Clinical Education Initiative
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BUPRENORPHINE IN NEW YORK STATE: A CLINICAL OVERVIEW

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Buprenorphine in New York State A Clinical Overview
[video transcript]

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Next slide please. Thank you. Now it's my great pleasure to introduce Dr. Ramsey before she begins. Dr. Ramsey is an internal medicine physician who has treated substance use disorders since 2004. She worked as medical director of an academic center based opioid treatment program in the South Bronx before working for a decade for a large FQHC in the Hudson Valley, where she created and grew an MAT program for OUD and AUD to 10 sites and 1500 patients. Dr. Ramsey currently works as the associate chief of Addiction Medicine at New York State OASIS. She has provided expert advice to the New York State Department of Health AIDS Institute, by serving on numerous committees for over a decade, including the co-chair of the HIV quality of care Advisory Committee, and until starting at OASIS in June 2020, Vice Chair of the Substance Use Guidelines Committee for the HIV Clinical Practice Guidelines, and co-chair of the Office of drug user Health's New York State Buprenorphine Advisory Group. Dr. Ramsey was the recipient of the New York State Department of Health commissioners special Recognition Award for contributions to drug user health in New York State in December 2018. She serves as the HCV and Drug User Health champion for the Capital District for Mount Sinai to provide educational support for CEI on HIV, Hep C, PEP, PrEP and Drug User Health through the New York State GUH, Dr. Ramsey is also the president elect to the New York State. AMBOD, Dr. Ramsey, you'll have to fill in for me what that is and serves as chair of their education CME committee, turning it over to you.

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Thanks, Jeff. For the introduction, its New York Society of Addiction Medicine board of directors. That's it, that is me before it, um, so let me go into the learning objectives, and then we'll get right into the talk itself. So number one is to identify how buprenorphine fits into a harm reduction framework to review federal and state requirements for prescribing buprenorphine. And I put a little asterisk down on the bottom that there are no New York state specific requirements around buprenorphine prescribing. So really, I'll be discussing federal requirements, and then discuss perceived challenges and buprenorphine implementation and strategies to overcome them. So first, let's discuss what is harm reduction. So harm reduction, I'm going to read the definition because it's very important. harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use. harm reduction is also a movement for social justice built on a belief in and respect for the rights of people who use drugs. It is based on a strong commitment to public health and human rights. So what are some of the principles of harm reduction, it employs a set of practical strategies by which harm related to illicit drug use is reduced. So what is what are some of the principles involved? It recognizes that drug use is common. It includes a spectrum of strategies from safer use to abstinence, it's low threshold. So in other words, entry requirements are appropriate to the targeted group that you serve. And they need to be adjusted depending on that group. And it ensures that people who use drugs have a real voice in the creation of programs and policies. So this is a reminder that recovery is individualized. Recovery may involve completely not using drugs or abstinence. But recovery really needs to be a partnership with that person in front of

you. So it's a process of change through which individuals improve their health and wellness, live a self directed life and strive to reach their full potential. So four of the most important components of recovery include health, home purpose and community. So health in other words, perhaps someone decides that they're not ready to stop using but they want to treat their Hepatitis C and cure a home. So if our patients are living in unstable housing or unsafe housing or homeless, they're far less likely to be able to even think about recovery. And then I think the most most important things are purpose and community. So people need to feel like their life is meaningful and have a purpose in their life in order to again think about what does recovery mean for them, and then community so many of our patients who come into care have never had healthy relationships in their lives. They may have dysfunctional or co-dependent or abusive relationships and so help them see the importance of healthy relationships and social networks in order to provide them with support friendship, love and hope.

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So harm reduction, as I mentioned lies on the treatment continuum. So some of the goals of harm reduction are to decrease illness, disease and deaths, so decrease blood borne diseases, both acquisition and transmissions, such as HIV and Hepatitis C, to decrease the rate of injection related infections, such as abscesses and endocarditis, and to decrease both fatal and non fatal overdose. And harm reduction services actually do increase engagement in services and care. So it's often the gateway to substance use disorder treatment, for example, with low threshold buprenorphine or more formal treatment, but also to medical, social and mental health services. So this is a depiction of the pathophysiology of substance use disorder. And obviously, I don't have a lot of time to get into this in depth, but just to remind us that this is a disease of the brain that causes both physiological and anatomical changes in the brain itself. So when we think about the cycle of substance use disorder, it involves three primary stages. It's there's the binge intoxication stage, which is when somebody is actually under the effect of a substance and experiencing most typically euphoria associated that with that, which is associated with an increase in dopamine, then the next stage is withdrawal and negative effect. And avoidance of withdrawal is a major driver of people continuing their use, and it's what drives them to a compulsion to use over which they have no control. And then, preoccupation. anticipation is the next stage. And that's the process of thinking about using having cravings. And this leads to the eventual eventual use again, which leads again into the binge intoxication phase. So that's a gross simplification, but it's just to give you a sense. So what are some of the vulnerabilities for developing substance use disorder? So the number one vulnerability is genetic predisposition. So depending on the drug we're talking about, that genetic predisposition can be approximately 40 to 60% of the risk though, it can be even higher for certain substances. So if there's any family history of any substance use disorder, regardless of the substance and including tobacco, that puts you at an increased risk for developing a substance use disorder. So having a concomitant mental health diagnosis is very common. So in the general patient population across the US the overlap between substance use disorder and a mental health diagnosis is about 35%. However, that varies depending on your clinical settings. So in my previous setting, which was an FQHC, the overlap was more typically 80% in most of our clinic sites, most commonly, the mental health. mental health diagnosis that we see with substance use disorder include bipolar disorder, any form of anxiety, whether it's panic disorder, PTSD, or social anxiety, etc. major depression, ADHD, specific personality disorders. antisocial personality

