SCOPE of PAIN: Safer/Effective Opioid Prescribing Education

Podcast - October 1, 2023

Episode 1

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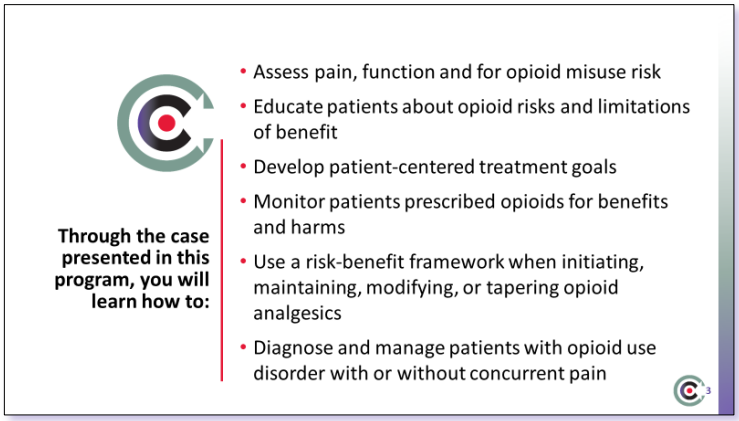
Ilana Hardesty: Thanks for listening to Boston University Chobanian & Avedisian School of Medicine's Safer and Competent Opioid Prescribing Education: SCOPE of Pain Podcast Series. I'm Ilana Hardesty.

This series has eight episodes. If at any point you want more information on receiving credit for this course, please visit our website, scopeofpain.org. There are also resources that accompany this series. All of it can be found at scopeofpain.org.

In the series, we'll follow the case of Michelle Jones to discuss management of acute and chronic pain.

SCOPE of Pain covers strategies for the safer use of opioids for managing acute and chronic pain, by reviewing best practices and sharing clinical pearls. As well, the content aligns with the 2022 CDC *Clinical Practice Guideline for Prescribing Opioids for Pain*, and counts toward the DEA education requirement as part of the new MATE Act. The training does **NOT** cover palliative care or end of life pain management, due to the differences in overall treatment goals.



Through the case presented in this series, we'll be assessing and managing acute and chronic pain and opioid use disorders. We'll focus specifically on more judicious and safer use of opioid analgesics.

Throughout the series, we'll be speaking with **Dr. Daniel Alford**, a primary care physician who is a Professor of Medicine at Boston University and Director of the Clinical Addiction Research and Education Unit at Boston Medical Center, and with **Dr. Erica Bial**, an interventional pain specialist in private practice in Massachusetts. They'll each respond to different aspects of the case at it develops across the series. We'll also have other guests, including a primary care nurse, a community pharmacist, and a patient with severe chronic pain on long-term opioids.

Before we present the case, let's set the stage. What is the current state of pain and pain care in the U.S.?

Dr. Erica Bial: So I think a first place to start is consideration of acute versus chronic pain, because, of course, pain serves a purpose, right? Acute pain is a life sustaining symptom. It's adaptive. It elicits motivation to minimize harm, allow for healing, and to permit for the immediate avoidance of an actual or perceived risk of harm.

In contrast, chronic pain is pain that persists beyond the point in time that it's still adaptive. This can be a disease in and of itself. This is a maladaptive disorder. It's influenced by genetic and epigenetic as well as many other factors.

So when we think about chronic pain, we tend to break it down into three large categories, two of which are usually more familiar. Nociceptive pain is that pain that comes from tissue or potential tissue damage, including somatic pain – so pain emanating from the bones, the joints, the muscles – as well as visceral pain: so situations of mucosal injury, organ distention, or ischemia. In contrast, there's neuropathic pain. So this is where the disease or the injury is affecting the nervous system itself. This can include central pain syndromes, situations of trauma, stroke, neurodegenerative diseases, or could be peripheral in origin. So if there's peripheral nerve compression or trauma or ischemia. There's also a third overarching category, and of course these kind of overlap, of chronic pain, which is nociplastic pain: situations of amplified processing of, or decreased inhibition of, pain stimuli at multiple levels in the nervous system. So some examples of this might include diffuse sensitization like fibromyalgia; functional, visceral pain, like irritable bowel syndrome; or regional somatic sensitization syndromes like complex regional pain syndrome.

So we also want to talk a little bit about the state of pain in the United States, because 21% of U.S. adults, approximately 50 million people, are reported to have reported pain on most days or every day. And up to 60% of emergency department visits are for pain related complaints. So pain costs billions of dollars a year in medical costs, lost wages and lost productivity. You know, taken together, we need to recognize that pain contributes to disparities also by disproportionately impacting females, the elderly, and those with lower socioeconomic backgrounds.

Dr. Daniel Alford: I think it's important at this time to highlight some barriers to treating pain, and I think there are many. Listen, our primary care system is overburdened with lots of competing priorities. We haven't been well trained in managing patients with chronic pain. We lack decision support to help us manage chronic pain. And I think importantly, there's a financial misalignment favoring the use of medications, right? It's a whole lot easier for me to prescribe a medication for someone's pain than it is to refer them to non-pharmacological treatments like cognitive behavioral therapy or acupuncture. There's a lack of access to people like Erica – pain specialists – people who can offer comprehensive pain care. And there are negative attitudes and disparities in pain care. And I think from a patient perspective, there are certainly language barriers and cultural differences in health literacy leading to poor pain treatment outcomes. From a clinician perspective, there is implicit bias that can result in racial and ethnic disparities, and there are lots of system factors that we're all well aware of, including kind of the lack of access to comprehensive pain management.

Ilana Hardesty: Let's introduce Don, a patient with chronic pain who is on long term opioid therapy. Don, what's been your experience with access to care for your chronic pain?

Don (Patient): I can picture being a physician and sort of feeling like, "you keep burning me on pain medication prescription," 'you' being sort of just the generic patient. At some point, generally any patient who comes in and needs pain medication just falls into that category. It's kind of "you again." I think that's in some ways the ultimate stigma because it's being reduced from an individual human being to just sort of an irritating category of patient. Plenty of practices and plenty of practitioners now just won't deal with pain patients at all. And that's just terrifying to me.

Ilana Hardesty: So there's an ongoing opioid crisis. What's the current state of opioid prescribing and opioid overdose deaths in the U.S.?

Dr. Erica Bial: You know, current state is the tough thing to capture because most of the time the data that we have are retrospective. But we do know that there have been some important gradual trends in opioid prescribing for pain. I remember when I was in medical school, we were describing pain as the fifth vital sign, and we were really encouraged to increase our liberalness with the prescribing of opioids. And what we saw is that there was a gradual increase over time in the total prescriptions for pain, and this kind of reached a peak or an inflection point right around 2010-2011, where the total number of prescriptions in millions, mirroring the total number of prescriptions per one hundred U.S. population started to fall precipitously. Now, it's important to recognize that there are racial differences in terms of trends in opioid prescribing for pain. So compared to white patients, Black and Hispanic patients are less likely to receive opioid analgesics for pain. And when they do, it's at a lower dose, even for the exact same pain complaint.

Dr. Daniel Alford: Yeah, it's also interesting to think about the trends in opioid overdose deaths, and you would think, okay, opioid prescribing has gone down; opioid overdose deaths must also be going down. But that's not the case. So let me take a step back. And really there are three main phases of kind of the opioid overdose death trend. While opioid prescribing was going up, prescription opioids were the primary driver of the increases in opioid overdose deaths. But then in around 2011, we started to see an increase in heroin use and then heroin-associated overdose deaths. And now the third phase is really related to illicit fentanyl or fentanyl analogs that are being manufactured overseas and being sent to the country. And this is the primary driver of overdose deaths, and we're seeing an increase in overdose deaths because of that. There are also racial differences around overdose deaths: whites had early periods of acceleration from 1999 to about 2016, and then we started to see a decrease in rate of change starting in 2016. But other populations, like the American Indian/Alaskan Native and non-Hispanic Blacks showed the highest increases in drug overdose deaths between 2019 and 2020.

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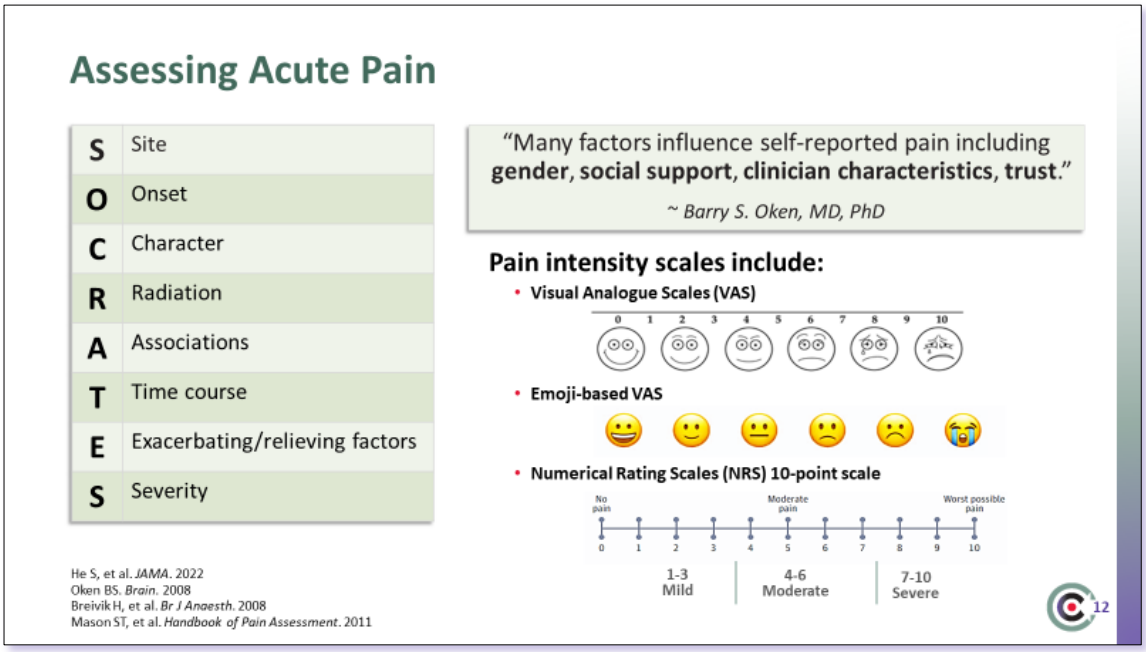
Ilana Hardesty: Now for our case presentation. Meet Michelle Jones. At 36, she was in a car accident, resulting in a right hip fracture. After successful surgery, her pain was managed

with nerve blocks and intravenous hydromorphone. What's the best way to assess a patient's acute pain complaints?

