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X-EXPRESS: BUPRENORPHINE PRESCRIBING FOR BEGINNERS

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X-Express: Buprenorphine Prescribing for Beginners

[video transcript]

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00:43

Thanks so much, Emily. And thanks to everyone who joined us today. I don't have any disclosures to mention. The learning objectives today really just are to prepare you to feel ready and able to prescribe buprenorphine for opioid use disorder. We'll go over some of the changes in the requirements that have recently been updated by the Biden administration. And we'll summarize some of the pharmacology, best practices about prescribing buprenorphine, how to initiate treatment, how to achieve stabilization, and maintenance, as well as discontinuation. So really rooted in clinical practice. And we'll go over a case that highlights some of the particular challenges and strategies that are successful in terms of engaging patients in an outpatient primary care setting, in a rural setting in particular, which is where I practice in upstate New York based in Ithaca, New York, but we serve patients across 40 counties in New York State.

01:52

Why are we here today? So, you know, prescribing buprenorphine, I will say, is one of my favorite things to do along with prescribing Naloxone and Renaclin. But it's really a pleasure to be able to work with patients to manage their opioid use disorder and recover, and really regain a lot of positive aspects of their life. It can be a really successful form of treatment. And of all medications we can prescribe, it's really one that is powerful in terms of reducing morbidity, mortality, and most importantly, improving the quality of life for our patients. Now more than ever, with overdose rates surging across the country, with the loss of life in many cases of very young people, these are all preventable deaths in most cases. And we can do so much more as clinicians to provide access to evidence based and life saving treatments to people living with substance use disorders. So that's why I'm here and you know, it's really great to be with you today.

03:06

So we have a few polling questions just to start out. What motivated you to attend this X-Express course today? And there's two choices here. Either A) I'm waived to prescribe buprenorphine, but need more clinical education, or B) I'm not waived to prescribe buprenorphine, but I'm interested in learning about it. Great. So some of you are already waived to prescribe buprenorphine, and about two thirds of you are not yet waived. And so we can talk more about buprenorphine and what are the next steps for everyone in terms of prescribing buprenorphine.

03:38

So just another polling question, do you plan to obtain a waiver to prescribe buprenorphine at the end of this course? And these are the choices, including one if you're not a prescriber, you're already waived, and whether you plan to prescribe or not. Great. So everyone either already has a waiver or plans to get waived to prescribe buprenorphine. That's amazing. You're in the right place.

04:01

So you know, I mentioned some of these in the introduction, but what are the big picture goals of buprenorphine treatment? Fundamentally, we think about reducing mortality. We'll go over some of the data around that, but essentially, it's associated with a reduction in mortality between 50 and 80%. So really significant risk reduction for patients. We also see a reduction in the transmission of blood borne viruses, including HIV and Hepatitis C, with buprenorphine treatment. I'll mention this, it's really important to consider the patient's quality of life and health overall, which have been shown to improve as engagement in buprenorphine treatment occurs. And then, you know, to the extent it's a patient's own goal, reducing the use of illicit substances like heroin and other substances is also part of the treatment goal.

04:57

And what are some of the therapeutic effects of buprenorphine? How does this work? It really works in a couple of different ways which makes it so effective. First and foremost, it prevents, I would put this first, it prevents opioid withdrawal. So you take someone who's experiencing opioid withdrawal, which is incredibly uncomfortable, horrible experience for patients, people do go to any lengths to avoid that or end that, and buprenorphine immediately can improve those symptoms. It also reduces or completely eliminates cravings for opioids. This is something we assess in our patients, are they experiencing opioid cravings? And many patients, if not most, will tell you that their cravings are eliminated, especially if they're on the right dose of buprenorphine. And then, if someone is on buprenorphine and uses another opioid like heroin, they're actually safer because that buprenorphine has a higher affinity for the opioid receptor, it's going to reduce their risk of experiencing complication like overdose. So even in the setting of ongoing use, it's much safer and even beneficial for a person to be on buprenorphine. That's important to keep in mind.

06:10

And what are the key principles of treatment? So fundamentally, treatment must be patient centered, it's about the patient's goals, objectives, and really overall approach. I would just strongly encourage you, there's no one size fits all approach to treatment. It's about partnering and collaborating with your patients to find an approach that works for them. That's over the long term. This is a chronic disease for the vast majority of people. People experience ups and downs, and that's typical, that's the norm. And so you want to be prepared to work with people collaboratively over a long period of time.

06:45

Taking a harm reduction approach. What does that mean? That means that even if your patient is engaged in buprenorphine treatment, you want to go over ways in which they can remain safe, protect themselves. And if they do return to use or use other opioids, review ways in which they can make that less risky to themselves, including having Naloxone available, not using alone, using a test dose because their opioid tolerance may have changed during the course of their treatment, being aware of the presence of fentanyl and considering using fentanyl test strips, accessing sterile syringe and needles through needle exchange program. These are all strategies that are evidence based. And viewing the medication as treatment, this isn't some sort of treatment where the medication is a supplement, it used to be kind of referred to as medication assisted therapy. And really, we see that medication is the cornerstone of treatment and is the most effective form of treatment. So it is the treatment. And other things may supplement that.