disorder is the most common followed by borderline personality disorder, antisocial conduct disorder diagnosed in adolescence. And again, whether these are diagnosed or undiagnosed or treated or not treated, they still increase your risk for developing a substance use disorder. Um, history of trauma and or abuse is very common in patients. When we're talking specifically about opioids, the rates of pre adolescent sexual trauma, and especially in females is exceedingly high. And often it's not necessarily a victim of trauma or abuse, but a victim of violence or a witness to violence. So, and we'll talk about the ACE score a little bit later, but again, that the ACE score can also help indicate who might be particularly vulnerable. So a person who has a high ACE score, most of my previous patients had poor coping mechanisms. Initially, it may be escapism as as leading to the initiation of substance use. But as I said, once a person meets the diagnosis for substance use disorder, it's a compulsion to use over which they have no control. So impulsivity can play a role in initiation of substance use and is particularly associated with bipolar disorder and borderline personality disorder. sensation, novelty seeking, again may play a role in initiation of substance use, and environmental triggers and sensory cues are, particularly cues to resume use and often lead to resumption of use when someone is trying not to so they become triggers, whether it's an odor or a song or place, etc. So the formal definition is what I was explaining in the previous slide. So a lack of homeostatic reward regulation or reward deficiency. So once a person's brain has been exposed to these dopamine surges that are really unique when associated with drug use, and they do not mimic physiological levels of dopamine which are far lower from natural pleasures such as food and sex, then essentially the brain becomes physiologically and anatomically oriented towards pleasurable awards. And so early substance use essentially prime's the brain and later on development of the prefrontal cortex, which is significant for decision making and weighing consequences of actions. So I mentioned this, so the aces adverse childhood experiences, and that consists of physical, emotional, emotional and sexual abuse, physical and emotional neglect. And then household dysfunction, such as depicted by an incarcerated parent mental illness and apparent domestic violence in the home with a mother treated violently, divorce and substance use among parents. So the impacts of aces are real on health outcomes. And that includes both physical health outcomes as well as mental health conditions and the development of substance use disorder, and actually leads to early death.

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So what are we here to talk about today, we're going to talk about opioids. So this is a picture of the opium poppy. So first thing I just want to talk about is the terms opiate versus opioid, because they're often used interchangeably, and they're often used incorrectly. So I want to just be sure that everyone's on the same page when we're talking about these words. So an opiate is actually referring to the drugs, both the natural drugs and the formulated drugs that come from the opium poppy. So opium is processed from the poppy heroin is processed from that and then the metabolites of either opium or heroin or morphine and codeine. So those would be considered natural opiates. So when we do a urine drug screen looking at opiates, only, that is all that will be picked up and it will miss most of the semi synthetic and all of the synthetic opioids. So opioid is a more general umbrella term that covers both opiates, as well as semi synthetic or synthetic opioids, all of them act similarly in the brain and then cause the same effects. But actually, the structures of the synthetic opioids and to an extent the semi synthetic opioids are quite different than natural OBS so they will not be picked up on a urine drug screen

for opiates. So for example, buprenorphine methadone fentanyl will not be picked up by an opiate drug screen and need to be sought specifically. So the potency of fentanyl and its analogs is sort of the next thing I want to cover briefly. So this depiction is showing equivalent potency amounts of heroin fentanyl and carfentanil which was a analog of fentanyl that came after fentanyl showed up in our drug supply. So as you can see, fentanyl is far more potent than heroin and carfentanil is far more potent than fentanyl. And there are some new or not so new synthetic opioids that are even stronger than fentanyl out there as well, which I don't have time to talk about today. So why is heroin so reinforcing? So heroin is highly highly lipid soluble, which means that it crosses the blood brain barrier within 15 seconds and accounts for the so called heroin rush. So after IV administration, almost 70% of heroin is in the brain within 15 seconds as opposed to less than 5% of morphine. And again, that has to do to its lipophilicity. So within 30 minutes, heroin is metabolized into morphine, so you're never going to find heroin, for example, on any kind of a tox screen because it's metabolized so quickly.