Dr. Erica Bial: It's such a good question. Remember, as we start this conversation, for right now, we're talking about assessing acute pain. So there are a number of ways that we do this. And we should recognize that many factors will influence self-reported pain. These might include gender, social supports, clinician characteristics, and, maybe most



importantly, clinician to patient trust and vice versa. Most commonly, in my practice, and I think in most others, when we're talking about assessing acute pain, a convenient tool are just pain intensity skills, which is why those self-reported pain scales matter so much. So asking a patient on a scale from 0 to 10, if zero is no pain at all and ten is the worst imaginable, how strong is the pain? We might use visual analog scales for this. There are emoji-based scales for this. We've all seen the numerical rating scales. It's also important that when we assess acute pain that we don't just ask questions about its intensity, which all of those scales are really asking, but that we also understand its characteristics. So there's a convenient mnemonic that we often use for this, which is SOCRATES. You don't have to remember, but it's important to remember where we're going with this. Which is

- the **site**: Where does it hurt?
- Its **onset**: When did it happen?
- Its **character**: What does this feel like? Which is often a really tough question for patients
- Does it **radiate**? To where?
- What other symptoms is it **associated** with? So if it comes with nausea, if it comes with headache, that's a very different pain pattern.
- What's its **time** course? How does it behave over the course of the day or since its onset?
- What makes it better? What makes it worse? So that E is for **exacerbating** or relieving factors.

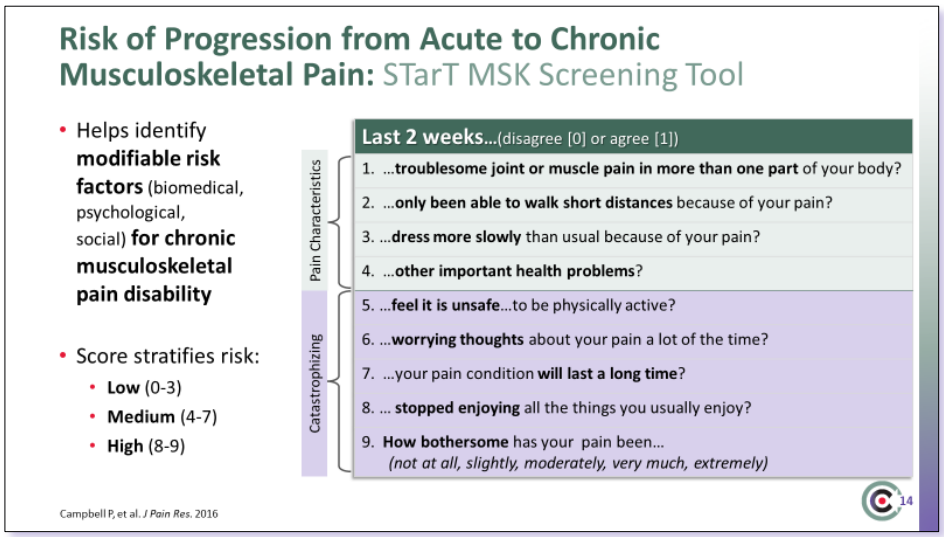
- And then the last one would be the **severity**: what we're really asking about with those pain scales.

Ilana Hardesty: What do we know about why some acute pain persists and becomes chronic? Could it be predicted in a patient like Michelle?

Dr. Erica Bial: There are some recognized risk factors for developing chronic pain. I think a really convenient example is the conversion risk factors from acute to chronic post-surgical pain. So we know there are a number of reasons that people might. Convert from acute to chronic pain. There may be alterations in expression of neurotransmitters, receptors, and ion channels. We should recognize that there may be alterations in the structure, connectivity, or survival of neurons themselves. And then we want to recognize which factors might influence those things that we could be aware of and thus maybe control.

There are patient related factors. So this may be a surprise to a lot of people: that patients at greater risk are younger patients, female patients. These are probably less of a surprise: patients with a history of anxiety, depression, catastrophizing (the belief that the pain will become terrible), preexisting pain syndromes and preoperative opioid use. These all increase the risk of that conversion from acute to chronic in the post-surgical environment. There are also, of course, intraoperative variables, so things that might change some of those relationships in the structure, connectivity, and survival of neurons. So what was the surgical procedure and the technique itself? Was there potentially nerve ligation or injury? Was there tissue ischemia? And also the anesthetic modality all might make a difference. Also thinking about the post-operative pain experience. So if the patient has uncontrolled high intensity pain or a longer duration of post-operative pain, we should be more aware that these things might represent a risk of progression from acute to chronic pain in the post-surgical setting.

Dr. Daniel Alford: So in primary care, it's not unusual for us to encounter patients who present with an acute musculoskeletal pain issue. And one question I have would be, you know, can we predict which of those patients will go on to develop chronic pain? And there is a tool called the STarT MSK Screening Tool, which does help identify modifiable risk factors that can predict which patients will go on to develop chronic pain. And it stratifies people into low, medium and high risk. And there are nine questions, and the first four are really dealing with pain characteristics in terms of how severe is the pain? Does it



involve multiple parts of the body? Is it adversely affecting the patient's ability to function? And interestingly, the last five are really all about catastrophizing. Does the patient tend to catastrophize when describing their pain, such as they feel it's unsafe to be physically active; they have worrying thoughts; they feel that the pain is going to last a long time, and they really have just stopped enjoying things that they usually enjoy. And then finally, the ninth question is really about how bothersome has your pain been? So I think this is a useful tool to predict which of your patients who present with acute pain might go on to develop chronic pain in a primary care setting.

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Ilana Hardesty: After her surgery, Michelle was discharged with home based physical therapy and orthopedic follow up. She received prescriptions for ibuprofen: 600 milligrams every 8 hours; and oxycodone: five milligrams 1 to 2 tablets every 4 to 6 hours as needed for pain. Her oxycodone prescription was for 40 tablets.

Is there a correct amount of opioids to prescribe after surgery or for any acute severe pain?

Dr. Daniel Alford: So that's a really hard question to answer. And I think the answer to that is evolving over time. What we do know is based on studies that were done back in the early 2000s that we were overprescribing in the acute pain setting. There are multiple studies that showed postoperatively over 70% of patients took half or less of the opioids that were prescribed to them during the acute pain setting. Even in like emergency department visits, 93% of patients had leftover pills. So there was this overprescribing, over- reliance, and sending people home with lots of pills. What's worrisome about that? Well, it turns out that individuals who misuse prescription opioids, about half of them, are getting them from family or friends. So these extra pills end up in non-patients or people who are in the community. We also know that about 3 to 5% of opioid-naive patients who receive an opioid for acute pain become long term users (that's more than three months). And there are some specific risk factors for identifying individuals who are at risk for becoming kind of a chronic opioid user, like being male, being over 50, having a history of mental illness, also having a history of substance use disorder. The good news is that since 2012 we've been prescribing less pills in the post-operative setting. In fact, there's been a decrease in opioid prescriptions for more than a seven-day supply, which is a good thing.

So in terms of answering your question, how should we be treating this patient for their acute pain and how much opioid should we be prescribing? When we look at things like dental pain after a molar extraction, it turns out – and this may be surprising to many – that non-steroidal anti-inflammatory drugs (NSAIDs) plus acetaminophen are more effective compared to oxycodone alone or oxycodone in combination with acetaminophen. So I think because there is that inflammatory response to the insult, that is the extraction, NSAIDs can be really helpful. There was also a study, a more recent study, looking at acute musculoskeletal pain in the emergency department, and they found that there was no significant difference in pain reduction among single dose treatments with nonsteroidal anti-inflammatory drugs, with acetaminophen, or three different opioid-acetaminophen combination. So again, we should talk to our patients about how effective NSAID plus acetaminophen is and that opioids aren't always needed. And this is consistent with the CDC

guideline that came out in 2022 that talks about: with acute pain, we should be maximizing nonpharmacologic treatment and non-opioids and only consider opioids if the benefits are likely to outweigh the risks. We also discussed realistic benefits and known risks with our patients. And finally, we really should not be prescribing a greater quantity of opioids, if we prescribe them than needed, or based on what you expect of the duration of that severe pain to last.

Ilana Hardesty: So ketamine is being used in emergency rooms for acute pain. What's the story with ketamine?

Dr. Erica Bial: Yeah, I think we're all hearing a lot about ketamine for acute pain these days as well as for a number of other indications. You know, ketamine was developed in the 1960s as a dissociative anesthetic. It's actually a medication that's derived from PCP, from phencyclidine. It's very useful in sub anesthetic doses for the treatment of perioperative pain. We do use it for neuropathic and nociplastic pain. And as I mentioned, it also does have some other more novel uses, such as depression and substance use disorders. What's unique about it in many respects is that it's analgesic as well as quite dissociative without respiratory depression. We are seeing increased use – IV, IM, off- label intranasal use – as an analgesic in the emergency department as well as in perioperative settings. We also do use it IV at times in outpatient chronic pain settings. It's believed that perhaps ketamine can be very useful because it is opioid-sparing; it decreases opioid requirements. But there are some challenges to its use. So it has low oral bioavailability, very low, and it has very limited evidence for use in chronic pain. Also, there are some pretty miserable dose-dependent adverse effects. So some of these some people don't find as miserable as others, including hallucinations, but also agitation, anxiety, dysphoria, in some cases euphoria. It can also cause nystagmus, tremendous nausea, and can be bladder-toxic. It does have misuse potential due to the psychoactive effects, but it can be really useful in the short term as a dissociative without needing to give patients opioids at all.

[Music]

Ilana Hardesty: Thank you, Dr. Bial and Dr. Alford. And thanks also to our patient, Don. Michelle's post-operative course was uneventful. She ended up with 15 unused oxycodone tablets, which she eventually threw away. She then moved out of state to care for her uncle.

We'll meet Michelle again in episode two when she returns 18 years after her accident. She now has chronic pain from arthritis in her hip and severe, painful diabetic neuropathy. She has been treated with chronic opioid therapy for the past five years. She'll be visiting a new doctor and will rate her pain off the scale: a 20 out of ten. And she'll be asking for an opioid refill on this first visit.

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Production by Rococo Punch.

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I'm Ilana Hardesty. Thanks for listening.

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Episode 2

[Music]

Ilana Hardesty: Thanks for listening to Boston University Chobanian & Avedisian School of Medicine's Safer and Competent Opioid Prescribing Education: SCOPE of Pain Podcast Series. I'm Ilana Hardesty.

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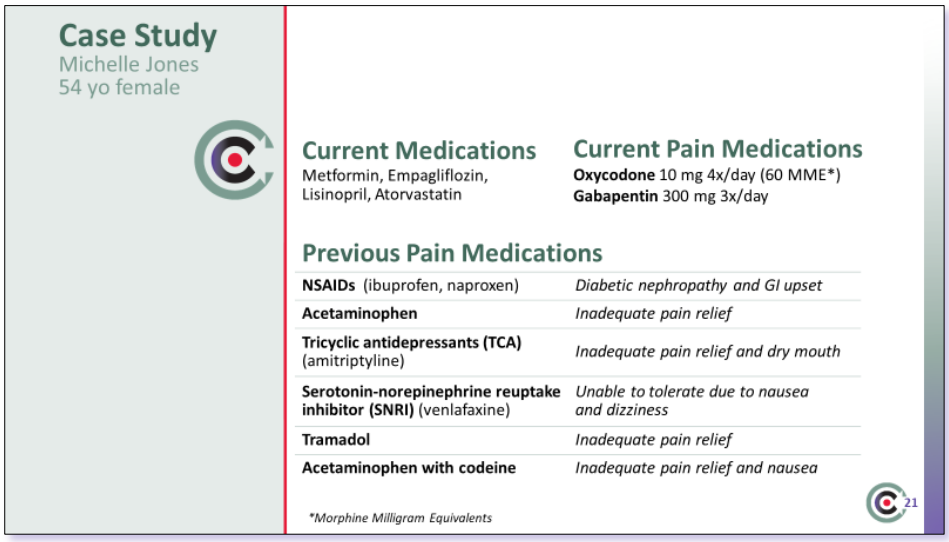
In this episode, we'll continue our conversation with Dr. Daniel Alford and Dr. Erica Bial about Michelle Jones, the case study patient we met in Episode One. We'll hear again from Don, a real patient with chronic severe pain on long term opioid therapy. And we'll talk to Kristin Wason, a primary care nurse at Boston Medical Center and assistant professor of medicine at Boston University.