07:45

You want to provide same day or rapid initiation to treatment. So there should be no delays to starting someone on buprenorphine if they're a candidate for treatment, and they're ready to start. And provide buprenorphine in a low threshold or low barrier way, that's the terminology that's used. Essentially what that means is convenient, accessible, same day, in a convenient location, in a friendly manner, high quality healthcare really is what we're talking about. And taking into account a biopsychosocial model of care, which is true for all chronic disease management, but definitely true for opioid use disorder. You want to take into account the different facets of the condition and how it impacts your patient and how they exist in their own life, their social circumstances. What does their housing look like, their transportation? All of these things may impact their engagement in care, and you need to therefore tailor care to allow them to continue to remain in care for as long as they choose to.

08:48

So who can prescribe buprenorphine? Fortunately, physicians, nurse practitioners, physician's assistants, CRNAs, CNMs, with a DEA are eligible to obtain an X waiver. And this is the key difference, in the past prior to this year, you needed to complete eight hours of additional training in order to prescribe buprenorphine for opioid use disorder. And that is no longer the case. Anyone with a DEA who is among the list above, can file a Notice of Intent with SAMHSA, that's the federal agency that oversees buprenorphine prescribing. You file this notice of intent, there's a link in the slides, and you can prescribe to up to 30 patients at any time without the formal training. However, if you want to prescribe to over 30 patients at any one time, the formal training to obtain an X waiver is still required. And that typically involves completing either eight hours of online training or a sort of mixed approach. And if you're interested in the full waiver training, I encourage you to reach out to Emily for more information. This is more information about how to apply to SAMHSA. There's a link with some quick steps. It takes five minutes, 10 minutes, you're really just registering and notifying SAMHSA that you're planning to prescribe buprenorphine.

10:21

So now we'll get into a little bit of the pharmacology of buprenorphine. It is a partial agonist at the mu opioid receptor. So it's a partial agonist, and that is in contrast to methadone or

oxycodone or heroin, which are full agonists at the mu opioid receptor. And also in contrast to naltrexone, which is an antagonist or blocker at the opioid receptor. So this is one of the unique characteristics of buprenorphine that make it so safe and effective. So it binds with very high affinity to the opioid receptors and activates those receptors, that's sort of how it controls cravings and also prevents withdrawal or eliminates withdrawal. But doesn't lead to any euphoria that full opioids may elicit in individuals who use them, nor does it lead to significant respiratory suppression when taken alone as prescribed. And so it kind of binds and blocks and is a very safe and effective. The Naloxone that is co-formulated with buprenorphine in several products, including what's known as the name brand Suboxone, which is a buprenorphine/Naloxone film, is not bioavailable or active when taken as prescribed, which is sublingually. That is co-formulated as a deterrent. So if someone takes a suboxone film, tampers with it to inject it, the Naloxone that is present will be active and it will blunt the effects of the buprenorphine. Happy to answer more questions about that at any time.

12:05

This is a graph that illustrates, sort of in a comparative basis, what I was talking about. Methadone being a full agonist compared to buprenorphine, which is a partial agonist, and Naltrexone, which is an antagonist. Looking at the dose over time and this sort of effect that it has, and what we see with the partial agonist, buprenorphine, is there's a ceiling effect. So essentially, depends on the person, but at the max dose, so say at 24 milligrams, somewhere between 16 and 32 milligrams, someone will have saturated all of the receptors and there won't be any additional therapeutic benefit or effect of the buprenorphine once all of those receptors are saturated. And so one thing to note here, because buprenorphine has a very high affinity for the opioid receptors, and it is only a partial agonist versus a full agonist, it can trigger something called precipitated withdrawal. So if someone uses heroin and then immediately takes a buprenorphine, they could experience that it puts them into withdrawal. And this is because of the affinity of the buprenorphine for the receptors, it will bind those receptors and kick out the full opioid agonist. And because it's only a partial agonist, the person will feel worse, not better. So this is just something to be aware of, patients are typically very aware of this also if they have any experience with buprenorphine. So we'll talk more about it, it's something to be aware of and talk to your patients about.

13:44

In terms of drug drug interactions, it's very safe and extremely rare for any significant drug drug interactions that you have to take into account in terms of prescribing buprenorphine. So you know, in terms of co-prescribing other opioid agonists or antagonists. So, for example, if you have a patient on buprenorphine and they have alcohol use disorder, you know, you wouldn't want to prescribe that person Vivitrol, which is an injectable form of Naltrexone, because that could interact and render the buprenorphine not effective. But these are rare, really rare instances. And for most patients taking most medications, there aren't any significant interactions. CNS depressants, so benzos, other sedative drugs, sleep aids, things like this, it's something to be aware of and to talk about with your patients. It's not an absolute contraindication to prescribing buprenorphine, in fact, buprenorphine would be the safest medication in that situation.

14:49

In terms of the formulations that are approved and available for the treatment of opioid use disorder, it comes in a variety of different formulations including tablets, films. Both the tablets and films are taken sublingually. And so there's the tablets and films come in co-formulations with naloxone, and there's also a mono product buprenorphine tablet without the presence of naloxone, and that's called subutex. There's also injectable long acting extended release forms of buprenorphine, coming in both monthly injections, which is known as sublocade, as well as weekly injections, which aren't typically used and there's some dose limitations for that one.

15:45

So one thing to be aware of in your state, the Medicaid formulary has very specific formulations and brands available on formulary, and this recently changed. So for patients on buprenorphine, the name brand film Suboxone, which is the blue box, is the on formulary formulation of buprenorphine/Naloxone films. And then the tablets are still the generic tablets, buprenorphine/Naloxone tablets. And then the mono product is available, and if someone needs to be maintained on that for a variety of different reasons, you do have to get a prior authorization. And then the injectable, sublocade, is only available in name brand currently, and is on formulary. And that applies to both Medicaid managed care and fee for service plans in New York State.