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So what do opioids attach to in the brain? So primarily, when we're talking about reinforcement, we're talking about its attachment to the new opioid receptors, so full agonists activate the immune receptor fully. So this is highly reinforcing. And this is the most misused opioid type. So essentially, it incorporates all opioids that are misused, and it does not include buprenorphine, which we'll spend the bulk of our talk today discussing, so I'll get to that in a minute. So what determines an opioids affects at the receptor, it has to do with the affinity for the receptor, how slowly or quickly it dissociates and its intrinsic activity at the receptors. So is it an antagonist so it does not activate the receptor? Is it a partial agonist, so it partially activates the receptor or is it a full agonist so it fully activates the receptor. So these are depictions of an opioid fitting onto the new opioid receptors. So on the left, opioids fit beautifully onto the new opioid receptor. So if it's a full agonist opioid again, it's going to fully activate that receptor. And then on the right is a depiction of the release of dopamine when the opioid attaches to the receptor, it causes a surge of dopamine to be released in the brain. And dopamine is highly reinforcing. And it's what we associate with pleasure. So this is just to give you an example of similar effects of other pleasurable substances in the brain and their and their effects on dopamine levels. So on the left hand side, you have natural pleasures, such as sex and food and their dopamine surges. Now, unfortunately, this doesn't give you this, the or it's hard to read the scale of the effects on dopamine levels in the picture on the right. But you can see, for example, that the curves are different. So the curves from stimulants such as amphetamines and cocaine are very different from the curves for morphine, nicotine is closer to amphetamine, and cocaine. But again, the scale for amphetamine is much higher. And if we were to look at methamphetamine, specifically, nothing mimics the surgeon dopamine levels like methamphetamine. So now I'm going to talk a little bit about opioid overdose deaths. I'm sure all of you are familiar with the stats. So this is looking at the three waves in opioid overdose deaths. And this picture is is depicting from 1999 to 2018. Showing the three waves the third, the first wave being deaths due to prescribed opioids, the second wave being on deaths due to heroin, and we are now in the third wave. And we've been in that wave since approximately 2013. With deaths being due to other synthetic opioids, which is really specifically referring to fentanyl and fentanyl analogs.

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So this is looking at a breakdown of the same time period 1999 to 2018. And looking at natural and semi synthetic opioids compared to heroin compared to methadone to compared to synthetic opioids. So you can see that we had some deaths due to methadone in sort of the mid early 2000s. And that was due to methadone being prescribed for pain purposes. And then there when there was a tightening around that, you can see that the deaths leveled off and actually decreased. And then as tightening with sort of I-STOP and other PMPs around the United States and a tightening of prescribing of opioids, you can see that deaths due to natural and semi synthetic opioids also decreased and then not led to the rises in heroin use and fentanyl use. So this is just a reminder that, that increase in overdose deaths, generally speaking has not been due just to people using opioids or knowingly using opioids. But we've seen a huge increase and deaths due to psychostimulants, which would include both cocaine and methamphetamine. And that is due primarily to fentanyl being added to that drug supply as well. So again, all patients should be educated on on opioid overdose, regardless of what their actual drug of choice is. So this is provisional 2019, CDC data, looking at US overdose deaths pre COVID-19. So for 2019, and actually, I'm in I'm going to talk about this more specifically in just a moment. But for the first time between 2017 and 2018, we saw a decrease in overdose deaths, but it increased again in 2019. So that was pre COVID. So again, the drug overdose deaths overall. So not just due to opioids, but overall in the US increased from 68,000 to 71,000, from 2018, to 2019. And opioid overdose deaths increased from 47,000 to 50,000, from 2018, to 2019. So this was a reversal of the OD trend from 2017 to 2018. And then specifically in New York State, I'm going to I'm going to have another slide right after this, more specifically breaking this down, but there actually was a decrease overall in deaths in New York State. In both total overdose deaths, as well as opioid overdose deaths. However, there was there were increases in New York City. This, again is from provisional CDC data. So this is not from New York state data, nor is it from New York City data, but rather from federal data. So this is a slide depicting what I just mentioned. So in rest of state, there was actually a decrease in both total overdose deaths and opioid overdose deaths. However, in New York City, both total overdose deaths and opioid overdose deaths increased again between 2018 and 2019. So I'm going to just reiterate that here. So drug overdose, dose deaths in New York state so counties outside of New York City decreased by 10%. From 2018 to 2019, and opioid overdose deaths in New York State, so counties outside New York City decreased by 12%. From 2018 to 2019. However, drug overdose deaths in New York City increased by 4%, from 2018 to 2019. And opioid overdose deaths specifically in New York City increased by 8%, from 2018 to 2019. Statewide 81% of all overdose deaths involved opioids. So we have had some anecdotal reports of increase in overdose deaths in the US during COVID-19. But this is just a reminder that our confirmatory data, which is basically medical examiner report data with confirmed toxicology is how we actually determine on proven overdose deaths. And I'm not saying that that that won't be proven true, but we will probably not have that data for at least six months. So most of this anecdotal reports of increase in overdoses currently is from OD maps, or from

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EMF data or from hospital emergency department visits. So in the AMA actually issued a warning citing reports from officials in 34 states of the increased spread of synthetic drug drugs and rising overdoses and suspected overdoses nationally, not all of them fatal jumped 18% in March compared with last year 29% in April and 42%. In May, according to the OD mapping

application program, as I mentioned that that is a federal initiative that collects data from ambulance teams, hospitals and police. In some jurisdictions such as Milwaukee County, they reported that dispatch calls for overdoses have increased more than 50%. So obviously, due to COVID, traditional supply lines have been disrupted and people may be using drugs from New suppliers or substances such as I alluded to newer, different synthetic opioids that they are not familiar with, which can increase the risk for overdose and death. We are seeing an increase in synthetic synthetic drugs and less common newer synthetic opioids in autopsy and toxicology reports, personal medical examiners, so we're increasingly seeing fentanyl move west. And methamphetamine again is rising in the east. So why are we here to talk about MOUD, which is my preferred term medications for opioid use disorder rather than medication assisted treatment, we're here to talk about it.