It's now eight years later and Michelle presents for an initial appointment with a new primary care provider. She has foot and hip pain and is asking for a new prescription for her opioid pain medications today. Her past medical history includes type two diabetes with painful diabetic neuropathy and chronic right hip pain due to arthritis from her car accident 18 years ago. She has hypertension, chronic kidney disease and high cholesterol, and is obese. Michelle is currently on metformin, empagliflozin, lisinopril and atorvastatin. She is also taking gabapentin and short acting oxycodone: ten milligrams four times a day, which is 60 morphine milligram equivalents or MMEs. She had previously tried NSAIDs, acetaminophen, TCAs, SNRIs, tramadol and acetaminophen with codeine. None of these offered adequate pain relief and many caused intolerable side effects.

Michelle has a part time job as a paralegal. She's married with no children. She doesn't smoke and only drinks wine occasionally. She does not use drugs, including cannabis. Her father is being treated for lung cancer. Her mother died from complications of alcohol-associated cirrhosis. She's been rationing her oxycodone prior to this visit to avoid running out. She took her last pill this morning. She gets the best pain relief when she takes her ten-milligram tablet four times per day. Her current pain is more severe because she's been spacing out her pills. She gives this new PCP her old medical records. Michelle reports mild to moderate right hip pain that's exacerbated by activity and relieved with rest. She has severe bilateral foot pain with burning numbness and tingling, which is worse at night. On a ten-point scale, Michelle rates her pain as a 20.

What does it mean when a patient reports their pain off the scale?

Dr. Daniel Alford: Yeah. So when I hear that, I think of mistrust. Patients may assume that you don't believe the severity of their pain complaint, and it's demonstrated exactly like what happened with this patient; that is, an exaggeration of the pain score that is over the scale. They may also exaggerate their functional limitations. You may ask, “What are you able to do on this treatment?” And they say, “I can't do anything. My pain is so bad”. And so I guess the follow up question is: so how do you build trust? What do you do about it? And I would say after you've done a complete and thorough pain history and you've done your focused exam and any appropriate diagnostic testing, I think one, you need to show empathy for the patient's experience. You could say something like, “It must be difficult to enjoy life with such severe pain.” And then to I would say we should validate that you believe their pain and suffering is real by saying something like, “I believe you and I want to help.” So I think those two things are critical. That is, be empathic and validate that you believe the patient's pain and suffering is real. I would say validating every single patient there is 0% risk. Why? Because just because you believe the severity of the patient's pain complaint does not mean that opioids are indicated. That is what we need to decide based on using a risk benefit profile, which we're going to be talking a lot more about.

Ilana Hardesty: Let's talk to our patient, Don. Don, what's been your experience in interacting with health care providers while you've been on opioids for chronic pain? Have you experienced that mistrust either on your part or the part of the clinicians? And what's that mistrust based on?

Don (Patient): You are sort of walking through this sort of gauntlet of suspicion, and that's not a comfortable thing. It has kind of corrupted the relationship between patient and physician. It's a weird kind of: if you don't make a big deal out of it, then what's the big deal? He's fine. He doesn't really need it. If you do make a big deal out of it, well, that's drug-seeking behavior, that's very suspicious. And sort of the more you push, the greater the resistance. The most frustrating thing is this kind of not being able to really explain. It's like the more you explain, the more trouble you're in, the worse you look. It sounds like you're trying to justify yourself. It sounds like you're nervous. It sounds like you feel guilty, which a lot of people do around this.

Ilana Hardesty: Dr. Alford, you mentioned believing a patient's pain complaints, but you still need to be able to assess that patient's chronic pain, right? How do you do that accurately to find the best treatment approach?

Dr. Daniel Alford: Yeah, it is complicated. And I know you heard my colleague Erica talk about uni-dimensional scales for acute pain, but I think we'd all agree, those are inadequate for chronic pain assessment. And I think we really want something that's more multidimensional. And there are absolutely validated questionnaires and surveys out there, including the McGill Pain Questionnaire, the Graded Chronic Pain Scale, and the Brief Pain Inventory. And if you can use these in your clinical practice, that's great. But in my primary care practice, they're too long, they're impractical. The good news is there is a brief, multidimensional scale called the Peg Scale – P-E-G, which stands for **Pain**, **Enjoyment,** and **General** Activity. And this has been validated in primary care settings. What are the questions it asks? Number one, what number best describes your pain on average in the past week, 0 to 10. Two, what number best describes how during the past week pain has interfered with your enjoyment of life? Three, how about interfering with your general activity? Doesn't interfere is zero; completely interferes with a ten. So we're asking about pain; we're asking about quality of life, which is enjoyment of life; and we're asking about function or general activity.

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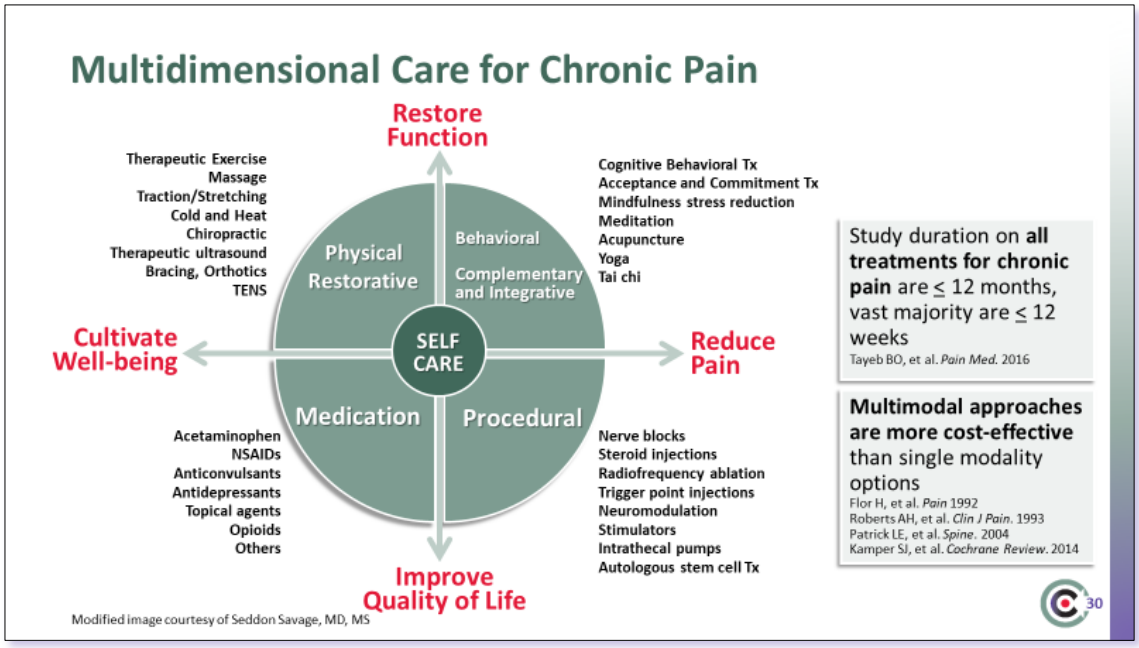
Ilana Hardesty: When asked the PEG questions, Michelle reported that over the past week her pain on average was a ten, and her pain's interference with enjoyment of life and general activity were both nine. Michelle's physical shows no acute distress and normal vitals, with a BMI of 32. She has normal cardiopulmonary function and a normal musculoskeletal exam, except for her right hip, which has decreased range of motion and pain on internal rotation. Her neurologic exam is consistent with her diabetic neuropathy.

Okay, now that you've assessed Michelle's chronic pain, what are the next steps? How do you come up with a treatment plan?

Dr. Erica Bial: It's a great question and it's a really challenging one. So now that Dan has talked about multidimensional assessment of chronic pain, we should also recognize that,



similar to assessment of chronic pain, we need a multidimensional care plan when we're dealing with chronic pain. There's a broad range of goals that we might want to cultivate. So well-being for the patient, functional restoration, pain reduction, improvements in quality of life all have an impact globally on the patient's pain experience and foster better level of function. So, physical restorative approaches are certainly one broad category: things like exercise, massage, traction, heat and cold, ultrasound or orthotics, a TENS unit. Particularly, these are modalities that are useful when there is a musculoskeletal origin of the pain.

We could think about procedural approaches for pain, things that I do for a living. So things like nerve block, steroid injections, radiofrequency ablation, spinal cord stimulation and neuromodulation, as well as a number of newer technologies like autologous stem cell transfers.

Of course, medications are a part of this overall treatment puzzle: things like acetaminophen and the NSAIDs, anticonvulsants, antidepressants – we shouldn't forget about when they're appropriate and kind of fit the pain picture. Use of topical agents like Lidocaine, as well as opioids.

And finally, things like cognitive behavioral therapies, acceptance and commitment therapies, mindfulness, and meditation. A lot of patients imagine that these things don't have an important role, but studies show they're actually as effective as the stuff that I do for a living when we look globally at patient function.

It's important to remember that study duration on all treatments for chronic pain are less than 12 months and the vast majority are less than 12 weeks, barely even meeting the criteria for chronic. It's also often surprising to people that multimodal approaches are more

cost-effective than single modality options, even though all of these things sound like an awful lot of work.

Dr. Daniel Alford: So, Erica, hearing you talk about some of the behavioral approaches, I'm reminded of a patient experience that really has changed my practice. And that patient experience was I sent one of my patients to a psychologist, someone who specialized in cognitive behavioral therapy, and he came back to me and he was furious. And I said, "What's wrong?" He said, "That doctor didn't even examine me." And I said, "Oh, my goodness, if the psychologist examined you, you probably could have sued him!" So it really taught me a lesson: that is, to send patients in a way that they understand why I'm sending them there and what to expect. I think oftentimes patients who are on opioids sometimes feel like they just need to do these things in order to continue getting the prescription that they want, as opposed to understanding that these modalities have evidence supporting them and they can help them get better. So I think that's important.

So, Kristin, I mean, as a nurse, I'm sure you had these conversations all the time with patients. What's been your experience and do you have any lessons learned about how to have those conversations?