16:43

In terms of the administration of medication, I would say this is one of the things that's a little bit unique about buprenorphine products that's good to be aware of. It's a sublingual or buccal administration, due to poor oral bioavailability. So if someone takes a tablet and just ingests it, swallows it, it won't be very bioavailable. And even when taken sublingually, the bioavailability is only about 30%. So patients should take the medication under the tongue or inside the cheek, not having eaten or smoked. That's an understatement, it doesn't have a pleasant taste. It's very unpleasant for many patients, and can be challenging. It's one of the most challenging aspects, but you know, most patients it's not a big deal. They take their medication. You want to take it over an at least five minute period of time. So many patients you'll encounter have experienced using buprenorphine, they're aware of all this, but for patients who've never experienced buprenorphine, we should be able to counsel them that it's used either under the tongue or on the cheek. They shouldn't eat or drink or talk while they're taking the medication, and it takes about five minutes to absorb.

17:59

In terms of adverse reactions. The precipitated withdrawal is something to be aware of, like I mentioned. And that will only occur if there's opioids on board. So if a person hasn't used opioids in days, it's extremely unlikely that they'll experience precipitated withdraw. When they're on the medication, or throughout their treatment for buprenorphine, there are some side effects that are sort of common, including constipation which is related to its opioid properties. Nausea, vomiting, these typically occur with administration of the medication and can be managed by pre medicating with ondansetron. And the constipation can be managed with typical approaches to constipation, including diet and other meds. Headache, you know, this is something we see in patients, especially for patients who have headaches typically, and

including migraines. So the treatment may worsen their headaches. Sometimes this will abate over time as they stabilize on treatment. Can be managed using NSAIDs or other approaches that are effective for that person's headaches. But sometimes it impacts the ability of the patient to continue on treatment. And typically, I would try different formulations or different approaches to how to take the buprenorphine, what time of day. And, you know, maybe try a tablet if they had tried a film, to see if that is less severe for them, because being on the buprenorphine is so important. It can be sedating, not in most cases, you want to find the right dose. Sleep disturbance, so it's actually activating for plenty of patients. So one thing to keep in mind is to not take it too late in the day. Some patients will experience insomnia if they take it afternoon. Other people take it before bed and it helps them sleep. So like many medications, there's paradoxical effects and it's really a patient centered approach. But these are all things to know about.

20:04

So your first patient, you know, continuing patients on buprenorphine is a great start, because these folks are on meds already, you're not initiating new treatment, and you can get comfortable with sort of the logistics of prescribing, which essentially are pretty easy. If a colleague is on vacation and they need coverage, it's a great opportunity to be like, 'hey, I'll refill your buprenorphine patients. Now that I've registered with SAMHSA, my notice of intent to prescribe buprenorphine, I can do that.' If people are transferring from other treatment settings, so we see some patients who are engaged in some sort of very, very rigorous either inpatient or outpatient treatment, and then they need to transition their care to the community. And so they're already on buprenorphine, they're stabilized on a dose, you're just continuing that treatment. Or maybe their prescriber retires and you can pick them up. It's a great service to patients, because people who are on buprenorphine, that is their lifeline. People have seen that being on buprenorphine has allowed them to completely stop using other opioids in most cases, and really just regain their life. And so the loss of access to buprenorphine can be terrifying for those people, rightfully so. So just having another prescriber in their community who's accessible and willing to prescribe buprenorphine to them is really important. And then incarceration, we know that people leaving jail or prison are at extremely elevated risk of overdose, at least, you know, 10 times, if not higher, greater risk of overdose in the two weeks leaving jail or prison. So it's a critical time for patients to either initiate treatment or continue treatment. Folks may have already started on treatment while in the hospital, and they're transitioning to the community. So these are great opportunities to continue prescribing to people.

22:00

In terms of starting new patients. Some of the easier candidates will include people with experience on buprenorphine. Because this is a chronic condition, you will encounter folks who say were on buprenorphine for three years, but stopped two years ago, hit a rough patch, they're back, they want to restart buprenorphine. Great person to talk to because they're going to know all about it and they can tell you about their experience. Likewise we see people all the time, they've been on, 'I've taken suboxone for nine months while I'm on a waitlist to get into a treatment program.' You know, so they're on buprenorphine, it's working for them. They just need someone to prescribe it to them to make their life easier and more stable. So those are

great candidates, and easy cases frankly. If someone is pregnant, if someone is on methadone or naltrexone and you're transitioning, or someone has severe liver failure, you know, those would be indications to refer the patient to a higher level of care from an addiction consultant.

23:07

So what does someone need, what conditions must be met for someone to start buprenorphine? Fundamentally, they need a diagnosis of opioid use disorder based on the DSM five criteria, which we'll review. They should be interested in treatment. You know, treatment is most effective when people are motivated to engage in treatment, you may encounter patients who are mandated by the courts to be engaged in treatment. And while, you know, in most cases, by and large, that's better than the alternative, which may be jail or prison. In some instances, you know, it may still be undesirable to a patient. So working with a patient to engage with them, in terms of their level of motivation. And have no absolute contraindication to buprenorphine, which there are basically very few, except sort of anaphylaxis allergy, which some patients have experienced. And then talking about the risks and benefits with them.