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Because

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medication for opioid use disorder reduces overdose deaths both due to heroin. This is an older slide. So it didn't incorporate fentanyl, but due to both heroin and fentanyl, so what we know is that if people are put on methadone or buprenorphine that their risk of overdose death on decreases. So this is looking at the general population without opioid use disorder, versus patients with opioid use disorder on no treatment, and then patients who are on medication for opioid use disorder. So you can see if you put people on buprenorphine or methadone, their risk for death due to overdose decreases almost equivalent of persons without a diagnosis of opioid use disorder, whereas persons who are on no treatment have a much higher risk for failure. So what are some of our goals for medication for opioid use disorder? So the number one goal clearly is to decrease risk for fatal and non fatal overdose and as I've mentioned several times, that is only due to methadone or buprenorphine naltrexone has not been associated with a decreased risk for mortality. It's for the patient. It's to alleviate physical withdrawal symptoms that drive the compulsion to use. Ideally, we're creating what's called a narcotic blockade. So we're saturating the new opioid receptors enough to deal with both physical withdrawal symptoms and alleviate drug cravings. Because drug cravings will lead to resumption of use as best as possible we are we hope that both methadone and buprenorphine will help to normalize those brain changes that I talked about on a physiological and anatomical level. And really, the most important thing for the patient is increasing functionality. So those goals are individualized, depending on what that individual hopes to accomplish. Do they want to just decrease their risk for death but still use? Well, that's definitely a harm reduction approach to using buprenorphine. And our obviously our goal is to have a patient who is alive. And we also want to decrease harm that I mentioned on a previous slide. So the incidence of infectious diseases whether that's HIV, Hepatitis C or Hep B and the incidence of infections such as endocarditis, synapses, so this is a depiction showing those three different types of activity at the receptor that I mentioned previously. So full agonists are the line on the top partial agonist or the line in the middle. And then antagonists are the line at the bottom. So full agonist activate the opioid receptor fully and you can think of it like no hold barred. So, essentially, the more of a full agonist opioid you take, the more euphoria you will experience until you go into an opioid overdose which would need to be reversed by Naloxone. So essentially, there's a higher overdose risk with a full agonist with a

partial agonist opioid such as buprenorphine, there is a ceiling effect. So the the risk for overdose is exceedingly low. And that's really important for both clinicians to understand and for patients to understand. So for example, say a patient newly engaged in care over uses their buprenorphine due to anxiety. They're not putting themselves at risk for an overdose, as they would be, for example, if they took extra doses of methadone. So I think that that's important to understand. The other thing is that as a partial agonist, given that it doesn't fully activate the new opioid receptor, what that means is that the person does not experience euphoria with buprenorphine, if they are already opioid tolerant or they have opioid dependence. So if someone were opioid naive, or not opioid dependent and took buprenorphine, they would sort of get like a light euphoria associated with that. But a person again, coming into you diagnosed with opioid use disorder is not going to experience that euphoria, they're actually just going to feel quote unquote, normal, which they may not have felt for a long time. And that may be a very uncomfortable feeling. So that may kick up a lot of those symptoms, they may have been masking with their use, such as anxiety or depression or trauma in memories, etc. an antagonist in contrast, does not activate the receptor at all. And it actually with with respect to naltrexone, an opioid antagonist used to treat opioid use disorder, it not only blocks, opioids that a person might use while they're taking the naltrexone, but it also blocks endogenous opioids that again, would release dopamine and give us pleasure. So it can be associated with increased dysphoria, which a person is already experienced, because once they stop using opioids, their baseline dopamine level goes down below their baseline at a normal at a normal level.

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So these are more depictions of what it looks like when these medications work in the brain. So on the left hand side, you have methadone as a full agonist fully activating that receptor. And then buprenorphine in the middle is a partial agonist. So again, limited effect on the receptor, and then naltrexone, which is blocking the receptor, so it's not activating it at all. sort of think of it like putting a key into a lock that blocks the lock, but it doesn't actually turn the lock. And then on the right, again, it's showing a depiction of buprenorphine at that receptor.

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what about the effects of buprenorphine on the new opioid receptor availability, so at a dose of say two milligrams, a relatively small number of the receptors are occupied so that that's variable depending on the individual, but it could be anywhere from, you know, about a quarter to less than a half of the receptors are occupied at a dose of 16 milligrams, approximately somewhere between 85 and 92% of the receptors are occupied at a dose of 32 milligrams, which historically was the maximal daily dose on the package insert. So when I started prescribing buprenorphine back in 2004, approximately 94 to 98% of the receptors are occupied. So most patients can be maintained on on 16 milligrams once they're stable. However, anecdotally, often patients need higher doses to address opioid cravings. So particularly fentanyl cravings. What I found clinically is that cravings for fentanyl appear to be much stronger than heroin cravings. And so this really needs to be individualized for the patient in front of you. So while perhaps 16 milligrams might work well, for somebody, maybe