Kristin Wason: Yeah, Yeah. And I'll say as a nurse, I definitely have had a lot of those conversations and typically they actually go really well, especially because as a nurse, you're a non-prescriber, but there's a lot you can do to teach people about their health condition and about ways to improve their quality of life and functioning. And so pain plays right into that. Generally, when I'm talking to patients about their pain, what we'll do is kind of start by talking about, "What do you know about your diagnosis?" Like, what do you know about your osteoarthritis or what do you know about this other pain syndrome that you have? And then we'll discuss ways in which that is affecting their quality of life and really try to get down to like the underlying cause of the pain than trying to treat that underlying cause. And a lot of times patients might say things like, "Oh yeah, someone mentioned physical therapy to me once; I did it and I didn't really like it and I never went back." And I'll ask if you do the exercises at home, and they're like, "Yeah, I do them sometimes." And so really, like you can tell they're not getting the full benefit of that. So talking about like, let's revisit the physical therapy, you know, let's strengthen the muscles to improve sort of your joint health and functioning and making sure you're not falling or in as much pain and trying to get them to go to even just like a couple physical therapy sessions. It's like a big win on our part.

Dr. Daniel Alford: So, Erica, you're pain specialist; I'm in primary care. I'm going to ask you a question that I already know the answer to, and that is, should I be sending you all my patients with chronic pain?

Dr. Erica Bial: No. As much as I would be flattered to receive that number of your excellent referrals, that, of course, would be overwhelming. And so it's important to recognize when you really do need help from a pain specialist. Just the same way that you don't need a cardiologist for every patient with a heart, you want to refer to a pain specialist any time that you need more help. So if you're unsure of the pain diagnosis, if you're unsure of what else we might be able to offer, or if you just need a fresh pair of eyes or you want a second opinion for an individual patient. But I do think it's critically important to know what services

that your pain specialist offers. And kind of much to your point before about having a patient come back to you in the primary care setting and feel very frustrated that the psychologist didn't even examine them; as the receiving specialist, I can also say that setting patient expectations is extraordinarily helpful because sometimes the patient thinks that I'm just a stumbling block to their continuing their opioid and they don't realize that I'm going to take a comprehensive look. Similarly, knowing what the question is from a clinician-to-clinician communication perspective is really, really helpful. So if I know how I can help and what the specific questions are in the quality of the referral, that's helpful. I do think it's extremely important also that you know what services the pain specialist offers. So if you send me a patient for an approach or modality that I don't do, it's frustrating for the patient, it's frustrating for me, and I'm sure it's frustrating for you too, as the referring provider. Other times that I think is important to address is when there isn't a pain specialist available. Don't forget that you might be able to get a second opinion from one of your colleagues. I do this in my office too, where I just need a fresh pair of eyes. It's also finally important to remain up to date with local or state requirements. There are some situations that might require, if available, a pain specialist referral.

Ilana Hardesty: You talked about multimodal care earlier and touched on the broad range of both nonpharmacologic and pharmacologic treatments. Let's drill down on the latter and start with non-opioids.

Dr. Erica Bial: This is a really important place to start because very often patients imagine when we talk about pain medicine that opioids are the first or only option. They think that that's a euphemism for opioids when in fact they're not even first-line. So let's talk first about the nonsteroidal anti-inflammatory medications. So of course, we had the nonselective and the selective agents. And particularly important to remember, we have the COX-2 selective agent celecoxib, which can be useful in patients who have GI sensitivity to the NSAIDs. The nice thing about the NSAIDs is that in addition to being analgesic and antipyretic, they are in and of themselves anti-inflammatory. So when you think in your formulation about the origin of the patient's pain, and it has an inflammatory component. It's logical to reach for these.

Sometimes we also reach for acetaminophen useful because it's analgesic and it's antipyretic, but no doubt, less effective than the full dose NSAIDs in relieving chronic pain that has an inflammatory component, but they have fewer adverse side effects in most patients.

So there are some general considerations here. Ceiling effect is a big deal because I definitely see in my practice patients who are taking either very large doses or too-frequent doses of the NSAIDs or of acetaminophen without realizing their toxicity. And at that point in our risk-to-benefit model, there's more risk than there is any benefit because of that ceiling analgesic effect. But there's no known analgesic tolerance and they can be synergistic. There's an additive role for NSAID plus acetaminophen. Some patients might respond better to one NSAID than the other, and we need to think about side effects, including the GI effects, renal effects, cardiovascular risks, especially in high dose NSAIDs.

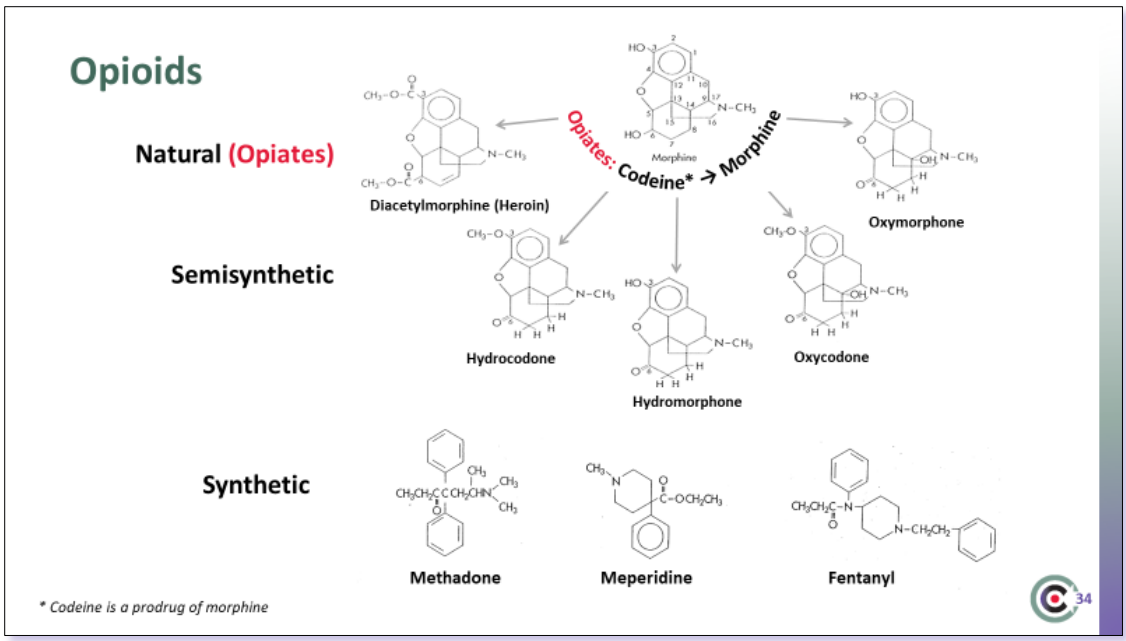
Also, I think it's helpful to not forget about the option, especially when patients have musculoskeletal complaints, of topical diclofenac, avoiding many of the systemic potential absorption and effects.

Also in the non-opioid pharmacotherapy category would be the analgesics with the primary indication other than pain. And these can be surprising to people that they are in fact analgesic. These are really the mainstays of treatment for neuropathic pain syndromes. So things like the antidepressants, namely the tricyclic antidepressants and the SNRIs. I do think it's worthy of just a quick mention: the SSRI don't really seem to have that same analgesic property. The anticonvulsants, typically the gabapentinoids and carbamazepine, the anti-spasmodics and the muscle relaxants. I think they have pretty limited utility, but certainly there is some. And don't forget about the local anesthetics; so things like topical lidocaine.

Just a quick caution though. There is misuse and addiction potential that's been identified with a number of these agents, particularly the gabapentinoids – so gabapentin; pregabalin – and some of the muscle relaxants, particularly carisoprodol. And this is because it metabolizes into a barbiturate-like drug.

So now that we've been talking about the non-opioids, Dan, do you want to talk a little bit more about the opioids?

Dr. Daniel Alford: I'd be happy to. And there are lots of opioids to talk about and I think of them in the following way. I start with the naturally-occurring opiates, which include codeine and morphine, which come from opium, which comes from the poppy plant. You can then take these opiates and alter them in the lab and create semi-synthetic opioids, that include something like diacetyl morphine which is heroin, or hydrocodone, or hydromorphone, and oxycodone. It's important to realize that they came from morphine



and codeine, because they can metabolize back to morphine and codeine or an opiate, and turn your urine positive for an opiate.

But that's different than the synthetic opioids like methadone, meperidine, and fentanyl. They never came from morphine or codeine or an opiate, and they will never turn your urine positive for an opiate. And you can test for all of these molecules separately in your urine drug testing.

So what do opioids do in terms of treating pain? They do a lot of important things, such as: they turn on the descending inhibitory pathway in the Periaqueductal Gray, which is a norepinephrine-serotonin system; it can be incredibly powerful. They also prevent the ascending transmission of the pain signal. They can inhibit the terminals of the C-fibers or pain fibers in the dorsal horn of the spinal cord. And they can also inhibit the activation of the pain receptors or peripheral nociceptors. We also know, and I think we've probably all have this experience, that there is variability and how one patient responds versus another and that not all patients respond to the same opioid in the same way. And the question is, why not? Well, we now know that there are thousands of polymorphisms in the human mu opioid receptor gene. So all of us probably have a different mu opioiod receptor system, and we may respond better to one opioid than another. And two, there are single nucleotide polymorphisms or SNIPs that can affect how opioids are metabolized, how they're transported across the blood brain barrier, and their activity at receptors and ion channels.

And then finally, opioids can activate the reward pathway, which is in the midbrain, which is a dopaminergic system, which is highly rewarding and reinforcing. And this is likely the cause of a lot of opioid misuse; that is, people trying to seek that reward. So we need to be aware of that as well.

Now, talking about opioids, there are two other things we should talk about right now, and that is tolerance and physical dependence. Both tolerance and physical dependence are physiologic adaptations to being chronically exposed to opioids. Tolerance means you need an increased dose over time to achieve a specific effect. Well, tolerance develops readily for sedation and respiratory depression. That's good. Less so for constipation. And in terms of developing tolerance to the analgesic properties of opioids, it's a little unclear. It seems that some patients may and some may not.

Now, physical dependence, that's signs and symptoms of withdrawal when you abruptly stop the opioid or you decrease the dose too fast, or you give the patient – or the patient's exposed to – an opioid antagonist like naloxone or naltrexone.

[Music]

Ilana Hardesty: Thank you, Dr. Alford and Dr. Bial. And thanks to Kristin Wason and our patient, Don.

We've learned about treatment options for chronic pain and discussed different options including non-pharmacotherapy, non-opioid pharmacotherapy, and opioids. But do opioids

really work for chronic pain? Is there any evidence that opioids are effective for chronic pain? Join us for episode three.

SCOPE of Pain was developed in collaboration with the Federation of State Medical Boards, and is supported by an independent educational grant from the Opioid Analgesic Risk Evaluation and Mitigation Strategy, or REMS, Program Companies.

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I'm Ilana Hardesty. Thanks for listening.

SCOPE of PAIN: Safer/Effective Opioid Prescribing Education

Podcast - October 1, 2023

Episode 3

[Music]

Ilana Hardesty: Thanks for listening to Boston University Chobanian & Avedisian School of Medicine's Safer and Competent Opioid Prescribing Education: *SCOPE of Pain* Podcast Series. I'm Ilana Hardesty.

This series has eight episodes. If at any point you want more information on receiving credit, please visit our website, scopeofpain.org. There are also resources that accompany this series. All of it can be found at scopeofpain.org.