24:03

So in terms of verifying the diagnosis, there's this sort of twofold way in which we diagnose opioid use disorder in the DSM. And there's the physical component, which is both tolerance to opioids, meaning needing a higher and higher dose of opioids to achieve the same effect, as well as experience opioid withdrawal. But those criteria alone do not mean that a person has opioid use disorder. So in order for a person to have opioid use disorder diagnostically, those conditions are present and there may be an impact on their social function, or a loss of control, or continued use despite negative consequences, whether it's in their social situation, their job, their family life, social interactions, unable to keep their obligations, psychological harm, physical hazards, and continued use despite these. And then based on the number of criteria a person meets, they will be categorized as having mild, moderate or severe opioid use disorder. And so you can go through these clinically and assess someone. Usually it's not difficult to make the diagnosis, there are some instances when a patient may have chronic pain and their opioid use is, there's some loss of control around their opioid use, but it's not crystal clear whether they have opioid use disorder or a complex pain. Those are instances to maybe seek expert consultation if there's any diagnostic question.

25:52

In terms of initiating buprenorphine treatment, there's two basic ways of approaching it, which are termed here, unobserved and observed initiation, what used to be called in office or home induction. And what we know about these these approaches is they're both effective. So a person can successfully start buprenorphine in an unobserved or home based setting. So the vast majority of buprenorphine treatment I initiate is with the person unobserved at home. And then there are some instances when the person has been in office and we've done an observed initiation for any number of reasons, including patient preference.

26:35

Okay, so one of the big points here is to wait to start the buprenorphine until you're in mild to moderate opioid withdrawal, which most patients have a sense of. Like when their withdrawal is

kicking in, they may have mild symptoms, and they want to kind of push through that point slightly to get to moderate withdrawal. And that is because the longer they wait, the less likely it is that they would experience precipitated withdrawal because the full opioid would be less present in their system, their body has metabolized the heroin, it's not present, it's not resting on the opioid receptors. And that's a great time to start the buprenorphine. There are apps that people can use or you can give a patient a checklist from your office to go through the COWS, the Clinical Opiate Withdrawal Scale, or your clinical staff, like your nurse could administer it if a patient's presenting to assess their level of opioid withdrawal. And on that scale, you want to be at least a five, if not a ten, to initiate buprenorphine. And people always want to know how long since you last used should you wait, everyone's different, but these are some rules of thumb that are nice to be aware of. For short acting opioids like oxycodone, at least 12 hours. For street opioids like heroin, as short as six to eight hours, but as long as 12 hours. For long acting opioid analgesics, at least 24 hours. And for methadone, which is much longer acting, you want to wait up to 72 hours. And illicit fentanyl can be variable, but waiting 24 hours might be recommended.

28:27

So how do you initiate? Usually, you would advise the patient to wait at least until they're mild to moderate opioid withdrawal, and then take four milligrams of buprenorphine/Naloxone sublingually. And then to wait about an hour, an hour and a half, and if they're still experiencing withdrawal, still not feeling well, to take another four milligrams. And to keep going, to keep dosing about four milligrams of buprenorphine every 60 to 90 minutes until they feel better, which is often when they've taken 12, 16, 20 or 24 milligrams of buprenorphine. And then on the second day, they could take that entire dose the next morning. Some patients prefer split dosing, which means they would take it twice a day. And in some instances, even three times a day. It's typically recommended to take it once a day in the morning, in most cases. And so this initiation can be done after a telemedicine visit, that is due to the public health emergency. So currently, under the public health emergency, you're able to see a person completely remotely by telemedicine and prescribe them buprenorphine. That was not the case prior to COVID, but that's the current practice.

29:54

We can answer some of these questions. You know the key in terms of when it's safe to start is, if you're in a hospital setting you can have a nurse administer a COWS score, and having a person score at least a five, if not a 10, you can manage symptoms people may be experiencing. Especially in a hospital setting with other medications that can make them more comfortable, including ibuprofen, ondansetron, loperamid, or Gabapentin, while they are experiencing and sort of get into a place where they're in moderate withdrawal. Typically follow up in about a week. I will say in our practice, sometimes we follow up in two weeks if patients, for example are already on buprenorphine and we're just continuing their buprenorphine from a different practice, that would be a setting in which we wouldn't require the person to follow up in a week unless they wanted to or were unstable in some way. Otherwise, for a new patient, you want to follow up in about a week. And I always advise them, give me a call if you have any problems before then, I want to know about it and we can adjust your dose as needed. These are for home inductions, have a nurse call them, check in on them, in the following days.

31:12

This is a guide for patients to take home. This is a guide that's available in PDF form or online. And it really goes over step by step how to do home induction. And one little sort of like tip I would say, in terms of the four milligrams, usually I recommend, you know usually I prescribe the eight milligram films and I'll have people cut it in half. And recommend that they cut it while the film is in the wrapper, because the films will disintegrate. So keep it in the wrapper, cut in half, take half of film, wait an hour or so, take the other half if you're still feeling like you're in withdrawal and repeat that up to 24 milligrams. And you know, so you'll do a week supply. I would say definitely for most people, you're going to be prescribing at least 16 milligrams a day. So that would be a quantity of 14 and up to 24 milligrams if someone has a high opioid tolerance, heavy use, past experience with buprenorphine and they know they've done best on 24 milligrams, I would go ahead and prescribe that up to 21 films, follow up in a week. You know, in terms of prescribing the lower doses, those are just less commonly available so that's a limitation. I mentioned that you can prescribe ancillary meds, I didn't say clonidine, also an option, to manage withdrawal during the induction period, but not necessary. And then make sure you're following up. One thing to be aware of throughout, I did this last night on call, calling the pharmacy, collaborating with the pharmacy and troubleshooting if there's some sort of reason why a person can't pick up the formulation you prescribed, either due to their insurance or due to what the pharmacy has in stock. Those are things that you can and should try to rectify by collaborating with a pharmacy. So befriend a pharmacist, I have friends, mostly friends, across the state at different pharmacies, and it can be really helpful to pharmacists and to us as prescribers to have that collaboration.