somebody else needs 20 or 24. And that dose is not able to be correlated with the amount that they're using. It really has to be individualized. doses less than 12 milligrams total daily are considered sub therapeutic. So that's something to keep in mind. So buprenorphine affinity for the new opioid receptor is very strong and it will displace full agonists such as heroin or methadone and it's dissociation from the receptor is slow. So therefore The way it works is by blocking other drugs from binding. So as I mentioned, buprenorphine has an exceedingly low overdose risk. high doses should not produce significant CNS side effects, such as nodding off, such as someone who is on a dose of methadone who may be higher than they actually need. And they will not experienced respiratory depression due to the ceiling effect. The risk is purportedly higher with concomitant misuse of other sedatives, such as benzodiazepines and alcohol. But neither alcohol use including active alcohol use an alcohol use disorder nor benzodiazepine use, either prescribed or illicitly is a contrary indication for buprenorphine use, a way of thinking about it is it's obviously much safer for someone to be using or misusing alcohol or and or benzodiazepines with buprenorphine, rather than with a full agonist opioid which would be putting them at higher risk for overdose. So the only deaths associated with buprenorphine were reported from France in the 1990s. It was a handful of patients. And this was when they were prescribing solo buprenorphine, so not co formulated with Naloxone. And people were using this dissolved with high dose alprazolam and injected, that's what led actually to the warning about alcohol and benzos on the initial package insert in the United States. But again, we have never seen that in the United States that was from France only. So this is a depiction of a variety of opioids and showing their relative risk of overdose associated with them. And as you can see, buprenorphine is the lowest relative risk with respect to all deaths and single drug deaths. So really important to keep in mind that it really does have a different safety profile than full agonist opioids. So if we look at efficacy, back in the early 2000s, the original studies are pretty well representative of the same numbers we see today. So over a one year period, approximately a 75% retention rate on buprenorphine treatment, and about 75% of your drug screens negative for other substances compared with a 20% mortality rate in the placebo group. So I can tell you based on data from my previous place of employment, our data was pretty similar. Depending on the clinical site, it was about a 70 to 80% retention rate is also dependent on when, during their engagement in treatment you're looking and the urine drug screen percentage negative for opioids was approximately of that amount as well.

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So I frequently I get asked the question, you know, how long do people need to be on medication for opioid use disorder? So the answer is long enough, and it's different for every patient. But we know that recidivism rates and mortality are higher for shorter courses of treatment or for no treatment. So at a minimum patient should remain on medication for six months to one year. But in reality, medication for opioid use disorder is often much longer and really should be considered a chronic medication because it's a chronic condition. So in a study that came out a couple years ago, the average duration of time on buprenorphine treatment was eight to nine years. And I really encourage you to reframe it as a chronic disease. So when we think about other chronic diseases like hypertension, and diabetes, we don't think about using medication short term or for a couple of years. So chronic diseases often require chronic medication. So think long term medication versus lifetime medication. And really, patients should guide that. So patients should remain on buprenorphine as long as they're deriving

benefit from treatment. So now we're going to look at the federal regulations. So prior to the passage of data 2000 federal law and judicial precedent, and this was based on a con a law passed in 1914. And some Supreme Court cases that follow that prohibited physicians from writing prescriptions for methadone or any other DEA schedule two medications for toxification from or treatment of opioid use disorder, except for in a federally licensed opioid treatment program. So what was formerly called the methadone maintenance treatment program. So this basically would be an OASIS in New York State and Oasis C SAT license detox rehab, intensive outpatient program, or OTP. So if you try to treat opioid use disorder, in the context of your general medical practice with methadone or anything else, it was a felony. So the data 2000 regulation basically was a new law passed. So it's called the Drug Addiction Treatment Act, and it's an amendment To the controlled substance acts. At that time when it was passed, it allowed physicians only to prescribe Narcotic Drugs scheduled 345 for the treatment of either opioid detox or maintenance treatment, but interestingly it it preceded the actual FDA approval of buprenorphine, which didn't happen until a little bit later. So buprenorphine is still the only drug that fits into that category as a schedule three drug obviously methadone didn't as a schedule two drug. So for the first time, this allowed for the treatment of opioid use disorder in physicians offices, in addition to OTPs. It had been prior to that illegal to do so since 1914. So since 2002, a licensed physician again back to the original waiver, could take an eight hour course either online or a hybrid or in person on prescribing buprenorphine and then applied for data waiver. That physician had a patient ceiling of 30 patients for the first year of the waiver, meaning they could only have 30 patients at a time on buprenorphine, and then could apply for an increase to 100 patients in the second year that they have the waiver, and they received a special DEA number which was an addition to their regular DEA number it basically removed the first letter of their DDA and replaced it with it.

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So then, CARA, the comprehensive addiction and recovery act expanded buprenorphine prescribed privileges. This was in 2016 to nurse practitioners and physician's assistants, but it was only for five years until 2021. And they inexplicably were required to take a 24 hour waiver training, and it increased the physician buprenorphine patient cap to 275 if there was a demonstrated need in the community. So in 2018, the regulations were further updated and Congress passed the support act and this and the Senate. So that was the house the senate passed the opioid crisis response act of 2018. And this codifies, buprenorphine prescribing for NPS and PAs would eliminate that sunset date and it codify the 275 buprenorphine cap for physicians and NPs and PAs in certain practice settings. And it expanded buprenorphine prescribing privileges to other advanced practice nurses such as nurse anesthetists and certified nurse nurses. Um, there are some exceptions to the federal regulations, so patients admitted to the hospital may be continued on their outpatient doses of either methadone or buprenorphine. And in the emergency department there is what is called the three day rule. So this means that not more than one day's dose of a medication may be administered or given to a patient at one time. So without a waiver, a provider in the ED may dose a person with buprenorphine, however, not give them a prescription or take out doses, they can do that three days in a row, but that would require would require the person to return to the emergency department three days in a row, and that 72 hour period cannot be renewed or extended. So what happened during federal regulations during COVID-19 so for buprenorphine, all visits were

