Announcer:

This is CME on ReachMD! The following activity, titled *Opioid Use Disorder: Expanding Access to Medication* is provided in partnership with TOPEC and supported by the National Institute on Drug Abuse.

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Your host is Dr. Matt Birnholz.

Dr. Birnholz:

Opioid Use Disorder, or OUD, is an ever-growing—if not epidemic—problem in the US. Every day we hear about the rampant increase in the misuse of prescription analgesics, the easy accessibility of opioids, and the skyrocketing opioid overdoses that demonstrate the need for physicians, nurse practitioners and PAs to not only understand more about these drugs, but also to offer meaningful
treatments.

This is CME on ReachMD, and I’m Dr. Matt Birnholz. Joining me today to focus on current and emerging approaches to the treatment of OUD is Dr. Joshua Lee, Associate Professor in the Department of Population Health at NYU Langone Health. Dr. Lee, welcome to the program.

Dr. Lee:  
Great to be here.

Dr. Birnholz:  
So to start Dr. Lee, I think that opioid use disorder is actually a relatively new term introduced in DSM-5. Could you just explain what OUD encompasses?

Dr. Lee:  
Yes, most of us who are even early, mid or late career probably remember opiate dependance or alcohol dependance or nicotine dependance, and also, there used to be opioid abuse, and that was DSM-4, or the Diagnostic and Statistical Manual 4th Edition. In DSM-5 they did some rethinking at a national committee level of how to define addictive behaviors and diagnoses. And what we now do is look at DSM-5 and the new criteria for a use disorder, and this is common to nicotine, gambling, cocaine, alcohol and opiate use disorder. There’s a number of criteria. If you meet 2 or more, you can be diagnosed with a mild use disorder. If you have a few more, you have a moderate use disorder. And if you have most of the diagnostic criteria, you’re going to have a severe opiate use disorder. Really, if you try and crosswalk it, a moderate-to-severe opiate use disorder in DSM-5 is about what we used to call opiate dependence in DSM-4.

Dr. Birnholz:  
And what time frame are we referring to specifically?

Dr. Lee:  
So it encompasses symptoms over the last 12 months. Usually, you’re talking about how the patient is feeling right this second and how they have been doing in the last 30 days or so, but really, any problems or symptoms over the last 12 months would build up to a current diagnosis of an opiate use disorder.

Dr. Birnholz:  
That’s great. Why don’t we get a better sense of the tools that are available to advanced practice clinicians, which include physicians, PAs, nurse practitioners, just to help them screen patients who may need to be clinically assessed for OUD?
Dr. Lee:
Yes, I wouldn’t get too in-depth with screening tools. You really need to talk to patients about what they’re up to, what problems they have and what the root of the problems are. So people complaining of taking too much of their opiate medications or having side effects or using other drugs and alcohol along with opiate use medications, people that are straight up complaining about using heroin, you don’t really need to worry about screening in or out of a use disorder. More to the point, you want to talk to them directly about their current problem, how it’s affecting their health, their overall life, and start planning for treatment. So it usually is blindingly obvious.

Dr. Birnholz:
Yes, “blindingly obvious” does seem accurate, Dr. Lee. But, once a patient has a diagnosis of OUD, what clinical features or presentations steer you towards looking at medication versus counseling? And are there any alternative treatments available?

Dr. Lee:
Well, MAT, which is commonly medication-assisted treatment, really just means using one of the FDA-approved medications to treat and control and improve the opiate use disorder. We don’t think a lot of kind of tough love or counseling or kind of traditional abstinence-based approaches to addiction treatment work very well for opiate use disorders, and that, again, gets to how they affect the brain, how they produce physiologic dependence in most users and how hard it is to stop using them without the help of these FDA-approved medications.

So, if someone has a heroin problem, they always, almost always, according to the data in trial after trial, are going to do better if they access 1 of 3 medications: methadone, buprenorphine products or naltrexone products. If the patient refuses or is somehow completely unable to access any of these 3 medications, then it’s completely fine, of course, to talk about what else could help the patient. That’s often, in specialty addiction treatment, some combination of residential treatment, like going to a rehab so-called and then graduating to outpatient follow-up and the like.

Dr. Birnholz:
For those just tuning in, you’re listening to CME on ReachMD. I’m Dr. Matt Birnholz, and I’m talking with Dr. Joshua Lee about current and emerging approaches to the treatment of Opioid Use Disorder.