In this episode, we'll speak again with Dr. Daniel Alford and Dr. Erica Bial, along with Kristin Wason, a primary care nurse. And we'll bring in Patrick Kelly, a senior lecturer in the Department of Pharmacy practice at the University of Rhode Island with a primary focus on the integrated pharmacy practice laboratories.

In the last episode, we reviewed the wide range of available therapies to manage chronic pain: treatments that include non-medications, non-opioids and opioids.

Let's start with the elephant in the room. Our case study patient Michelle is taking chronic opioids, 60 morphine milligram equivalents, for her chronic musculoskeletal and neuropathic pain. But do opioids really work for chronic pain?

Dr. Daniel Alford: Well, there have been some meta analyses that have shown that opioids versus placebo, looking just at high quality studies, that opioids actually have a statistically significant, however small, improvement in pain and physical functioning. What about opioids versus non-opioids? Well, those are really low to moderate quality studies that show there's similar benefits between the two. What's really key to understand here is that these studies, the follow up ends at six months. Most of them are around three months. So what happens after six months in terms of efficacy? We don't know. It hasn't been studied. There was a randomized controlled trial (RCT) that looked over 12 months, looking at musculoskeletal pain-related function, comparing opioids versus non-opioids and found that they were similar. Okay. Whenever you look at an RCT, you should think about does this study generalize to the patient sitting across from me? And there are some limitations to generalizability. When you look at the methods, they excluded any individual who was already on long term opioids. So our patient here, Michelle, would not have qualified for this study. And of those that were eligible, 89% said, No, thank you. I don't want to be enrolled in this study. So of the 11% who were not already on long term opioids who were eligible, there's no difference between opioids and non-opioids. So again, think about the generalizability.

There were two longer term follow up studies that were observational studies with an outcome of at least 50% pain relief, and they found that 44.3% of individuals on chronic opioids had at least 50% pain relief. So it's not 0%, it's not 100%. So that's what we know about efficacy. Erica, what do we know about safety and risks?

Dr. Erica Bial: You know, there are two sides to every coin and they do carry safety challenges and important risks. I think the first risk you always want to think about with any substance that you're going to expose a patient to is allergy. True opioid allergies are quite rare. But there are other important risks that we don't think about much, things like immunosuppression. So in fact, in animal models, opioid-induced immunosuppression does exist. And we do know that humans who are on chronic opioids, especially at high doses, do seem to have an increased risk of pneumococcal disease, as well as community-acquired pneumonias. There are direct and indirect organ toxicities related to opioid exposures, especially endocrinopathies, so adrenal suppression as well as gonadal suppression, can in fact be problems. And particularly at high doses, so greater than 50 MMEs, these doses are associated with a two-fold increase in fracture risk, and it's not clear whether that's directly related to changes in bone metabolism or if they're related to endocrinopathies or another factor. There are also direct adverse effects of the opioids. Nausea, sedation, urinary retention, and sweating are all frequently seen, especially in institution of or with changing of dose therapy. Constipation, which sometimes really does not tolerate, hypodynamic bowel and quite dry stool. Pruritus occurs for many patients. And the most important one, the one that's the key takeaway here, is the risk of respiratory depression and death.

So how might we want to manage those adverse effects? I made it sound terrible. Well, you know, when we do make the choice to use an opioid, nausea and vomiting will actually usually resolve in a few days; just exposure to the substance, and that kind of acclimatizes. You could certainly use antiemetics, or just switching agent for many patients is adequate to resolve that symptom.

We need to always, always recognize the risk of sedation. So if a patient is experiencing sedation, especially when you're instituting opioid therapy or when you've had a dose increase, the treatment is decrease the dose because sedation is a preamble to respiratory depression and death.

Constipation is the most common problem that we see with chronic opioid therapies. And really it should be anticipated and planned for. So anytime you're instituting therapy, you should be talking to patients about a bowel regimen. So a range of options: stool softeners, osmotic stimulants, peripherally-acting opioid antagonists, or you could try switching opioids, which sometimes works. But we want to remind patients to avoid bulking agents, so things like fiber supplementation, they are not useful and can actually cause harm in this circumstance.

When patients experience pruritis with an opioid, that also usually only exists at the institution of therapy, but you could rotate or switch agents, or you could apply an antihistamine, either systemically or topically.

When you see urinary retention, you could rotate opioids, so switch agent, or you could try decreasing the dose.

Dr. Daniel Alford: I think in addition to just knowing general adverse effects, we should also think about our patient. Do they have specific risks because of who they are? For instance, as our patients age, there is a decline in therapeutic index and there is a predisposition to adverse drug effects and there's an increased risk of falls and worsening cognitive function when we prescribe opioids in some of our patients who are aging.

Also, some of our patients will have liver disease or kidney disease, and there are certain considerations for those patients. For liver disease, we know there's a decrease in opioid clearance. Specifically, morphine, oxycodone, and hydromorphone need to have their doses reduced or we need to prolong the dosing interval.

For patients with kidney disease, there is a decrease in opioid excretion. The preferred opioids would be hydromorphone or fentanyl or buprenorphine or methadone. Oxycodone would be considered a second line opioid due to the active metabolites, and we should probably avoid morphine and codeine because of their active metabolites.

Now, I also know that there are specific drug-drug interactions (DDIs) and I'm going to turn it over to our pharmacist, Pat, to talk to us about how should we think about opioids and other drugs?

Patrick Kelly: Really, what I would recommend when you're prescribing is to kind of do a holistic view, which you're doing already, which would be a best practice. What other medicines is this individual on? As a pharmacist, what I go through is, is there anything here that would be a contraindication, and then I start looking, is there any issue where we're worried about additive effects? Are other CNS depressants that may not be opioids, may not be used for pain, may not be controlled substances, but still have a sedating effect because all of these things can be additive and could make someone experience respiratory depression or something along those lines.

Dr. Daniel Alford: So how do you generally communicate those concerns with prescribers and then with patients?

Patrick Kelly: Well, it depends. Ideally that would be an actual conversation and most of the time that's going to be over the phone unless you're in some kind of clinic where the pharmacist and the provider are sharing space, you know, you could grab someone and you know, between exam rooms. But most of the time it's going to be over the phone, ideally, and you want to talk to the prescriber directly, especially if it's something that's serious enough to rise to the level of, Hey, as a pharmacist, we need to do something about this drug-drug interaction. That would probably be the main course of action and that would be the first line of communication. And then there would always be that follow up with the patient as well. So the pharmacists are really communicating with both and sometimes acting as a mediator between the two, trying to get bits of information, as possible, from both parties to kind of form some kind of opinion.

Ilana Hardesty: What about addiction? Aren't we all at risk for developing an addiction?

Dr. Daniel Alford: Well, that's what some people think. And I'm going to dispel that myth, based on probably the best study that I'm aware of, which was a systematic review of 38 studies. About a quarter took place in primary care and about half in pain clinic settings, and the other quarter were in other specialty clinics treating patients with pain. What did they find? Well, they found that opioid misuse rates were somewhere between 21 and 29%. So misuse means that the patient took the opioid contrary to the way it was prescribed or the reason it was prescribed. For instance, you're prescribing it for their neuropathic pain and they took it for their headache, or you're prescribing it for their back pain, and they took it because it helped them sleep. That would be considered misuse. So about a quarter of your patients might do that. But what about addiction, which was really your question? And it's somewhere between eight and 12% in this study. Addiction was defined as a pattern of continued opioid use, despite negative consequences, despite harm. And so, again, that was about 8 to 12%.

Dr. Erica Bial: Dan, I'm really glad you brought that up because, of course, the risk here is not only to the patient, but also there are collateral risks in the community. Right? Just having those medications around presents risks to others. So there are risks to young children and inadvertent ingestion and overdose. Adolescent experimentation can lead to overdose as well as to addiction. And, of course, other family household contacts: family, visitors, others. How do we mitigate some of those risks? We need to talk to our patients, particularly about safe storage, like a lockbox; safe disposal, and we can provide some resources for ways to dispose of opioids safely in one's community; as well as opioid overdose education and naloxone distribution. I think this one cannot be stressed enough. We want to use a number of different risk mitigation strategies, including naloxone co-prescribing every time that we're prescribing a chronic opioid.

So of course, I would be concerned that these risks might also increase with higher dose opioids. Dan, how do you deal with that, especially in primary care?

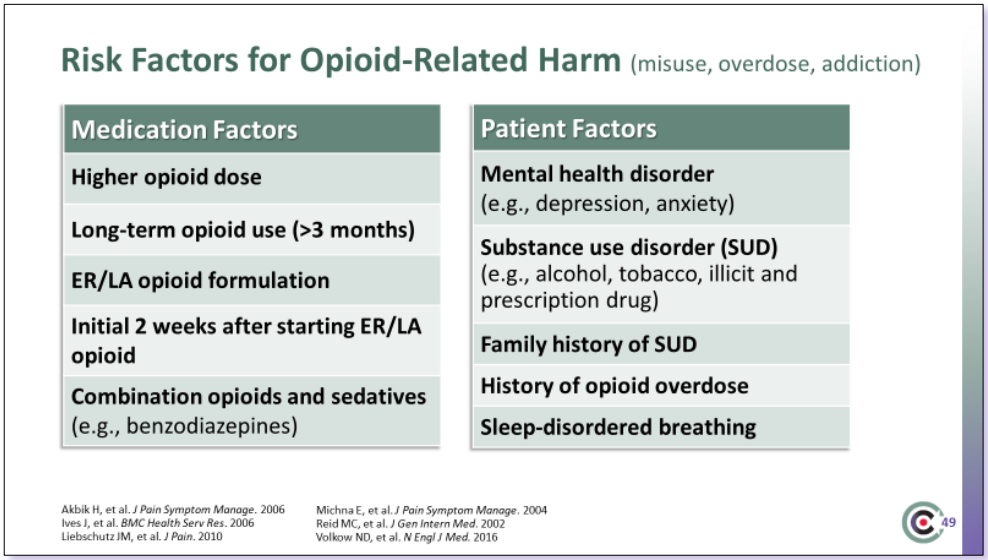
Dr. Daniel Alford: Yes, that's a good question. And higher doses are absolutely associated with risk, such as developing hyperalgesia, which is increase in pain sensitivity; a risk of decreased function; immunosuppression, which you had talked about; and overdose. And there have been a number of population-based studies that have looked at dose compared to overdose risk. All of the studies show a gradual increase that's dose-dependent. And some studies have shown that the overdose risk actually is two-fold once you get above 20 morphine milligram equivalents and it actually jumps up to nine-fold when you get above 100 morphine milligram equivalents. So we need to be aware that increasing the dose of opioids carries increased risk.

And the CDC guideline addresses this issue of high dose opioids by saying when starting opioids prescribe the lowest effective dose, use caution with any dose, make sure you talk to patients about the risks when considering increasing the dose, and really try to avoid increasing doses above levels with diminishing benefit relative to risk.