allowable and continue to be allowable as long as there's a national public health emergency via telemedicine. So, prior to COVID-19, the initial visit for buprenorphine had to be in person and maintenance visits could be via telemedicine, but during COVID-19 all visits are allowable by a telemedicine so also for telemedicine visits regardless of insurance, both the provider and the patient can now be at home so they don't need to be at clinic sites. And it also does not need to be using a HIPAA compliant platform. So again, prior to COVID-19, it had to be a two way audio visual HIPAA compliant platform for the telemedicine platform. However, during COVID-19, it could be done by a variety of social media platforms such as FaceTime, Skype, Whatsapp, Facebook Messenger, Google Hangouts, etc. You could not use public facing platforms such as Facebook Live twitch or Tick Tock for visits. It also allowed telephonic audio only visits for all medication for opioid use disorder appointments. So including initial appointments for buprenorphine, which again, this was revolutionary. And it also allowed an increase in patient waiver capacity that could be requested without meeting the time requirements. So one year for 100 patients two years for 275. And the increase in waiver capacity is valid for six months. And again, we do not know what's going to happen when the public emergency ends. So let's look at some of the problems encountered with buprenorphine treatment. So there there are quite a few issues. One is that 90 almost 90% of patients with substance use disorder actually don't access treatment. So that's a problem in and of itself. And 25% of providers with a buprenorphine waiver, only have ever actually written a prescription for it. So three quarters of providers who get a waiver, don't write prescriptions ever for it. And if those that actually write prescriptions, often they are writing for far fewer patients than their waiver capacity allows. Often there's a glut of buprenorphine providers in a community, one community and then no buprenorphine providers in another county or community. Many buprenorphine providers don't prescribe buprenorphine in a harm reduction context, but rather use an abstinence based recovery model and punitive measures with patients with opioid use disorder. So for example, they discharge them if they have a urine toxicology that is positive.

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And many buprenorphine prescribers have a high threshold for entry. So meaning if you are a poly substance user, then you cannot be in my practice. If you have comorbid mental health conditions, if you're pregnant, you cannot be in my practice. So again, that's very problematic. And then many buprenorphine providers don't accept insurance and only take cash payments, which obviously makes it challenging for patients. So there are many perceived challenges to buprenorphine treatment. And a lot of this has to do with stigma. So many of the phrases that I have here are really just another way of illustrating stigma. So I don't want those patients in my waiting room, the floodgates will open. I don't want to be a social worker and don't we need to provide psychosocial counseling. buprenorphine induction is too challenging. I don't know what to do with poly substance use. I don't know how to order interpret urine drug screens. What about buprenorphine diversion? Are people going to get high on my prescriptions, there are too many insurance and prior authorization issues, I need support, those patients are too needy and too difficult. Those patients will disrupt the clinic and patient flow, I'm not confident in treating opioid use disorder. And I don't feel that I received adequate training. So some of these are stigma. And some of these are valid problems that unfortunately, our educational system for all of our medical providers, whether it's physician assistants, nurse practitioners, and physicians has really still failed to address is really making sure that providers graduating from training feel

comfortable with harm reduction, and with addressing persons with substance use disorder. So just to remind us about stigma, so the image on the left is an unfortunate sign that was in somebody's clinic, I don't know whose clinic but it says stop hurting yourself cook something else for dinner, there's a better way to live. So again, maybe they thought that that was well intentioned, but that's extremely stigmatizing towards persons who inject drugs and persons who use drugs. So healthcare providers have high levels of stigma and bad feelings towards people who use drugs. And in part, they use often derogatory or dehumanizing language all too often. And studies indicate that the language use corresponds with providers providing poor treatment, and stigmatizing attitudes towards certain behaviors and groups are widely accepted, culturally endorsed and enshrined in policy. So this is just a reminder that it's really important that we address stigma whenever we see it in our workplaces, and that we really focus on our language. So again, we should be using person first language. So a person who uses drugs, a person with opioid use disorder, etc, and really not be describing someone as an addict and abuse a substance abuser or an alcoholic, for instance, the terms clean and dirty should just not be used at all, whether it's talking about people or talking about urine drug screens. If we're talking about people then we should be talking about persons not actively using or persons who have resumed use, for example, or if we're talking about a toxicology as positive, negative, expected, unexpected, anticipated, unanticipated, etc, that are really neutral terms. Some of the other terms are a little bit more controversial. As far as drugs, or substances, probably a better term. I often still use the term drug and then lapse relapse slip. Again, often these are controversial. So some morally neutral terms would be resumption of use or recurrence of symptoms, etc. So when we talk about buprenorphine treatment, one of the stated barriers with inductions so I think it's really important to normalize this. So for persons who have not been prescribing buprenorphine, they may think of buprenorphine induction as a barrier because it seems more challenging than it really is when it's depicted in a buprenorphine waiver training. So home induction is really standard of care. And I haven't done an office based induction since 2006. Patients prefer it 90% of patients who walk through your door will have experienced buprenorphine previously. So whether that's that they were receiving it from a prior provider, they got it in detox or rehab or they got it from a friend or family member, or they tried it on the street. So they will know how to take it. Really the only person who maybe needs additional instruction on how to actually use it as a person who has