So, Dr. Lee, let’s continue our discussion on medication for OUD. Now, there are a number of approaches involving medications, but could you just elaborate on what those approaches are and what their mechanism of action are?

Dr. Lee:
Methadone and buprenorphine are themselves opiates. They’re very long-acting, kind of slow-boring opiates, so they’re great for treatment. They stabilize the opiate system, and they also block the effects of other opiates, so if you’re on methadone and buprenorphine and then you go use some heroin, it’s generally ineffective. And then naltrexone is a total opiate antagonist or blocker of the mu-opiate, and so that’s an approach of kind of relapse prevention where once you’re off opioids, you’ve detoxed, you go on the naltrexone, and that preserves an opiate-free state. And the one we use the most is extended-release naltrexone, it’s given once, and then it lasts for 30 days. Methadone, of course, is only available through methadone clinics or opiate treatment programs. That’s the traditional, classic, go every day, get your dose, leave, go back the next day, get your next day’s dose. A lot of patients are not interested in going to the clinic every day, and you, yourself, in primary care cannot prescribe it for opiate use dependence.

What you have at your disposal in primary care are buprenorphine products and naltrexone. So, buprenorphine is the easiest to use. It is something you can prescribe the same day that someone is using heroin, and you coach them on how to stop using heroin and go on to buprenorphine. The most famous version of it is Suboxone. That’s buprenorphine-naloxone. That was branded first as a tablet, and now it’s the brand name Film, but there’s generic tablets, there’s Film, there’s going to be generic Film soon. The naloxone is added in there so that people don’t crush and inject the compound, trying to misuse it in that way, and that’s a common kind of strategy now, a lot of tamper-proof opioids. So, what they’re getting when they take it sublingually is just the buprenorphine. It’s very safe. You could prescribe a month at a time. Someone could go home and swallow all that and is very unlikely to overdose and die because buprenorphine is a partial agonist.

So buprenorphine was approved for office-based use as a Schedule III controlled substance. You do have to do the X-waiver, it’s not a pass/fail thing. Everybody is going to get their waiver that is interested in doing that, and then you can prescribe buprenorphine. That’s a maintenance approach. People are going to stay on it for months and months and hopefully years and years. It works better the longer people stay on it. But if people kind of abruptly or prematurely stop it, they’re leaving a safe, medically prescribed opioid; they’re going to get some withdrawal effects, and they usually have relapse after quitting buprenorphine.

Dr. Birnholz:
I want to come back to one of the medications that you touched upon, which is the extended-release naltrexone, and we know that that has a unique patient readiness and treatment process. Could you explain, Dr. Lee, this process and any short or long-term benefits that a patient might receive by choosing to go through the readiness assessment?
Dr. Lee:
Yes, readiness in the sense that if you are, on Monday, talking to me and you’re using heroin and you want help, I cannot start extended-release naltrexone. You have to, either as an outpatient or more easily as an inpatient, undergo some type of detox and put a couple days of non-opiate use between the last use of opiates and the first shot of naltrexone. Not every patient is able to kind of get the support they need to make it through that process. It can be more difficult to do as an outpatient than as an inpatient, but inpatient admissions can be more expensive, bigger deals and harder to get access to, so that might be the essential kind of evaluation. And that takes a week or so or 2 weeks, and that is beyond the reach of many patients in terms of staying kind of motivated and in touch and able to do that. It’s far easier to work with naltrexone if someone is already detoxed but realizes they are facing a high risk of relapse. It’s very easy to start naltrexone as long as they are ready and agree to do it and understand the treatment they are pursuing.

Dr. Birnholz:
So, with that in mind, why don’t we cover some of the data behind the use of naltrexone. Can you talk about the significance of the X:BOT study that was just published, I believe?

Dr. Lee:
Yes, X:BOT was a large NIH/NIDA funded study that was comparing buprenorphine-naltrexone Film, brand name Suboxone, to extended-release naltrexone, brand name Vivitrol. It was the first head-to-head comparative effectiveness study that we’ve conducted in the United States. It was really done to put the newer one, extended-release naltrexone, in the context of what was the gold standard of care, and still is in the US in terms of office-based treatment. X:BOT, recruited people from detox centers around the country. It flipped a coin and randomized people to either buprenorphine or naltrexone, and then people were expected to do 6 months of outpatient treatment on either medication. What we found was that it was harder, even in an inpatient environment, to start naltrexone. That was not very surprising, but I think it was an important result.

