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EXPEDITED PARTNER THERAPY IN NYS

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[video transcript]

00:09
Dr. Jason Zucker is an instructor with the Department of Medicine Division of Infectious Diseases at Columbia University Irving Medical Center and he is also with the New York City PTC core faculty who is collaborating with us today. I'll go ahead and turn it over to you Dr. Zucker.

00:36
Good morning. Thank you so much for having me today and for joining us today. So we did want to take just a couple of minutes to introduce you to expedited partner therapy in New York State. Expedited partner therapy is the clinical practice of treating sex partners of patients diagnosed with chlamydia, gonorrhea or trichomoniasis by providing prescriptions or medications to the patient for their partner without examining the partner. Next slide.

01:02
So why do we think EPT is important? Well, EPT is needed because sexually transmitted infections are both prevalent and increasing. Chlamydia, gonorrhea and syphilis have all increased for the fifth straight year, and represent almost two and a half million infections yearly. Recent modeling in the STD Journal estimated in 2018 there were nearly 68 million infections, and that one in five people had a sexually transmitted infection. During that year, there were an estimated 26 million new infections, costing approximately 16 billion in direct medical care with almost half of those occurring in adolescents and young adults. So why are sexually transmitted infections so common and consistently increasing? Well, one reason is that reinfection of patients is common. reinfection due to non treatment of sexual partners occurs in a significant proportion of those infected and reinfection could be prevented by improving partner treatment. And expedited partner therapy provides an alternative strategy to ensure that exposed sexual partners get needed treatment. Next slide, please.

02:05
So treating partners is important, but why do we recommend EPT to do it? In an ideal world, patients would come into the clinic when their partners were diagnosed, we would empirically treat them and test them for STIs including HIV. However, real life is not the ideal world and it's oftentimes challenging to get patients into clinic due to insurance issues, time issues, or concerns over stigma and embarrassment. EPT is a way to lower the threshold to providing treatment to these patients and there's evidence that it works. I'll highlight two randomized controlled trials that looked at expedited partner therapy. In this first study of heterosexual men and women with gonorrhea and chlamydia infections, they randomized patients testing positive to expedited partner therapy or a standard referral to clinic. In that study they found reduced rates of recurrent gonorrhea and chlamydia in patients assigned to the expedited partner therapy arm. Furthermore, those assigned to the expedited partner therapy arm were more likely to report that their partners were treated and significantly less likely to report having sex with an untreated partner. In the second study, they randomized heterosexual men with urethritis to either expedited partner therapy, standard referral to clinic, or an enhanced referral

that included a referral booklet. They found that among heterosexual men with urethritis, expedited partner therapy was again better than standard referral for treatment of partners and prevented recurrence of chlamydia and gonorrhea infection. So it's clear that expedited partner therapy can reduce reinfections amongst index patients. This means that a greater number of people with STIs are being treated and as we know, treatment is one form of prevention. So now that we know that EPT works, a question I frequently get is am I allowed to prescribe medication without seeing a patient? Next slide, please.

03:53
So EPT legislation has been expanding nationwide as the STI epidemic has grown. It's now permissible in 45 states, allowable in four states, and prohibited by only one state. In New York State in December, there was recently updated guidance to the New York State Public Health Law, which expanded expedited partner therapy to permit any sexually transmitted infection for which the CDC recommends expedited partner therapy. Prior to this change, EPT was only allowable for chlamydia. While this change to encompass the CDC guidelines means that EPT is now an option for chlamydia, gonorrhea and trichomoniasis. It's important to note that EPT is not a requirement, and the decision to treat the partner is best made through a shared decision making approach between the patient and provider. So next slide.