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precipitated withdrawal prior because they didn't receive any instructions, and they took it when they were not in enough withdrawal. Or a person who truly is buprenorphine, naive wishes I said should be about less than 10% of your patient population. So in this slide, it's showing that outcomes are equal as far as whether someone is induced in the office or in the home. And this is just normalizing poly substance use. So again, best practices is not to discriminate against persons who have poly substance use because most patients are poly substance users. So this was the clinic that I actually did my residency in in the Bronx. This is their data showing that poly substance use is very common among patients initiating buprenorphine treatment. So 42% of the patients also used cocaine 25%, use marijuana 15% use benzos and 23% used alcohol. And then this is showing that actually once people engage in care and they stabilize on buprenorphine, and often, they actually decrease their use of other substances. And that's one because they may not be frequenting either the places or with the people that they engaged

with previously when they were actively using opioids. But also being engaged with a provider is therapeutic. And they they may motivate them to decrease their use in with other substances if that is their goal. This is just to remind us that UDS interpretation isn't straightforward, particularly for opioids and for benzodiazepines. And this was actually a study which looked at internal medicine physicians and their confidence level in interpreting urine drug screen. So here you see that 56% felt confident of their ability to enter interpret a urine drug screen, and yet when they tested them on their knowledge, 73% failed. So this is a reminder that if you did not get any training in this and you do want to do buprenorphine prescribing, you should have a mentor or someone that you can run cases by so that we're not inadvertently making mistakes in our interpretation. The other thing to remember is a urine drug screen for me is just a data point. I never made clinical decisions based on a urine drug screen, it was really more for me to be able to let patients know. For example, often if they were using something that wasn't an op that they didn't think was an opioid like they were using cocaine, often I was the one telling them that there was fentanyl in their urine that they were unaware of. So again, this is just showing you the complex metabolites for opioids and for benzodiazepines. And so again, just to get a mentor. This is just helping us to understand diversion of buprenorphine. So, diversion is common. It happens with many medications, and it actually has happens less with buprenorphine than with other open opioids such as full agonist opioids, and it has doesn't have consequences such as diversion with full agonist opioids would. So this is general population versus patients with opioid use disorder and looking at percentages of sharing meds with others and taking meds from others. And as you can see, the percentages are pretty common between the two groups. So this is very common. So a study came out last year that looked at why people divert buprenorphine and what the uses are of buprenorphine from people who are acquiring it on the street. So it's really important to understand that the primary reasons why buprenorphine is diverted and why people are acquiring it on the street is because they are unaware to have how to access treatment. They've had a bad experience accessing treatment, or they you know, they they just aren't ready to access treatment, whether it's in a low threshold clinic setting or in a substance use disorder treatment program. So the most common reason why people accessed buprenorphine was to avoid or ease withdrawal symptoms, or to maintain abstinence from other drugs. So meaning that they were treating their own opioid use disorder, or because they knew they wouldn't have access to their drug of choice, their opioid of choice. So they use that to bridge between use regardless of this. This decreases their risk for overdose. In a recent study showed that diverted buprenorphine that people acquire on the street actually does decrease overdose deaths. So this shows where people get it from most often. So most often From their dealer, followed by a friend or relative or from a prescription. So again, this is reminding us that dealers are savvy and so they are selling buprenorphine alongside of full agonist opioids. And then when you look at how people use it, they use it very similarly to how they would use it if they were prescribed it. So they use it once a day or more than once a day most commonly. And they use it sublingually, most commonly as they would use it if they were prescribing.

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So this is a reminder of best practices those there was a document that came out from New York State OASIS and the Department of Health, New York State Department of Health looking at best practices for prescribing buprenorphine. So these are really important to understand so

that we should be continuing access to buprenorphine. Even in the absence of counseling, we should ensure continued access if they're unwilling or unable to participate in counseling, they should not be discharged because of inappropriate urine drug screens, including poly substance use, we should strive to minimize diversion. But again, we should not engage our prescriptions based on that and reverse that slide. So what are some models of care for engaging people who use drugs so obviously the most enhanced or open access you can have for patients, including walk in and same day appointments or again, a telephone appointment or a tele med appointment same day so you can get people started, is the best model and partnering with your local county jail or prisons if they're in your area or emergency departments for direct linkage of care, making sure that people are triage to appropriate level of care debunking myths within your practice setting about both medications for opioid use disorder and towards people who use drugs, destigmatizing dual diagnosis and decreasing barriers to care for persons who are dually diagnosed and really having a low threshold harm reduction setting for initiating care. So truly meeting people where they're at not just paying lip service to that. Um, so creating a culture of non stigmatizing care with all clinical staff, including the person who sits at the front desk, or the person who answers the phone for appointments, because you want that person to have a seamless experience from when they make initial contact onwards. I personally believe in encouraging multidisciplinary teams where possible and doing case conference conferencing and mentoring and supportive supervision. So developing relationships with whoever you have in your communities. So whether that's mental health programs, or harm reduction sites, or syringe service programs, your OTPs, or community care management, etc. So what can you do to engage people who use drugs around harm reduction in substance use disorder treatment, so people use drugs to actually interface a lot with the healthcare system. But often, they are not asked about their substance use disorder or they're treated in stigmatizing ways. So then they, they actually don't get the care that they need. So really recognizing someone's substance use and then recognizing their needs that they have, and providing those services will lead to their increased engagement. So for example, if someone comes to you who's actively using and seeking Hep C treatment, treat their Hep C, and if they're treated with respect and empathy and dignity, they're far more likely to return to engage in other services, including if if and when they're ready for treatment with buprenorphine. And just remember that accepting treatment is really individualized. So whatever set of circumstances moves, a person who use drugs to be ready for treatment is not predictable. And so you just need to be there for people wherever they're at. So what are some innovative practices that have occurred during COVID with respect to harm reduction, so a lot of agencies, including OASIS are doing virtual and naloxone and trainings, you can get mail order Naloxone and other harm reduction supplies, sent directly to the homes of people who use drugs at www.nextdistro.org. Not happening in New York State, but around other parts of the country are no touch syringe service programs and syringe vending machines. And then there's the never use alone overdose prevention call line. So if someone is obviously using alone, which in the context of COVID is happening more often due to social distancing, then they can call this number and that person will stay on the line with them while they're using and if at some point, they stop responding to them, then they will call 911. These are some

