to check whether or not this strain of gonorrhea is going to be sensitive to cephalosporins, for example. The Office of Family Planning is actually having a look at now higher tech GC cultures, specifically to be able to use the information about cephalosporin resistant gonorrhea to make clinical decisions. Absolutely it will not be available as a screening test. It would only be available when a person who has a positive NAAT test and probably even more specific instructions around that.

Dr. Ina Park:

Mike, can you see and hear me again?

Dr. Michael Policar:

I can. Yes.

Dr. Ina Park:

Oh great. And just to dovetail on that. I was trying to put the link to California's Treatment Failure Guidelines in the chat, and I'm not sure that it showed up. So Nicole and I will work together to try to figure out how to send that link out. When we send out the Q and A, we'll send out the link to that document. It lives online.

Dr. Michael Policar:

Okay. Great. I'll answer one or two more questions while you guys are doing that. Does Family PACT cover syphilis treatment? The answer to that the traditional treatments, which are either for primary, secondary, and early latent syphilis with one shot of Benzathine penicillin, Family PACT covers that. And then in addition for late latent or syphilis of unknown duration where the treatment is three shots of Benzathine penicillin, Family PACT covers that as well. So the answer is yes, Family PACT does cover those treatments with Benzathine penicillin on an outpatient basis. I'm also fairly sure that we also cover the alternative of a longer course of doxycycline. But then there are other circumstances, for example, when people have penicillin allergies and need to go through a desensitization regimen and

Family PACT does not cover that part. But for the one shot of Benzathine, the three shots of Benzathine, absolutely Family PACT does cover that.

Dr. Ina Park:

Nicole, I'm not able to see my questions right now. Do you want to ask me a question? Because we have a couple more minutes.

Nicole Nguyen:

Oh yes. Yes. I think one that came in is can doxy still be used for syphilis treatments as last resort? It is not listed as an alternative treatment, but it is listed under special consideration.

Dr. Ina Park:

Yeah. I think they didn't want to actually give it its own box and say this is an alternative treatment because they didn't want people to overuse doxy and they really want as many people to get Benzathine penicillin as possible. But absolutely, we have lots of observational data that doxy does work well. It's been used in both folks living with HIV, as well as those not living with HIV. The issue is that for early syphilis, you have to use two weeks of doxy, and for late latent syphilis, you need to use four weeks of doxy. So obviously adherence is the major issue in this scenario.

Nicole Nguyen:

And then in addition to that question about doxy, when CDC states to use doxy, which one are they referring to, doxycycline monohydrate or hyclate, or does it not matter?

Dr. Ina Park:

That doesn't really matter. The dosing, whether they give you monohydrate or hyclate, if it's 100 bid, that would be fine.

Nicole Nguyen:

I have concerned about using Fluoroquinolones on a routine basis for treatment of my microplasma due to toxicity. Is there another antibiotic that can be used for that second week of dosing?

Dr. Ina Park:

When we get a resistance guided therapy, if we get a test for azithromycin resistance, then we would hopefully be able to use azithromycin extended dose instead of moxifloxacin. Yes. I have had people who've had tendon issues or tendinopathies after taking fluoroquinolones. That is a serious concern. People who are taking multiple drugs that prolong the QT interval and you take moxifloxacin, that can also cause issues. So, it's not a benign drug, which is why we don't want to screen everybody and treat all cases of *Mycoplasma genitalium* at this point. But right now we don't have another good second drug alternative other than moxifloxacin.

Nicole Nguyen:

Okay. I think that would conclude because we're at 1:46. So I just want to be respectful of everyone's time. Thank you so much everyone and for our wonderful presenters who was willing to stay on an extra

15 minutes to answer these questions. Again, we will collect all these questions. Anything that didn't get answered today will go out in a Q and A, and then of course in a follow-up email, it will also include the CME certificate link, the recording and slides. And then lastly, I just want to thank our wonderful presenters. This is one of the best webinars so far. I'm so glad you guys get to tag-team again. It's always exciting when you both get to present. Yes, I think that's it and I hope you enjoy.

Dr. Ina Park:

Thank you all again.

Nicole Nguyen:

Yeah.

Dr. Michael Policar:

I just want to add one thing. It's actually a plug in for the California Prevention Training Center and the work you've done. As you've been hearing us say on a number of occasions, Family PACT has a whole series of these webinars. Of course, the one that I mentioned earlier about Ina and I talking about gonorrhea and chlamydia, but there are webinars about Family PACT billing. We did one a couple of months ago that had to do with some of the new rules for evaluation and management, E/M coding for family planning visits. Patty and I did one about, I don't know, nine months or so ago on the ASCCP guidelines for management of abnormal cervical cancer screening tests.

Dr. Michael Policar:

All of those are available on the FamilyPACT.org website. They are recorded just like the one today where you can click on the recording or see the slides. And also, we've memorialized the questions and answers that came up and all of those different webinars like we will for this. They are available to you on a whole variety of topics, not only about sexually transmitted infections, but family planning, cervical cancer screening, tons of information about billing Family PACT. We still get lots of questions that have to do with telemedicine in Family PACT and specifically how to bill for both audio and video visits and telephonic only visits. That was a webinar too about a year ago, and those are all available to you.

Nicole Nguyen:

Yes. And then just lastly, please make sure you fill out the evaluation questions and also the document on the comparison between the 2015 and 2021 guidelines are available to you. So with that, thank you so much. Thank you to our wonderful presenters. Thank you for joining us today and hope you all stay safe and have a great rest of your week. Thank you. Bye.

Dr. Michael Policar:

Bye.