33:30

And so especially as we seek to expand access to this medication, which is viewed either skeptically or even fearfully by both prescribers and pharmacists, in some instances, we really want to move towards understanding buprenorphine as a safe and life saving medication that we need to expand access to and limit delays for patients to access. So call, collaborate. And this will minimize patient stress. So patients are both in opioid withdrawal which is uncomfortable, and can be very anxious about accessing that medication. So I would just use the terminology of being sort of trauma informed, being aware that your patient's level of anxiety may be informed by other factors about their experience as someone living with opioid use disorder, that could manifest or present as frustration on their part. And really understanding that for what it is, which is anxiety and stress, and you can be part of helping manage that and not contributing to it, by collaborating with them and working to get them access to medication.

34:40

So, you know, being aware of things like the formularies, what's available, making sure your your X waiver number is on the prescription in the note to the pharmacy if it's not uploaded into your EMR already. Scheduling office visits to coincide with refills, this is a very great pearl I would say, because then you'll ensure that it's a great way to promote engagement and have basically low no show rates. Our no show rate is below 10%, has been throughout our practice and that's because we give patients, I would add to this, don't do 30 day prescriptions, because then refills will fall on the weekend periodically. Do increments of seven days. So we do seven

day prescriptions, 14 day prescriptions, 21 day prescriptions, and 28 day prescriptions, and have that person's follow up be four weeks later, two weeks later. Or have it be 29 day prescription if their follow up appointment corresponds to 29 days later. That's something we do and I think it's useful. You want to keep record of this, for regulatory purposes, just a simple log, if your EMR can generate a report that says how many people you've prescribed buprenorphine to that, as I understand it, is adequate. And you want to be checking the PMP before you're prescribing buprenorphine as a controlled substance, that is required. And methadone may not appear if it's dispensed from an OTP. So if someone's on methadone from like a methadone treatment program and they tell you that, but then it's not in the PMP, that is consistent.

36:29

In terms of labs, this shouldn't delay starting treatment. So you don't need to see someone in your office, get labs, wait two days and then start treatment, just because there's really no result that would prevent you from prescribing buprenorphine. You know, there's no renal dose adjustment in terms of liver failure. I would use your clinical judgment or assessment if someone's presenting in with either history or clinical signs of liver impairment, that I think might be an instance when you would want to get a consultation or get some lab work, but that's pretty unusual. And so in the vast majority of cases, you can prescribe. If you don't have a pregnancy test, you can prescribe, even if you haven't checked CMP. But you could, and perhaps even should, check all of those things during the course of your treatment because we know these comorbid conditions including STIs, TB, or certain risk factors, incarceration, having lived in a shelter, other factors, exposure to blood borne infections like HIV or Hepatitis, are common. So all things to check and address during the course of your treatment, but not necessarily that you have to do it day one.

37:48

In terms of urine drug testing or toxicology. It's a clinical tool, and it's not essential to do a urine drug test with the presence of opioids in order to start buprenorphine, because someone may have opioid use disorder based on the DSM five criteria, not have used opioids for some time, but now they're experiencing cravings, they want to get on Suboxone. So that is fine to absolutely treat them with the absence of opioids in their urine drug screen. And conversely, there may be the presence of other substances like cocaine, methamphetamine, benzodiazepines, and that should not preclude you from prescribing buprenorphine. And just to note, CEI has a lecture on urine drug screens that's worth checking out. There's a lot of false positives, false negatives, misinterpretation of urine drug screen. So I think it's not something you can hang your hat on, and something also to be aware of is buprenorphine typically isn't on a routine opioid screen because it's a synthetic opioid so you have to actually ask for the buprenorphine or norbuprenorphine to be checked. Likewise with fentanyl, Tramadol and methadone. So, if you want to confirmatory tests, you usually just put a note in to the lab that you want them to actually check for buprenorphine.

39:19

Buprenorphine does not treat stimulant use disorder, cocaine use disorder, alcohol use disorder per se, but they can be co occurring and like I said, shouldn't prevent someone from being started on buprenorphine. It may help, but not specifically. And so you will stabilize someone

over a course of two to four weeks in most cases, you may want to follow someone weekly until they're stabilized, or biweekly, and that can be done via telemedicine or in person. We do a ton of telemedicine at REACH, and it's a really effective form of engagement and treatment, and we've initiated over 800 patients through telemedicine since COVID. And our no show rate, I mentioned, is under 10% and our six month retention is over 70%. So it's a really effective form of treatment. And you can adjust the dose by increments of two or four milligrams every five to seven days as stable, and most people will live at a dose around, I would say, 16 to 24 milligrams is most common. I have some patients on two milligrams, I have some patients on 32 milligrams. In New York State, you have to obtain prior authorization for doses exceeding 24, the absolute max would be 32. In some states, like out west in Oregon, they can prescribe up to 32 milligrams, so that's standard out there. Whereas in New York State, 24 milligrams is the more standard max dose. And you know, if someone's on 24 milligrams and has a period of time requiring more due to pain, or other situations like pregnancy, we can get prior auth of up to 3, but most people are gonna be at 16 to 24.