Now, what about patients who are already on high dose opioids? What do you do about those? And we should manage them as higher risk. How do we do that? Well, you're going to increase the amount of monitoring and support that you offer them. And again, the CDC addresses this specific issue. And that is, for patients who are already on high dose opioids, carefully kind of measure and weigh the benefits and risks. If the benefits outweigh the risks, continue the opioids, but optimize other therapies as well. However, if you think the risks are greater than the benefits, optimize other therapies and gradually taper opioids to lower doses. Very importantly, they say, and I agree, unless there's some life-threatening issue, that is, an impending overdose, do not discontinue opioids abruptly or rapidly reduce opioids from higher doses. So we need to be really careful here when we decide that opioids need to be tapered, we should do it in a controlled and evidence-based way.

Ilana Hardesty: For our case study Michelle, or any patient on opioids, is there a way to determine the risk for opioid misuse and harm?

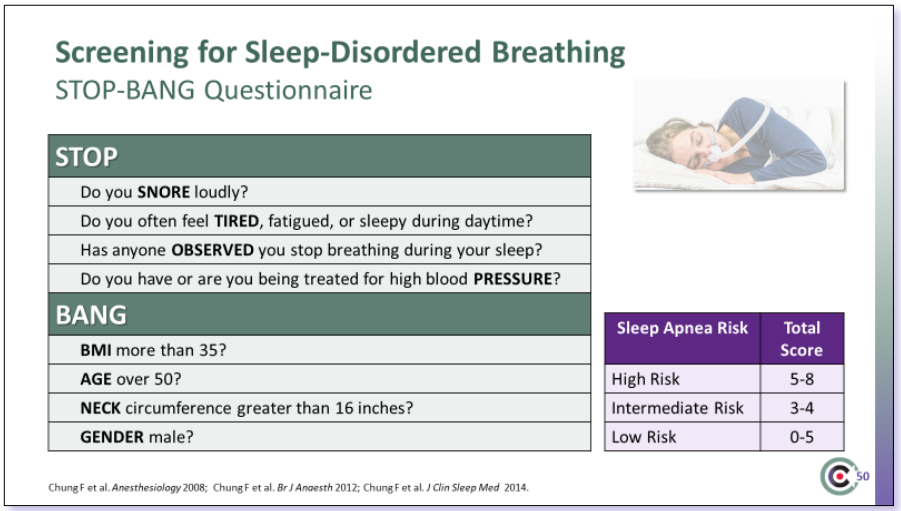
Dr. Erica Bial: It's a great question. It's impossible to 100% predict the risks of opioid misuse and harm, but certainly there are risk factors that the clinician can be aware of to help us side. To find those patients that might need to be monitored a bit more closely. So there are factors related to the medication choice: so higher opioid doses; if the patient is taking these medications long term, which I would define as more than about three months; patients who are on long acting formulations; and any time that there is the institution of therapy or any time that you are starting to rotate the patient from short acting to long acting therapy, those first two weeks are a critical period. And any time that the patient is taking medications that have a synergistic increased risk. So particularly combinations of opioids and benzodiazepines which carry that black box warning.



In addition, there are patient factors that we should be aware of and thoughtful about. So co- presentation with mental health disorders, including depression and anxiety. If a patient has a known preexisting substance use disorder, whether that is opioid as the substance or another substance, so things like alcohol, tobacco, as well as illicit and prescription drug use. If there's a family history of substance use disorder, certainly if the patient has a history of prior opioid overdose and if the patient has sleep disordered breathing. So a challenge in recognizing all of this is that that's an awful lot of risk to be assessing and monitoring and screening for. Dan, how do you do it in a primary care environment?

Dr. Daniel Alford: Great question. You know, in primary care, we have lots of competing priorities. So how do we actually screen for these patient-related factors? So I'm going to talk a little bit about it, but then I'm going to hand it over to Kristin, because, to be quite frank with you, a lot of these screenings are done before I even see the patient. So I'm going to have her talk about how that gets done.

But let me just talk about one in particular, and that is screening for sleep-disordered breathing, because it's so critical that we know whether our patients have sleep apnea because of the risk of overdose. What I use is one that I can remember quite easily, and



that's called the STOP-BANG Questionnaire. So **STOP** stands for Does the patients **snore** loudly? Does the patient feel **tired**? That's the T. The O is, has anyone **observed** the patient stop breathing during sleep? And then the P is, is the patient being treated or do they have high blood **pressure**? P for pressure. So snore, tired, observed, stopping breathing and pressure. The BANG part is: is the patient's **BMI** more than 35? A is **age** over 50. N is **neck** circumference greater than 16 inches. And G is **gender** for male. And based on the number of these items that are positive, you can classify your patient as being low, intermediate and high risk for sleep apnea.

Okay. So what about psychiatric comorbidities, which are really important in terms of risk stratifying our patient for opioid misuse. And they're common in our patients with chronic pain, whether we look at sleep disorders, depression, anxiety, personality disorders, PTSD, and substance use disorders. Not only are they common in patients with chronic pain, but there is a bi-directional relationship. These psychiatric co-morbidities make pain worse and harder to treat, and chronic pain makes these psychiatric co-morbidities worse and harder to treat, and we should be looking for them and co-managing them. So these psychiatric co-morbidities are common. We heard from Erica that they can predict risk to opioid misuse if patients have them. And the question is, in primary care, how do you screen for them? So, Kristin, can you talk to us about how you screen for sleep disorders, depression, anxiety?

Kristin Wason: Yeah. And so I'll say this is a great way to utilize other members of your care team because patients a lot of times are like seeing the nurse first or a lot of times we can have more casual conversations with patients sometimes. And so I think with that, like we get a lot of face-to-face time with folks and nurses are trained on chronic disease management. And so chronic pain is like right in our wheelhouse. We really are also trained in having this whole-person approach and really trying to understand, you know, someone's sort of mental health, their physical health, and their social wellbeing. And so again, like

pain and mental health conditions play right into here. And so in our practice we do this a few ways. When patients are coming in for primary care visits, a lot of times as they go and check in at the front desk, they're handed like a one-page form that has a few different screening tools on it. I work in a large academic urban medical center, so we have this form available in many, many languages, and typically the patients will fill it out as they're being roomed and the medical assistant or the nurse will actually go in and check on the patient and then enter and all that information into the electronic medical record. And any positive screen is then brought to the provider so that the provider can then go in and sort of address this in more detail during their visit.

So we have a number of like abridged tools. First one that I'll mention is our tool that we use for screening for sleep disorder, and what we use is an Insomnia severity Index or something called an ISI-3. And what this is, it's a short screening tool that's used to identify clinically significant insomnia. And so it's a shorter version of our longer seven item ISI screen. It's three quick questions that ask patients to rate the severity of their insomnia problem over the last two weeks from a scale of 0 to 4. And so a zero would be that you are very satisfied with this particular component of your sleep. And a four would be that you're very dissatisfied. And so those three questions have to do with the satisfaction with your sleep. How is sleep interfering with your daily functioning, and are you worried or stressed about your sleep? Anyone that screens less than a seven would be a negative screen and then you're basically done. But if it's a seven or more, then that would be a positive screen. And so that person really would need to have more of a discussion and maybe a diagnosis about like the type of insomnia that they have and how we should pursue treatment.

Dr. Daniel Alford: And what about depression and anxiety?

Kristin Wason: The tool that we use is the two-question PHQ-2. And what this PHQ-2 screening tool is, is it ask patients over the last two weeks, how often have you been bothered by having little interest or pleasure in doing things or two, feeling down, depressed or hopeless? And patients will answer basically as a zero, it's not an issue at all up to a three, which would be this is occurring to me like every day or nearly every day. And so what we'll do is we'll add up these scores of 0 to 3, depending on the severity of their symptom. And anyone that screens 3 or more is, again, a positive screen. And then that person would buy themselves a PHQ-9, where we ask more questions about their depression, where we can sort of help lead us to if this is a true diagnosis or not.

For anxiety, we use a GAD-2, which again looks at symptoms over the past two weeks, how often have you been bothered by any of the following: one, feeling nervous, anxious or on edge, or two, not being able to stop or control your worrying? And so again, we're rating these as like a zero, it's not an issue to a three, this is something that is really affecting my day to day life. And a score of 3 or more is where we would then move on to the more thorough GAD-7 screener.

Dr. Daniel Alford: Kristin, I should also mention that there are short screeners available for screening your patients for PTSD and suicidality. And these are really important issues that need to be looked for in our patients with chronic pain.

I also want to talk about screening for substance use. And again, in primary care, we're looking for the briefest way to do that. The tool that I would like to use is TAPS. T-A-P-S. T is for **tobacco**, A is for **alcohol**, P is for **prescription** medications, and S is for other **substance** use. And it's all about in the past 12 months, we ask how often have you used tobacco or any other nicotine? And that includes e-cigarettes and vaping. Had five or more drinks (for men) or four or more drinks (for women) containing alcohol in one day? Used any prescription medication just for the feeling, more than prescribed, or they were not prescribed to you? And then finally, used any drugs, including marijuana, cocaine, crack, heroin, methamphetamine? It's really critical that if you have others asking these questions in your practice, that they ask it the way it was validated. They don't say, "do you use drugs?" or "you don't use drugs, do you?" It's important to say in the past 12 months, **how often have you**…? Because even if somebody's under reports the amount of times they had four or more or five or more drinks, anything other than never for any of these questions is considered positive.

[Music]

Ilana Hardesty: Thank you. Doctor Alford, Doctor Beal, Patrick Kelly and Kristen Wason.

Michelle screened negative for sleep disordered breathing and negative for insomnia, depression, anxiety and substance use. Join us for episode four when we need to respond to our patient's request for opioids to be prescribed at this first visit. Remember, she just ran out.

Should the new PCP prescribe opioids or not? We will discuss how to determine when and if opioids are the appropriate choice for the treatment of chronic pain.

[Music]

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SCOPE of PAIN: Safer/Effective Opioid Prescribing Education

Podcast - October 1, 2023

Episode 4

[Music]

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In this episode, we'll speak again with Dr. Daniel Alford and Dr. Erica Bial. And we'll bring back Kristin Wason, a primary care nurse, and Don, a patient on long term opioid therapy for chronic pain.

Last time we talked in general about the risks associated with opioids. But now it's decision time for our case study Michelle's new clinician. How do you decide whether to continue prescribing opioids for a new patient with chronic pain who's already on short acting opioids, like Michelle?

Dr. Daniel Alford: Great question. And I would say when pain is severe; when pain has a significant impact on function and quality of life; and also when the patient has a specific pain type that I think will likely respond to opioids, because we know that not all chronic pain is opioid responsive. For example, fibromyalgia and migraine headaches, not so much. They don't really respond to opioids very well, but certainly chronic pain related to musculoskeletal issues and neuropathic issues can be opioid responsive. In a patient like the one we presented. I'd like to know if they've been tried on non-opioid modalities and how did they work and were they ineffective? And finally, again, for a patient like the one we've described, is there any documented benefit on her current opioids?

So let me just put opioids and chronic pain in perspective. And the first thing I just want to emphasize is that the efficacy of long-term opioid therapy for chronic pain has been inadequately studied. That's the bottom line. And therefore, opioid prescribing needs to be more judicious because we need to remember that opioid misuse can be fatal, including overdose and opioid use disorder; and that opioids for chronic pain are really only indicated after alternative safer options have been found inadequate. And remember that they're only one tool of a multimodal approach for managing severe chronic pain. This is consistent with the CDC guideline, which again, maximize non-pharmacological therapies and non-opioids before considering opioids and only consider opioids if you expect that the benefits, namely pain and functional improvement, outweigh the risks. And before starting opioids, we need to make sure we discuss realistic benefits and known risks. And really, it's important to establish treatment goals and how opioids will be discontinued if the benefits

no longer outweigh the risks. So this is a good time to hear from our patient, Don. Don, how do you conceptualize the risks and benefits of opioid therapy?