04:43
So we've covered that EPT is important and that EPT is legal. So the next question is, who do I provide it to? And how do I provide? In terms of eligibility, the CDC has said that the index patient's partners in the last 60 days, or if they've had no partners in the last 60 days, since their last STI screening are eligible for expedited partner therapy. New York State in their guidance letter suggests that any partner since the index patient's last STI screening are eligible, which may have occurred more than 60 days prior. This again goes back to talking with your patient and taking a shared decision making approach, deciding with your patient which partners they're willing and able to approach for expedited partner therapy. This does mean that patients can receive expedited partner therapy for more than one partner and there is no maximum limit. While the eligibility is very broad, there are only two categories of patients that are ineligible. If the index patient is concurrently diagnosed with syphilis, they're ineligible. And if the index patient is suspected of being abused or assaulted, they are not eligible for expedited partner therapy. In terms of what medication is prescribed, I'm going to go a bit out of order and start with gonorrhea. Many of you may have read the most recent CDC guidance published in the MMWR regarding the updated guidelines for the treatment of gonorrhea. This update included an increase in the dosage of ceftriaxone from 250 milligrams to 500 milligrams. And while that was a switch, the larger switch was that they removed the routine use of azithromycin in gonorrhea. In it's place they recommend the use of doxycycline if chlamydia infection is not excluded. There were a number of reasons for this change, including rising rates of gonorrhea resistance to azithromycin, general antibiotic stewardship, and more recent studies showing that azithromycin is less effective for rectal chlamydia. At the same time, you'll see that we still have both doxycycline and azithromycin listed. While doxycycline is the preferred agent, I still consider azithromycin in patients who are or may become pregnant, patients who may have issues obtaining medications since a single dose of azithromycin can be given in clinic, or patients who admit to having a hard time taking or tolerating medications for seven days. For

partner therapy for gonorrhea, I always prioritize trying to bring back patients to clinic for STI and HIV testing and IM ceftriaxone, however that's often not possible. The expedited partner therapy for gonorrhea is cefixime at 800 milligrams, an increase from the dose many of us remember using in the past, combined with either doxycycline or azithromycin if chlamydia was not excluded in the index patient. In terms of treatment for chlamydia, it's either doxycycline or azithromycin, with doxycycline preferred. They are using the same reasoning as we discussed earlier. Partner therapy is generally the same as the index patient unless there's a contraindication. And finally, for trichomoniasis, the standard treatment is metronidazole or tinidazole, with the same treatment for the partner. Next slide, please.

07:44
So now that you know what to prescribe, how do we prescribe expedited partner therapy? Well, the preferred method of providing expedited partner therapy are with partner packs. These are packs that include the medication, information both about the STI and about the medication the partner will be receiving, and a referral to come to clinic for STI testing. As these medications are not coming necessarily from a pharmacy, it's important that they are labeled with the name and address of the dispenser, directions for use, date of delivery, and name and strength of the drug. For clinics that are unable to provide partner packs due to cost or institutional restrictions, you can provide a prescription to your patients for EPT. These prescriptions can be completely anonymous with just EPT in the body of the prescription. They need to have the medication, dosage, and how to take the medication, and are exempt from the New York State electronic prescribing mandate. As all the information is not provided in a nice pack, you need to make sure to explain to the index patient that they should notify their partners that they may have been exposed to an STI and should seek evaluation and treatment even if they are asymptomatic. You need to provide them educational materials that they can give to their partners about STI screening and preventing reinfection, medication side effects, and potential allergies or drug drug interactions, and about the need to come into clinic for HIV and other STI testing. You also need to counsel the index patient to instruct their sexual partner to read the partner information prior to taking the medication. In addition, in all cases you should advise the index patient to return for medical care three months after treatment for follow up and additional STI screening to rule out reinfection. Next slide please.

09:25
Last but not least regarding the information that must be provided to patients, New York State currently has only made an information sheet for chlamydia. Information sheets for gonorrhea and trichomoniasis are being developed. And you can also modify the New York City Health information sheet for patients exposed to STIs during COVID. This sheet includes a lot of the information you need to provide patients on both STIs and medication for treatment. A list of the information you're required to include for patients and their partners is available in the guidance document from the State. I hope I didn't take up too much of our time today because the goal is to hear what your questions are today. And so with that, I think we'll do some frequently asked questions?

10:02
Okay, great.