41:07

In terms of the duration of treatment, it's a chronic condition. So most people, you know, are on the treatment somewhat indefinitely, but at least a year when starting out. You can see people monthly, that's what we do in most cases. For people that are extremely stable, we can see them every two to three months, which means you can put refills on the buprenorphine prescriptions. If we're going to see someone in eight weeks, I would say do a 20 day supply with a refill and see that person again in eight weeks. If you're going to see them in 12 weeks, do a 28 day supply with two refills and see that person in 12 weeks via telemedicine or in person. For complex cases, some patients, different patients benefit from different forms of treatment, and so it's good to be aware of options. And some people, just like with diabetes, some people are managed in the primary care setting, some patients benefit from seeing an endocrinologist. So it's same thing for buprenorphine, and some patients on buprenorphine may benefit from transitioning to an opioid treatment program where something like methadone might be offered.

42:15

In terms of toxicology testing. It's really to evaluate adherence, so is someone taking the buprenorphine you're prescribing, that's the purpose, and really to talk to them about other substances and harm reduction if they are using other substances.

42:31

I'll give you an example, I had a patient very stable on buprenorphine, not using opioids but presence consistently of cocaine. This was like a 54 year old man, just talking to him about them and asked him about symptoms, and we talked and he said, 'Oh, well, I do get chest pain when I'm using cocaine.' So we were able to talk about, you know, the risk that may pose to his 54 year old self compared to his 27 year old self, when he wasn't experiencing anything like chest pain, and that actually motivated him to stop using cocaine. So it's useful if you can have a collaborative, non judgmental, conversation. These urine drug screens should never be like observed, there's really no reason I would recommend that.

43:14

And when you're assessing treatment, when you're seeing someone, 'how's it going? How's the medication working for you? How is it helping you? Are you experiencing any side effects? Do you have any concerns?' If you do a urine drug screen, you can discuss the results. Inquiring about their level of support, or if they need additional support, and any other health needs that are going on. Some of our patients have no other touchpoint with health care, may not have a primary care provider, and so they may have other health needs that are going unmet. And so it's an opportunity after someone stabilized on buprenorphine treatment to really engage them. 'Do you want a flu shot? Do you want a COVID vaccine? Oh, you've been coughing, tell me more about that.' You know, so this is an opportunity. And the best way to do that, to engage people in care, is to really provide a welcoming and non judgmental environment, and to understand that people with opioid use disorder, with substance use disorders, with mental health conditions, with social determinants, like homelessness, frequently experienced stigma or are stigmatized in healthcare settings. And so we need to actually know that exists and work to undo that harm that we've caused as healthcare systems. And first and foremost, just avoiding ongoing use of stigmatizing language which is listed here. Even things like clean and dirty are stigmatizing. Patients may use this terminology. I don't even say negative or positive, I may say 'the presence, it showed the presence' just be objective. 'I saw cocaine in your urine drug screen.' That's just a statement of fact, not that it was clean or dirty. And so it's really critical that we utilize person first language, person centered approaches and not perpetuate stigma.

45:10

In terms of discontinuation, most patients benefit from long term indefinite treatment. Many, many patients will tell you, 'I want to get off this.' People find face stigma, or they're ashamed that they're on Suboxone, even though from my perspective, it's a sign of strength, they're engaging in treatment, they're building their life back, they're taking care of themselves, they're seeing a doctor, all the things that we know their family wants them to be doing. But in fact, because they're on Suboxone, people will say they're not fully abstinent or clean, or what have you, all these stigmatizing lenses that we impose on substance use disorder compared to other chronic diseases. So I will talk to people about that and just say that, you know, 'this is a chronic condition, people experience ups and downs.' I'll go over stigma as it plays a role in frequently motivating people to get off treatment, I'll say, you know, 'how is buprenorphine helping you?' And they can list 'Oh, I was able to get a car, keep my car payment, I have an apartment. Oh, I actually have custody of my kids and I have a job.' I'm like, 'Wow, this seems to be really working for you. What what are some of the reasons you want to stop buprenorphine?' 'Well, you know, my girlfriend wants me to.' And you know, so it's an opportunity to engage in conversation in sort of a motivational interviewing type of way. But despite that, and people have legitimate reasons why they want to taper or at least get to a lower dose, it's a slow approach, patient centered approach, collaborative approach, and that can be reversed at any time. So I have a patient, highly motivated, super successful, went back to college, etc, wants to get to lower dose just because he feels better at a lower dose. Have tapered him down and then he said, 'oops, I'm feeling some cravings coming back, let's go back up a little bit,' We'll increase that by two milligrams, or we'll increase that by four milligrams and reassess. And then I have patients that have stopped. And I just urge them to have Naloxone and suboxone available, to call immediately, have a plan in place if they find themselves craving opioids.