Don (Patient): It's a diagram of a couch with a semicircle on the wall behind it with a sort of old-fashioned elevator dial pointer. If the pointer is going straight up to the highest point on the semicircle, I would call that sort of the sweet spot for pain medication prescribing its maximum time off the couch. If you go to the left, there's no prescription. You're on the couch because of pain. If you go all the way to the right, then you're taking so much pain medication that you're not getting off the couch. And that's not useful either. And I think that's probably when going into long-term opioid treatment, it should be made really clear to the patient that getting rid of all of their pain is not a realistic expectation. I guess I've become something of an apostle of good enough.

Ilana Hardesty: Dr. Bial, how would you assess Michelle for her misuse risk prior to writing any prescription?

Dr. Erica Bial: So as we're talking about our specific case and we're talking about a conversation with the patient about the risks of starting opioids, we should also, before prescribing, assess a patient for those misuse risks so that we can have a strong sense going in to this: What are the concerns that we might have in a way that's tailored specifically to our patient? So we use a number of tools for assessing opioid misuse risk. Urine drug testing, right? We should get a urine drug screen before prescribing. We should check a urine drug test to confirm the patient's substance use history. Prescription drug monitoring programs so we can query our particular state's or our region's PDMP to confirm medication and prescriber history. Again, one of many useful data points. One tool in the box that is underutilized is old medical records. So we should, when they're available, review the prior records from the patient's prior prescribers or other providers. And if you can, talk to the prior clinician, those conversations really give us a stronger sense of what's really going on with our patients. So we also have available a number of screening tools. Now there's no gold standard and there's a lack of evidence for the use of these tools, but they might be useful. And of course, using a tool carries no risk at all. So things like the Opioid Risk Tool, the SOAPP (the Screener and Opioid Assessment for Patients with Pain), are a few of the available instruments that we might use to have a standardized way of trying to help screen our patients for opioid misuse risk.

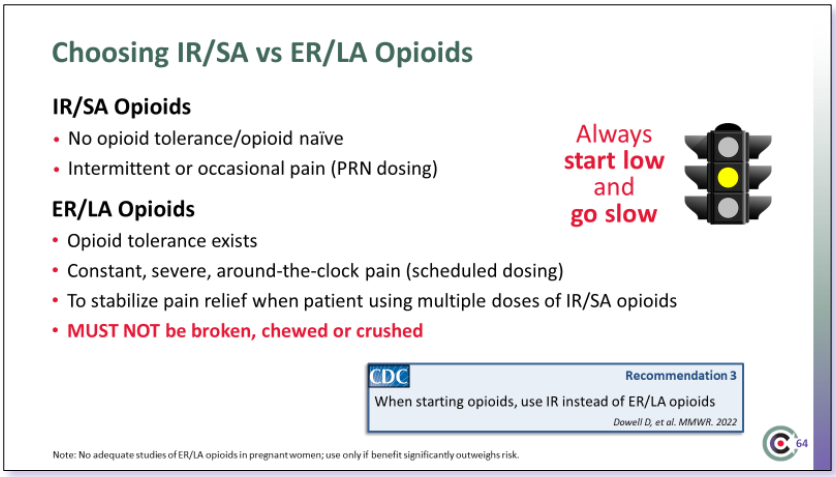
[Music}

Ilana Hardesty: As we return to our clinical case. Keep in mind that Michel came in asking for an opioid prescription today. The state prescription drug monitoring program confirmed that she has been getting oxycodone from only one doctor and one pharmacy, and it was last filled seven weeks ago. The PCP arranges for a follow up appointment in two weeks, prescribes a two-week course of oxycodone ten milligrams, four times per day, and has Michelle leave a urine sample for a drug test. Michelle's problem and medication lists are reconciled, and the PCP reviews her records from her previous doctor. There is inadequate documentation about benefits and an incomplete record of monitoring, including urine drug testing. But there's no evidence of misuse of her prescription opioid.

After the first visit, the new PCP was unable to contact Michelle's previous PCP. Her urine drug test returned positive for oxycodone only, as expected. On her follow up visit two weeks later, Michelle reports a six out of ten on each of the three PEG scales, but notes that her pain is sometimes a nine out of ten immediately before her next oxycodone dose. She denies sedation and she completed her two-week oxycodone prescription on schedule.

Based on this history, should the provider make any changes to Michelle's opioid prescription? Should she be changed to a long acting opioid to avoid the increase in pain she's experiencing before her next dose?

Dr. Daniel Alford: So it's important to think about our opioid choices in two buckets: the immediate release/short acting opioids and the extended release/long acting opioids. They're essentially the same molecules. It's just how they are formulated. We're talking about morphine, hydrocodone and hydromorphone. And in one formulation, they're immediate release and another formulation, they're long acting. So I think we need to decide whether the patient would benefit from short acting or long acting.

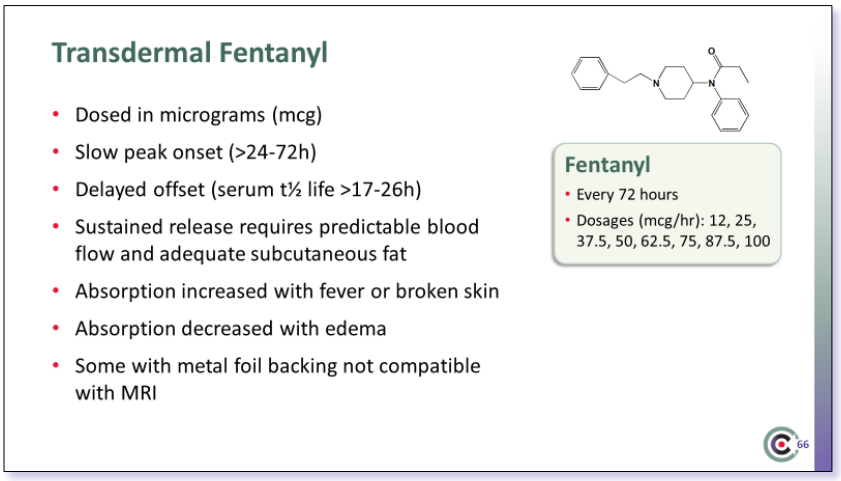


So how do we make those choices? Well, I think about short acting or immediate release opioids in a patient who has no opioid tolerance; that is, they're opioid-naive. And if their pain history tells me that their pain is intermittent or occasional, so they don't need around the clock scheduled pain relief. I would think about extended release/long acting opioids in somebody who already has some opioid tolerance, they are no longer opioid-naïve; that their pain history is telling me that their pain is constant, severe and around the clock, so they would benefit from scheduled dosing. Or if a patient has pain in a way that I want to try to stabilize it by preventing them from needing to use multiple doses of short acting opioids during the day, similar to our patient that we're describing here. It's really important to emphasize at this point that when you prescribe extended release/long acting opioids, our patients must understand that they should not break, chew, or crush these tablets because the long acting nature of these medications is dependent upon an intact tablet. Regardless of whether you use short acting or long acting opioids, it's important to remember to always start low and go slow. Now that may seem pretty simplistic. However, if you think about it, some of our patients are really in a hurry to feel better, and they are in a hurry to increase their dose to feel better. But we need to do it slowly to make sure that they're able to take the medications safely and that we titrate it in a safe way. I will mention that the CDC guideline, one of their recommendations, talks about when you start opioids, always start with an immediate release opioid as opposed to a long acting opioid. Again, that speaks to the never starting a long acting opioid in someone who is opioid-naive.

I think now it's important to talk about what are the uncertainties about using short acting versus long acting. And first of all, there's insufficient evidence to determine whether long acting opioids are more effective or safer than short acting opioids. And there's even debate about whether the bolus dosing of short acting opioids versus the continuous exposure of long acting opioids is more likely to result in things like opioid analgesic tolerance or hyperalgesia, which we'll talk more about, which is kind of an increased pain sensitivity, or addiction. So what do you do? You need to individualize your treatment. That is, to choose the options that best meet your patient's need based on your pain assessment and the risk profile of that particular patient.

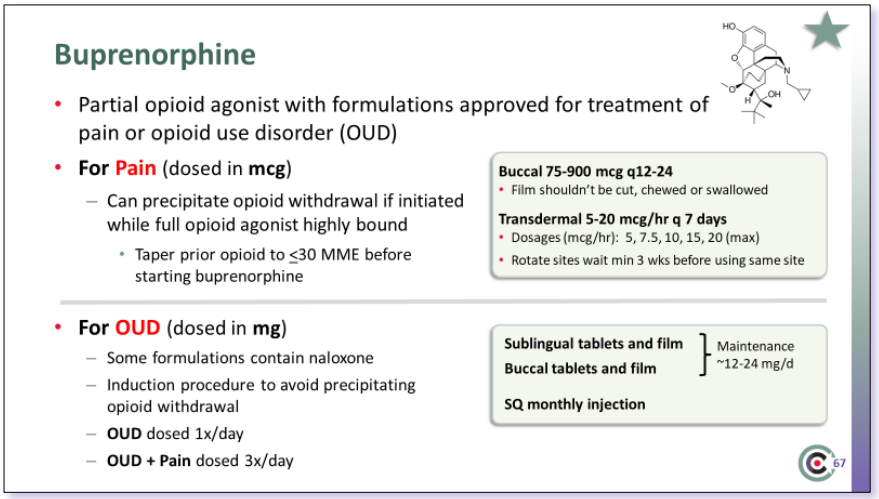
Dr. Erica Bial: Yeah, as you're talking about that, I think it's important, of course, that when we start, we want to start low, go slow and always start short acting. But there are some particularly long acting agents that I think are really worthy of conversation.

So the first would be talking about transdermal fentanyl. So fentanyl is an opioid that's getting a lot of press right now in its immediate release format. But we do find that it has a lot of utility in certain circumstances in its long acting format. so transdermally delivered. Remember that fentanyl is dosed in micrograms, an incredibly potent substance. When we're dosing it transdermally, the way that it works is through development of a depot underneath the skin, so in the subcutaneous fat, and so there's a slow peak onset – 24 to 72 hours after a patient applies the fentanyl patch – before they start to achieve a steady state. Similarly, there's a delayed offset, so removal of the patch, the medication will take some time to wear off. The serum half-life is between 17 and 26 hours. So, as I mentioned, because transdermal patches work by forming that subcutaneous fat depot, the medication, sustained release will require predictable blood flow and adequate subcutaneous fat in the region where the patch is applied. So, if your patient is very, very thin and you've applied a transdermal fentanyl patch and they don't seem to be achieving any analgesia, even though it's been enough time and it's properly applied, remember that they might not be adequately absorbing it. Similarly, absorption is increased if there's fever or broken skin and decreased with edema. So conditions that might influence blood flow to and from the area where that subcutaneous fat depot of the medication exists. It's also just a little side tip to remember that some fentanyl patches might have a metal foil backing and it could be incompatible with an MRI. If you choose to use a fentanyl patch, usually it's dosed every 72 hours that the patch would need to be changed.