10:03
Again, I'd like to introduce both Dr. Daniela DiMarco and Dr. Marguerite Urban. They're both Infectious Disease doctors at the University of Rochester. And they're both clinical staff for the CEI Center of Excellence here in Rochester, New York. Thank you and I'll hand it back over to Dr. Urban. Thank you.

10:30
Okay, thanks. So we are going to do some questions that have come to the three of us over the last month or so since New York issued the new guidance. So the first one is do the educational materials that the provider needs to give to the patient to give to the partner have to be on paper? This is difficult when the patient is treated by an e-prescription once test results are back and after they've left their providers office. If that needs to be paper handouts, that patient would have to come back to the office to get those. So the answer is no. It is acceptable to provide a URL link to deliver materials to the patient, who would then either send the link to their partner or actually print them themselves and deliver it to the partner. This link could be sent via patient portal in your electronic record, or text, or email. And we do get some questions about having the updated materials that Dr. Zucker alluded to, for gonorrhea and chlamydia. And as he said, the New York City Department of Health during the COVID pandemic had issued some materials that could be used for EPT with gonorrhea and trichomonas. I've got samples here. It's sort of a long web link, but if you just google New York City Department of Health EPT, you actually pull this up right away. And it's a several page document that goes through all three conditions with information for the partner and information about the medication. Pass it to you, Daniela.

12:12
Sure, so another question. Am I required to offer EPT to my patients and along the same line, what if a patient specifically asks for EPT but I feel uncomfortable? And so the answer to both of these is no. But it is important to provide some options and so some things to think about would be referral over to a local STI clinic that can provide EPT or perhaps even a telemedicine visit or a traditional visit.

12:45
Okay, the next one to you, Jason. So EPT in general, so may EPT be dispensed to minors without parental consent? So the answer to this one is yes, in New York State individuals under 18 years old may give effective informed consent for service related to screening, treatment, and prevention of sexually transmitted infections including HIV. Again, the exception to this is if sexual abuse or assault is suspected.

13:16
So if I as the provider dispense EPT and later the syphilis test drawn in the same day for the initial patient is positive, am I liable in any way since EPT is not permitted for those co infected with syphilis? And here we did inquire about this with the State and if the diagnosis of syphilis was not known at the time that EPT was prescribed, there is no liability. However, depending on the stage of syphilis, that partner may have been exposed to syphilis as well and need post

exposure prophylaxis or even treatment for syphilis. So they will need to be brought back in and tested and potentially treated.

13:59
I can take the next one. If a patient reports no prior STI testing and has had multiple partners in the last year, how many partners should receive EPT? So in New York State, there's actually no limitation on how many partner prescriptions you can provide under the realm of EPT. So what you could consider is going through the recent partners, if somebody has no STI testing recently or within kind of a reasonable time period, so the way you might look at it is if a person whose last STI testing was in the remote past or non existent, you could consider just going back 60 days worth of partners to make the effort more feasible.

15:02
I'm up. If a patient tells me that their partner does not have insurance or cash to pay for EPT prescription, is it allowed to provide patient with a prescription for two doses of medication, one for the patient and one for the partner? So no, this is actually specifically spelled out in the law for EPT is that individual prescriptions must be issued for each partner for whom EPT is being provided. So it's actually specifically excluded from being able to provide a double dosage to your patient.

15:33
I'll jump in there. Also, I've inquired about this with the State as well. And in the event that a patient would use their insurance to get that double dose, then that's considered insurance fraud. So really, this is not allowed. All right. So if I as the provider diagnosed someone with clinical urethritis via telehealth, am I able to provide EPT to that patient since no testing was ever done due to the telehealth visit? New York State law does allow EPT for clinical or laboratory diagnosis of gonococcal, chlamydial, or trichomonas infection. So in this situation, you would likely be treating the index patient with clinical urethritis with medications for gonorrhea and chlamydia. And it would be allowed to offer EPT and prescribe those same medications for the patient's partner as you used for the initial patient.