47:19

There's some best practices here from the New York State Department of Health. An extensive initial assessment is absolutely not necessary, basic history confirming the diagnosis of opioid use disorder, not needing to get labs, checking the PMP, and starting same day is really what we'd recommend. Poly substance use is common. We shouldn't discharge patients, and we shouldn't prevent them from starting treatment in the setting of use of other substances. Counseling is not required, and it hasn't been shown to improve outcomes, generally speaking. And so we offer it, we don't mandate it, about 50% of our patients at REACH engage in behavioral health services, but 50% don't, or they get it from an outside provider. So some, but not all will benefit and it should be on their own terms.

48:10

So when treatment is discontinued, the return to use of full opioids like heroin is very high. You know, some estimates of 90% of people who discontinue will return to use, and that's very risky. So it's just making patients aware of that, talking about tolerance, their tolerance may be less than it was in the past, and talking about services, including harm reduction services and peer supports. Again, this is the notice of intent to SAMHSA.

48:40

And before we get into the case, I'll just briefly summarize some of what we went over today. Sorry, I talked really fast, but there's a lot to cover. Bottom line, buprenorphine, reduces mortality, reduces opioid use and improves quality of life. The number needed to treat with high dose buprenorphine, 16 milligrams to 24 milligrams, to engage one patient and care is 2. So we have an NNT of two for a life saving medication that's associated with mortality reduction of up to 80%. So there's just no better medication we can prescribe than buprenorphine. And, you know, you can now prescribe to up to 30 patients without completing the full waiver training by simply notifying SAMHSA through the NOI that was provided. It should be initiated to any person with opioid use disorder who's interested in treatments, and most people require long term treatment. And it can be done inpatient, outpatient too. Can be done by all of us. So that's great.

49:46

Moving into the rural case, you know, in rural settings where I see patients, there's tremendous stigma, limited care options for most patients, transportation is a huge issue. Cross county transportation through a Medicaid cab can be a limitation, pharmacies often have limited supplies. The criminal legal system may not view MOUD favorably and may not view buprenorphine treatment positively, so it's something to be aware of and consider offering harm reduction services through your office because patients may not have access to harm reduction services in their rural setting. And telemedicine may be a powerful tool to lower these barriers and increase access in rural rural setting.

50:33

So this is a case of a 37 year old man with a history of opioid use disorder, intermittent stimulant use, who was previously engaged in care on 24 milligrams per day, but you hadn't seen him for two years. He was lost to follow up. He calls you, requesting an appointment as soon as

possible saying he was recently released from state prison and he was not receiving treatment. So this is someone at high risk for overdose who was previously engaged in treatment and wants to get back on treatment, but hasn't been on medication and hasn't used opioids in years. So what should you advise them about restarting buprenorphine? So A) restarting buprenorphine after a period of abstinence is not advisable, B) he should try naltrexone before restarting a partial opioid agonist, C) he should restart buprenorphine or D) you should advise him to seek care at a methadone clinic in a city about three hours away. So the answer is C. In this case, because he has a diagnosis of opioid use disorder and he's interested in treatment. That is what he's expressing interested in. Methadone or naltrexone could be options in terms of treating opioid use disorder, but in this case, your patient is asking to restart buprenorphine. So that's what I'd recommend. And it is safe to restart after a period of abstinence, the initiation will involve starting at a lower dose and they may require a lower dose at that point. So what other clinical interventions should you consider offering this patient? So A) co-prescribing Naloxone nasal spray, B) offer HIV and Hepatitis C testing, C) review safer use practices or D) all of the above? 100% voted for D. Okay, great. You guys are amazing. So co-prescribing Naloxone nasal spray or intranasal Narcan, I would recommend in all cases when prescribing buprenorphine, that's the overdose reversal medication. There's a CEI webinar on it, if you're interested in learning more. But basically, we want to get Naloxone into the hands of individuals who use substances who have opioid use disorder. And a lot of times patients will reject this, and I'll just say, you know, 'you can't use it on yourself by and large, this would be to help someone else, save those loved ones around you who may be still struggling with with opioid use disorder.' And people typically, you know, receive it favorably. In terms of HIV, Hepatitis C testing, this is someone who's been in the prison system. So they may have actually undergone testing and even treatment for Hepatitis C or HIV, but I would still recommend it in all patients, particularly people with a history of IV use. And then safer use practices, so this is someone who may be at high risk for using and you want to talk about not using alone, not using behind a locked door, using a test dose because your tolerance may have varied, and having Naloxone available. So you guys know all that which is amazing.

53:38

So continuing the case, you see him in your office, and you're prescribing buprenorphine/Naloxone and Naloxone nasal spray. You receive a call after hours from the patient stating the pharmacy is unable to fill his prescription, he expresses frustration and is irritated due to this delay. So what do you do? A) tell the patient he should call back tomorrow during business hours, B) call the pharmacy to gather more information, or C) discharge a patient from your practice for inappropriate behavior? And I'll just say, I mean, these may seem like kind of silly options and it's quote unquote obvious what to do, but all of these things happen all the time to people and they're major reasons why people are lost to follow up or disengage with care. And again, I would just highlight the need for sort of a trauma informed approach here, which is someone's presenting with frustration, irritability, and you can choose, you can deliberately understand that behavior as a part of what's going on with them with respect to engaging in treatment for their opioid use disorder and not as some sort of bad behavior. We put all these labels on patients and so I just wanted to call attention to just calling the pharmacy, figuring out. So what do you do? You call the pharmacy, you learned the patient's insurance requires name brand Suboxone rather than the generic medication you prescribed, you resend