Once people got on to either medication—about 95% got on to buprenorphine, and about 72% got on to naltrexone—they did similarly. Both medications looked quite good in terms of keeping people on them and keeping people opiate-free, not using in terms of their urine or what they were telling us at study checkup visits for the next 6 months, and overdose rates while on either medication were very low. Overdose rates were higher if people failed to get on the medication in the first place or if people stopped the medications prematurely.

So it was a study that really kind of said, “Hey, these are both good.” That was new information in terms of naltrexone relative to buprenorphine. I think there’s been a lot of skepticism at how well naltrexone for opiate use disorder worked, if at all. The oral tablet, which we had for many decades,
never worked very well for opiate use disorders, but the injectable 30-day formulation seems to work a lot better.

That was the X:BOT main finding, was that buprenorphine overall was easier to start but once people were on either medication, they did similarly, and that was, new and good information for extended-release naltrexone. I think it gives us all confidence in the primary care setting that we can use either one.

Dr. Birnholz:
So, Dr. Lee, as we wrap up, I’d just want to turn our attention for a minute or two to the subject of how we can make medications for the management of OUD more widely available for patients in need. Now one way, of course, is just by helping patients understand the value of these options in treating OUD. But another is actually becoming a growing effort, and that’s developing primary care-based models. Could you speak to these approaches?

Dr. Lee:
I would simplify things and say there are about 2 basic models. One is you’re a physician in a physician practice. Are you going to get your x-waiver? And now you’ve done it. Congratulations, you can just start writing prescriptions. You want to see the patients. You want to engage them in a long-term chronic kind of disease model, if you will, and you want to be providing them buprenorphine that they are taking themselves on a daily basis. you’re probably going to be seeing them maybe once a week on average to begin, but then once they are stabilized, maybe once a month. That’s typical of most US buprenorphine office-based practices. And you want to extend that as long as possible.

Probably most important and most famous other model is a nurse-based model where there is a prescriber, say a clinic director physician-type person, and a lot of the day-to-day management, though, of a panel of patients can be done by interested and trained nurse and/or you can imagine other physician extenders, but nurse care management models are probably a good and very cost-effective way to treat a lot of patients and extend kind of the reach of one physician’s DEA and X-waiver. That said, we’re now in a new era where nurse practitioners can also get the X-waiver credential, and you could have an entirely nurse-run practice from here on out.

I practice in a large, academic, urban hospital, so we have a bunch of docs who kind of share patients in a kind of team approach. We’re all physicians in this case, but it could also be a mix of PAs, physicians, nurses. We manage a panel of about 150-plus patients.

What we’re really trying to encourage is that more people get involved as prescribers and more people kind of learn about how really easy it is to help people with this condition. it can be very rewarding in that you can turn a patient around who looked really bad on Monday, and within a month they look and
feel a lot better, and you can extend that out for years and years if these medications continue.

Dr. Birnholz:
That’s fantastic. And I’m sure that is really rewarding to see patients turn around in such short time and doing a lot better. So, Dr. Lee, before we close the program, let me just open up the floor to you again to see if there’s anything else you’d like to share with our audience on this subject today.

Dr. Lee:
I think just that, that it’s a public health crisis but one that is easily answerable through medications, through treatments and through the medical workforce in ways that are not new and are not particularly sophisticated and are really accessible to all providers. It certainly helps if you’re in a state where Medicaid pays for Suboxone, so I do realize there are other limits and barriers that still need to be overcome. But that said, there really isn’t any reason why all family medicine docs in the US couldn’t be buprenorphine prescribers, and that would make treatment… that much more widely available than it is now, particularly in rural counties and in rural parts of the country. it is extremely important and it would really move the needle on your state’s overdose epidemic if more and more docs in those type of areas were able to prescribe this type of treatment.

And then I would remind you, if naltrexone is something you’re interested in, that is not a narcotic. Anybody can describe that, and anybody can give the injections. There are no controls or barriers to that one other than insurance coverage.

Dr. Birnholz:
Well with those takeaway comments, I very much want to thank you for your time, Dr. Lee. Clearly there’s a lot more work to be done as we’re facing an opioid epidemic in the country, but I think we can take encouragement from the fact that we’re moving in the right direction with these strategies for better diagnosis and medical management of OUD.
Dr. Lee, it was great having you with us, thanks again.

Dr. Lee:
Thanks for having me.

Announcer:
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