16:37
So I can take this one, what about the cost to the partner? This is not an easy question to answer. And there's quite a bit of variability depending on a person's insurance or lack of insurance. So cefixime can cost anywhere from $20 to $55 for 800 milligrams, which is two tablets. Azithromycin, anywhere from $7 to $39. The course of doxycycline, anywhere from $11 to $138. And then metronidazole as a single two gram dose anywhere from about $3 to almost $14. And so again, it varies by insurance. Sometimes with insurance coverage, there might be just a couple of dollars worth of copay. There are again, STI clinics that can provide point of care medications. And so if the medication can be provided free of charge, that is an ideal option for those without insurance.

17:45
Should EPT be provided for both gonorrhea and chlamydial infections if gonorrhea is known, but chlamydial test result is pending. So this is really a clinical judgment, the CDC recommendation

is that EPT for gonococcal infection include a regimen for chlamydia, if chlamydia infection has not been excluded in the index patient. And so it's a little hard in this case to know exactly what that means, because you have a patient who if you have really good follow up with them, you could wait for the results of the chlamydia test and then treat them as needed. If it's a patient where you may have less faith in follow up, you may want to treat them as if you don't know whether the chlamydia is positive or not, with treatment for both. So it's really a clinical judgment about what you think and what your follow up is with your patients.

18:32
All right, can cefpodoxime substitute for cefixime as EPT if there is no available cefixime in your area. Some of you may realize that in some geographic locations, there have been cefixime shortages. So cefixime is clearly the first line however, CDC issued guidance in April due to COVID. And that guidance is still active on the website, that included cefpodoxime at a dose of 400 milligrams po twice a day for one day. So two doses, as an alternative oral therapy for GC during the pandemic given possible medication shortages. So it does seem reasonable to assume that you can substitute this since you could use this for treatment for the index patient, but you would only do that in the setting where you don't have cefixime.

19:27
So another common GC question that's been posed is if your index patient is diagnosed to have both GC and chlamydia infection, when is it acceptable to substitute azithromycin for doxycycline? It's likely that with the next iteration of the CDC STI treatment guidelines that doxycycline will become the first line treatment for chlamydia and azithromycin will become an alternative. Azithromycin still remains your drug of choice in pregnancy. If the partner has a known allergy to doxycycline, if the partner is thought to be unlikely to finish the total week of the doxycycline, and also if the partner is going to be unable to obtain it, for example barrier related to cost. And then perhaps there on site there you can get access to point of care azithromycin to dispense to the patient for their partner as an ideal alternative. We do just want to mention that there is a concern about the effectiveness of using the single dose azithromycin regimen for treatment of rectal chlamydia, it may be less effective than doxycycline. And if this is the case, you do want to consider doing a test of cure, if you're using azithromycin when there is concern for rectal chlamydia.

20:58
Chlamydia, so can either azithromycin or doxycycline be used for EPT if the CDC guidelines for the treatment of chlamydia haven't changed since 2015? So I think this overlaps a little bit with the last question we just talked about. But yes, the New York State guidance lists both azithromycin and doxycycline as possible medications for use for EPT. In the 2021 CDC STI guidelines, doxycycline is likely to be recommended as the first line treatment with azithromycin as an alternate, so it's still an option. And I think Daniela just really outlined nicely some of the instances where you'd really think about azithromycin over doxycycline. Of special note, this the same note as the previous one, but I think they're the recently completed randomized controlled trial that was stopped early because doxycycline was more effective for rectal chlamydia than azithromycin. And so I think that's certainly an area of concern.

21:49
I think this might be our last one. Since there's no direct communication between the provider and the partner who will receive EPT, I as the provider don't think I would be comfortable providing doxycycline to partners who might become pregnant. Is it acceptable to use as azithromycin preferentially for any partners who might be pregnant, rather than rely on the educational materials to advise the partner to not take the med if they were pregnant? So a little bit of the same question, this has come up quite a lot. This is really up to clinical judgment. But if the practitioner is concerned about pregnancy and feels like they can't confirm that the partner is not pregnant, azithromycin is still an acceptable alternate. In our clinical setting, we have sometimes actually just asked the patient to call their partner and gotten the last menstrual period date so that we could feel comfortable giving the doxycycline. And I think that's it. We'll go to, looks like we have quite a few questions in here. So we can go to some questions in here. And one was, in your in the initial presentation, Jason, you mentioned anonymousness, does that mean not writing the partner's name on the prescription?