it. Suboxone dispensed written which is meaning name brand, and the patient's picks up the medication that evening. He calls you back and says he's feeling much better and thank you and you know, he's scheduled for follow up in two weeks after his initial appointment. The day of his appointment, he calls to report his Medicaid cab didn't show up and he can't make the appointments. So what do you do? Do you A) discharge him from the practice for missing his appointment and send him a \$50 no show fee, B) reschedule his appointment and Medicaid cap for another day, or C) switch his appointment to a telemedicine visit? So we have 100% answered C. Great, and this is awesome that it's an opportunity to do that now. It's a silver lining of COVID being the expanded use of telemedicine, particularly with opioid use disorder. So, you know, a little bit of follow up on this particular case, you transition him to telemedicine and complete the visit. Any delay, if you say, 'Oh, we have to reschedule you,' that's going to put them at risk for being lost to follow up. And that's just really is the key to keeping people engaged, it's being flexible and pragmatic and working with them. He's doing well, but he has some cravings. You had started him out on 16 milligrams a day because he hadn't been on any opioids for a period of two years, but he's still having cravings. And so you discuss with him, decide to increase his dose to 24. He decides to do split dosing, he takes 16 in the morning when he wakes up, and eight later in the day. It doesn't cause him to wake up at night, he's not having any side effects. And you ensure you know, he has access to Naloxone and you schedule his next visit as a telemedicine and then he stabilizes at that dose, following up monthly.

57:05

So that's a typical case that we see, you know, there's bumps along the way, but if you can roll with it and try to collaborate and support your patients through it, they can really do well.

57:21

In terms of reimbursement, we are, as far as I know, reimbursed at the same rate, and if so, how long will that be the case? Unknown, big question mark. We're doing a lot of advocacy to try to maintain the use of telemedicine for buprenorphine because we saw a disproportionate increase in access in rural zip codes in particular. So a bigger percentage of our patients, new patients engaging through telemedicine were from rural zip codes, and prior literature supports that it has this disproportionate impact on rural settings as well. It is not automatically prescribed, it should be, and there may be some health systems in which the naloxone is automatically co-prescribed. And by Naloxone, I'm not talking about the co-formulated, I'm talking about Narcan nasal spray, the intranasal spray that comes in four milligrams and that's for overdose reversal. The Naloxone that's co formulated with buprenorphine in suboxone does come automatically. So I'm not sure exactly what the question was there, but to prescribe the nasal spray for overdose reversal, that's a separate prescription, but the co-formulation is part and parcel with the suboxone prescription. We can prescribe more than 24 milligrams a day, up to 32, 32 is the max limit. But in New York state, you have to get a prior authorization to go above 24. And then, in terms of what if persistent withdrawal with maximum dose? You know, that is super challenging. Sometimes you can provide support with other medications. Sometimes patients need to transition to methadone, because there's not a ceiling effect with the methadone and you can keep going up on the dose, and sometimes you can try to do the 32 milligrams a day. So it's challenging. It's not that common, especially after a period of time. So

as people stabilize over two to four weeks, after four weeks that would be when we wouldn't expect persistent withdrawal on the max dose. And if we did, we have to change course. In terms of letting the pharmacy know, this is still playing out because it's so new with the new approach. But I would say putting a note to the pharmacy is a great idea. And so the first step is notifying SAMHSA, waiting up to 45 days. I've always called SAMHSA just to proactively call them, when I applied initially for my waiver and then I went up to 275 slots, call them and then they will mail it to you, like a new DEA with your X waiver. In terms of the notification, I think putting in a note to the pharmacy is a great idea but we can follow up in terms of troubleshooting that if anything comes up. And in terms of refills, yes. So like Tramadol for example, pregabalin, different controlled substances have different schedules based on the DEA, so buprenorphine is one in which you can prescribe with up to five refills, typically. You know, in clinical practice, it's best practice to do no more than two refills and see a person every three months. And so it functions like Tramadol or pregabalin in that way, compared to a benzodiazepine, a stimulant like Dextroamphetamine, or a full opioid agonist like Oxycodone for which you couldn't prescribe with refills. Quickly transitioning from methadone. So I would say the big things are tapering the methadone dose down to at least 40 milligrams a day or less, and then waiting a period of time, at least 48 to 72 hours, before initiating the buprenorphine after the methadone. Those would be what I would say. In terms of it not being necessary to prescribe the naloxone. And just to be clear, this is Naloxone, not naltrexone. It's absolutely best practice to prescribe Naloxone, including to patients on long term chronic opioids, because we know people with opioid use disorder, highest risk for overdose and that opioid use disorder is a chronic condition in which the typical path for most people is ups and downs. So someone may initiate buprenorphine and still occasionally use or have relapses or periods of return to use, and absolutely prescribing it, getting it out to people who are experiencing it, couldn't agree more with that statement that we need to get into the community among peers, people who are likely to witness or need it themselves or others, absolutely 100%. Buprenorphine reduces the risk of overdose. Naloxone can save someone's life in the event of an overdose. So you can take someone who's experiencing an overdose, and without intervention will likely pass away from that, and you can actually save their life with naloxone. It's 100% safe, there's no risk to administering Naloxone if someone's not experiencing an opioid overdose. And if they are, it can be life saving. This is a leading cause of death of people under 50, so this is life saving treatment, it should be co-prescribed. And in fact, in New York State, there's a blanket prescription and people can request it from a pharmacy. It's logistically challenging and there's tremendous stigma, but it's a life saving medication.

1:03:17

All right, thank you very much for taking the time to be here today and answering all these questions.

[End]