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OASIS overdose prevention resources that are found on these websites. And this was some social media messaging that we did over the summer. So again, just to kind of sum it up, so Best Practices for engaging people who use drugs. Empathy is number one. Utilizing harm reduction principles, as I outlined prescribing syringes to people who are injecting if they're not able to access syringe service program locally that is a New York State Department of Health endorsed best practice utilization motivational interviewing to meet people at whatever stage of change, they're and make sure that your counseling matches where that person is giving the naloxone kit or prescribing Naloxone, again, to anybody who's using any drugs or at witness or at risk of witnessing an overdose. And then really, truly integrating your services is a key to effecting change, think outside the box and support support your staff. So the benefits of doing this in the office are it removes a lot of the stigma, it can be e-prescribed patients are self medicating, which I think is empowering. And providers are engaged in their patients opioid use disorder and the opioid use disorder is existing in the clinic setting. Regardless, though, providers may not be asking about it, so may not be aware. And it also allows them to engage with other medical issues that I've talked about, like HIV and Hep C. So just to sum up on the last slide, hopefully we just have just a couple minutes for questions. As you can see, opioid use disorder is prevalent, it is a chronic disease, moud is very efficacious and often is needed chronically, it does decrease overdose risk. So again, a harm reduction approach with buprenorphine is a very reasonable approach, as well as chronic long term maintenance. Please remember harm reduction, education and giving naloxone be non judgmental with folks, this is not a moral issue or a character defect, it really is a chronic medical condition. And incorporating moud into general medical practice is really the ideal forum. And it is an absolutely rewarding part. And so if if you haven't done it, I think you'll be amazed at how good you feel at the end of the day. And I see a bunch of things in the chat box. So I'm just going to see if anyone, I think people may have just been introducing themselves, but I'm going to just quickly check for questions.

57:19
Kelly, I'll actually read it off for you. When talking with a patient, what might they mentioned, that would encourage the prescriber to increase the dose from 12 milligrams to 16 or 20 or up to 24?

57:33
Okay, so, um, I mentioned this briefly, but it's a great question. So, um, physiological, opioid withdrawal symptoms will be treated and handled at a lower dose of buprenorphine than cravings will. A patient may be doing just fine on 12 milligrams with respect to physiological withdrawal. But again, cravings require a higher dose. And if you don't treat the craving dose, then that person is much more likely to resume use. And it may be an increase dose for a period of time, it may be due to a specific trigger that happened, maybe it's an anniversary, maybe it's a particularly stressful time in that person's life. Maybe they ran into their former dealer, etc, etc. But we really need to be talking to our patients and asking them about cravings every time we see them. And we need to be asking them about drug dreams. cravings can manifest in a bunch of different ways. And so it's important that we we tackle that question. So I think it may also be the question maybe also looking at provider reluctance to increase doses and again, you want to you're going to be getting the PDF of my presentation, you want to share the slides that showed the new receptor availability and the decreased on the low risk of overdose would be

perfect. I think those are really important, because I think that buprenorphine gets lumped in the same category as full agonist opioids and pharmacologically it is exceedingly different than full agonist opioids. And if people can understand that and understand that it is like a very, very, very, very, very infantile, small risk for overdose, like a person is not going to overdose on their buprenorphine alone. It's really important for them to understand, and maybe that will help get them over some of their concern about prescribing higher doses of buprenorphine.

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Thank you. Here's an important question. Do prescribers have to provide other forms of therapy or are they allowed to solely prescribe buprenorphine?

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So that what what it's suggested in the package insert is that people have access to psychosocial counseling. So what that means is ideally, a buprenorphine prescriber is providing motivational interviewing and supportive counseling in the context of their regular visit with a patient and that is adequate. However, just as a reminder, many patients may have additional That that provider may may or may not be skilled enough to deal with. So the important thing is that when people enter in, often they are not ready for anything else. And so we know when we put a bunch of hoops in place for them to jump through that often discourages them from remaining in treatment with us. So I think it's really important to get the person stabilized on medication. If that person needs additional support. Often the patient will recognize that themselves after they're stabilized. They're not in withdrawal anymore. They're not feeling cravings, as I said, Because buprenorphine does not give them give folks euphoria who have opioid dependence, it is going to unmask things that they have may have been masking, so they may be more anxious and more depressed when they start buprenorphine than they were when they were using because they didn't notice it when they were using a full agonist opioid. So it's important to prep patients for that and just to be aware of that, as the prescriber that you know, you know, when you get stable on buprenorphine, you may experience depression that you haven't felt in a long time, that trauma that you shared with me, memories of that may come back and so we'll deal with that as those things come up for you. Maybe that providers going to add, you know, an antidepressant or maybe that provider is going to add some sort of anxiolytic medication like clonidine or hydroxyzine, etc. Or maybe they'll decide that they really do need an Office of Mental Health, level of care for their, their mental health condition. So all of that can be teased out, but absolutely the psychosocial counseling that that provider just provides in the context of the visit is adequate, the person does not have to do anything else. So I

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want to thank you so much, Dr. Ramsey for this excellent lecture.

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