23:10
That's correct. The prescription can be completely anonymous, where it only needs to have EPT on it, it does not need to have the name of the index patient or their partner on it.

23:19
Okay, another prescription question. We only use electronic prescriptions. How do you write for partner treatment with an electronic prescription?

23:30
Anybody want to jump in?

23:33
I can tell you in our setting, you actually can request prescriptions from the State for just this purpose, so that you can have paper prescriptions on site. And at least with Epic, as your electronic health record, it is possible to put into your Epic a prescription that will print at your site. So it's not electronically conveyed, it prints on on location. The only situations I've heard of people successfully offering electronic prescriptions are when they had something that was not Epic and they had an agreement with a pharmacy where they could within the patient's chart, write an electronic prescription for someone else with the patient's permission that that name was in the chart. I don't know if anybody else has other solutions.

24:31
No, we have the same problem where we've done the printing of paper scripts from Epic because there was not an electronic workaround for us, to send it electronically at least.

24:42
There is another, can you provide a link to CDC guidelines for EPT for trich? I am only seeing it for GC and chlamydia. I can address that it's worded a little bit differently. I'm looking for guidance about trich, it's sort of a may be acceptable type of wording for expedited partner therapy for trich. But the legal determination when the new law went in in New York State was

that that was sufficient and trichomonas would be covered by the wording in the law, which was issued in January of 2020. The actual formal regulations to that law haven't come out yet, and that's why there's this Dear Colleague guidance that came out in December. But the determination was the wording in the CDC guidelines was sufficient to cover trichomonas.

25:38
We have another question from the q&a. And you mentioned it briefly, Margie, but how do you request the paper prescriptions from the State?

25:51
So there's actually a link to it on the EPT site, there's a link to request prescriptions. So if you go to New York State and look for expedited partner therapy, there's actually a link there where you can request prescriptions.

26:10
And then one more, what is the time for a test of cure testing, as mentioned, I think test of cure for rectal infection?

26:25
I can take that one. You know, generally, you want to wait at least a few weeks after the person has completed the treatment. So you're trying to avoid the risk of detecting sort of DNA from prior organism. So generally, you're going to wait at least a few weeks. Anytime you're treating someone for chlamydia, you're generally going to test them again three months later regardless, due to the high rates of reinfection.

26:53
That has been just listed just in a draft form for the upcoming CDC guidelines. And they didn't mention a time. So it's possible they'll change that because they've changed the GC pharyngeal test of cure timing a couple of times. But I agree, it's usually three weeks at least. I think that might be our last question. Am I missing any?

27:21
There was a question about whether or not you can double the amount of medication to give to the index patient. So we did answer that one before but just as a reminder that you don't want to double the medication for the index patient. You do want to make sure you're giving a completely separate prescription for the partner. And there's one more question here. To clarify, we are often remote when we send the electronic prescription for the index and can't get paper prescriptions for the partner.

27:59
Yeah, that is difficult. If in the era of telehealth, what we have done in our sexual health clinic is essentially do a telehealth visit with the partner and then electronically prescribed since we've then created a chart for that partner. So it's not really EPT anymore, it's a telehealth as a self reported partner to whatever, GC, chlamydia, or trichomoniasis. But short of mailing the prescription to the index patient, the paper prescription if you've done it remotely, there just is

not an easy solution to electronically prescribing EPT. Anybody on here has successfully done that.

29:06
I just wanted to point out Jason has put into the chat, so we can share that with all the attendees the link for the paper prescription request.

29:21
And someone has asked if they can get the presentation by email. I think we can send a PDF of the slides to anybody that wants it.

29:33
Yeah. Okay, thank you very much, Dr. Urban, Dr. Zucker, and Dr. DeMarco.

[End]