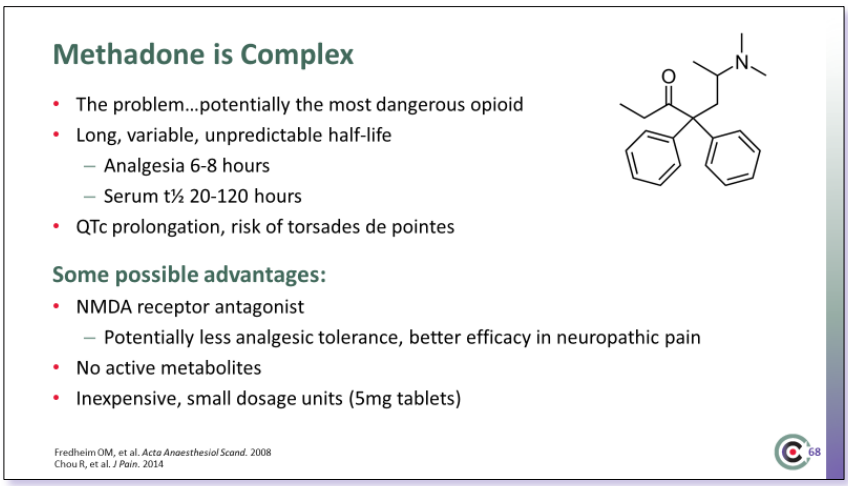
Also, there exists buprenorphine. It's important to remember when we talk about buprenorphine that it is a partial agonist. So it does have formulations, and these are the

immediate release formulations, that are approved for the treatment of pain or opioid use disorder. So when we dose buprenorphine for pain, we dose it in micrograms. So this is available as a transbuccal film or in a long acting format as a transdermal formulation. This can precipitate opioid withdrawal because it is that partial agonist. So if it's initiated while full opioid agonist is highly bound to the patient's mu receptors, the buprenorphine can come along, knock it off the receptor and only provide partial receptor stimulation. So you need to taper prior opioid to fewer than 30 MMEs before starting buprenorphine. In the transdermal patch, there's a very, very broad dose range which can be useful; it gives the clinician a lot of flexibility. But it can be irritating to the skin, so it's important – this is a seven-day patch usually – that we need to rotate sites, and the patient will need to wait a minimum of three weeks before using the same site again to avoid those reactions.



Now, in contrast, when we use buprenorphine for opioid use disorder, we're dosing it in milligrams. Some formulations will contain some sequestered naloxone. And again, there's the importance of an induction procedure to avoid precipitating opioid withdrawal. When we prescribe buprenorphine in opioid use disorder, it's dosed once daily. But remember that when you are treating both conditions – so patients might present both with an opioid use disorder and a painful disease – that you want to dose it three times a day. Interestingly, and more newly developed, buprenorphine is also available as a subcutaneous monthly injection when it's used for OUD.

So methadone, another one of these medications that we think of, particularly in chronic pain, is a really complex molecule. I have never once taken a board exam and not been asked this question. And so I want to take a quick sec and advertise the right answer, which is: the problem with methadone is it's incredibly useful, but it can be the most dangerous opioid. And the reason is – this is the commonly tested question – it causes QTc prolongation, and so it includes a risk of torsades de pointes. So it has a long variable and very unpredictable half-life. Similarly, the analgesia is actually kind of short. So usually when



we're dosing methadone for chronic pain, this is a TID medication. Analgesic half-life of the medication is 6 to 8 hours, but the serum half-life is somewhere between 20 and 120 hours. So highly variable.

But it has some possible advantages, and this is something that is rarely tested but I think is cool to know, it is an NMDA receptor antagonist and so it might yield less analgesic tolerance and better efficacy, particularly in neuropathic pain. It might carry a lower risk of development of opioid induced hyperalgesia, and it has no active metabolites. It's also convenient for dosing. So it's available in some very small dosage units, only five mg tablets. so you get the ability to really kind of dial up and down your dose; and it's inexpensive, making it more readily accessible to many patients.

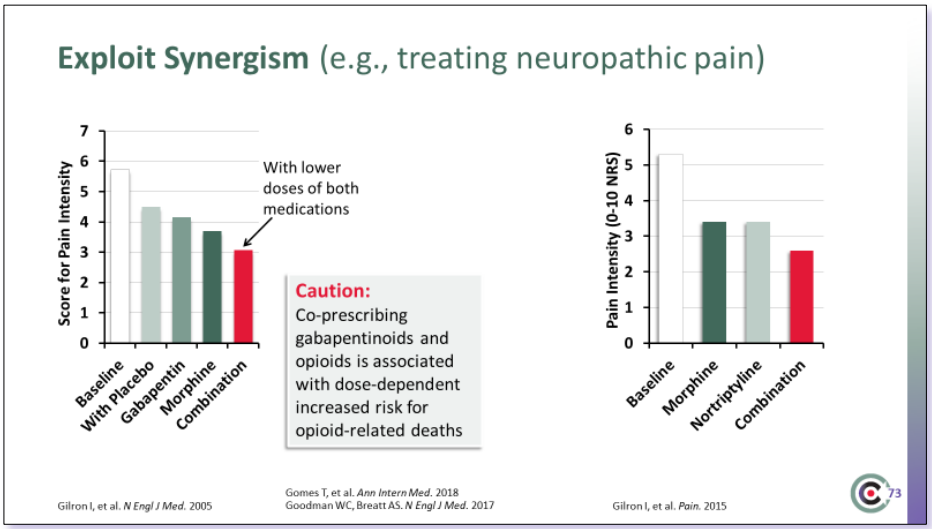
Let's also take a moment and talk about dual mechanism opioids. And some people are surprised to hear that we include these in a conversation about opioids. But these two substances do in fact bind the mu receptor. So we're talking about tramadol and tapentadol. And these are dual mechanism opioids. They also yield norepinephrine and serotonin reuptake inhibition and as a result they carry seizure risk as well as risk of physical dependence, as well as a risk of serotonin syndrome. So when you get that phone call from the pharmacist, when you've prescribe tramadol in a patient who's also on another serotonergic medication, thank the pharmacist for calling and alerting you to that risk of serotonin syndrome and an increased risk of seizure. These are, in fact, controlled substances and they do carry addiction potential. They're subtly different. So tramadol is a weak new opioid receptor agonist. It has a minimal norepinephrinergic effect, but a very prominent serotonergic effect. In contrast, tapentadol is a stronger mu receptor agonist. It has a more prominent norepinephrine effect and a more minimal serotonin effect.

Ilana Hardesty: What about the newer abuse resistant opioids? How do they work?

Dr. Daniel Alford: So in response to the problem with extended release oxycodone, where people weren't taking it as prescribed; crushing it, they were sniffing it. And that was causing the extended release oxycodone to turn into a short acting oxycodone with a lot of milligrams in that tablet. So what the pharmaceutical companies have done is to create barriers to the crushing or use or misuse of the opioid in that way. So, they've created physical barriers. That is, you cannot crush the tablet or if you do crush it, it turns into a gel. But they've also done creative things like put in a sequestered antagonist; that is, if you don't take it as prescribed, there is an antagonist which might cause withdrawal. They've also put in some aversive components. If you, again, take it incorrectly, you might get some flushing or some other kind of aversive reaction. They've created pro-drugs. So again, if you don't take it as prescribed, you don't get the medication and so forth. Now, we do know from surveillance studies that there is a decrease in diversion and street price of these medications. So, there is some effect in that regard. But even though they can't be altered, it doesn't prevent people from taking too many of the intact tablets, which can be problematic. And they tend to be expensive and some insurers don't cover them. So I think probably the take home message here is that currently there are no 100% proven misuse resistant opioids. So regardless of whether or not you use one of these formulations, you still need to do it cautiously and monitor the patient for safety.

Ilana Hardesty: Are there other things to consider when you're thinking about prescribing an opioid?

Dr. Erica Bial: I think so. I mean, I think that probably one of the most important things that we can do as health care providers is to think creatively and tailor our treatment approach to the multiple points of potential intervention when we have a patient before us with pain. And we want to think about rational polypharmacy. There are multiple mechanisms-specific treatment targets that we could consider. So rather than monotherapy, imagining all of the points along the pain pathway that we could potentially intervene. So we think about in situations of peripheral nervous system sensitization: so we can intervene with non-steroidal anti-inflammatory medications, tricyclic antidepressants, lidocaine affecting the sodium channels as well as the opioids. We want to also think about intervention at the level of the spinal cord: so modulating central sensitization, our targets here might be the calcium channels or the NMDA receptor. So again, substances like tricyclic antidepressants, the gabapentinoids, as well as the opioids might all have an impact here. And also considering ways in which we can enhance descending inhibition from the brain. So again, use of the tricyclic antidepressants, the SNRIs, as well as medications like tramadol and the opioids, might all play a role in helping us to have a rational polypharmacy approach in addressing the patient's pain at multiple points in the pain pathway.



Additionally, we want to exploit synergism. So a convenient example comes from the treatment of neuropathic pain. And we know, just like when we treat many other diseases, that if we use lower doses of multiple substances addressing the symptom at multiple target points, we might achieve a greater outcome with fewer risks. So for example, there was a study where they evaluated a patient's pain against baseline and against placebo with treatment with gabapentin alone, morphine alone, or with a lower dose combination of both medications. And they found that patients who were receiving combination therapy, even though the doses of the individual substances were lower, that they had greater impacts on scores of their pain intensity. So just a word of caution: that co prescribing gabapentinoids and opioids may be associated with a dose-dependent increased risk, however, for opioid-related death. So on the one hand, we want to respect the risk of using these multiple substances, but also be aware that we may be able to get an equal treatment benefit but with lower doses of either medication.

Ilana Hardesty: We've talked a lot about many different opioids in this episode. What's your take away?

Dr. Daniel Alford: Some of the things we talked about is to consider the duration and onset of action based on the patient's pain history or the pattern of their pain. Is there pain intermittent? And I might think about a short acting opioid. Or is it constant and around the clock? And I might consider a long acting opioid if they're no longer opioid-naïve. I'm also going to consider the patient's prior experience. Remember, we talked about all of the mu opioid receptor polymorphisms and the differences in how our patients metabolize opioids. So I really want to know, what have they experienced in the past? Have they been on an opioid and how did it work, both in terms of benefits as well as side effects? Again, I want to think about the patient's level of opioid tolerance. I'm always going to assess that before considering a long acting opioid formulation. And I also want to consider other medications they're taking, their age, and other disease, comorbidities. Consider the route of administration. Maybe a patient would benefit from the transdermal formulation as opposed to taking a pill. And then finally, really importantly, is the cost and insurance issue. So is this medication going to be covered by this patient's insurance, or am I going to need to do a prior authorization? So those are some of the things to consider.

[Music]

Ilana Hardesty: Thank you, Dr. Alford, Dr. Bial, and Don, our patient. The PCP decides to continue Michelle's opioid therapy for her chronic pain, but changes her regimen. Since she tolerates short acting oxycodone, but has significant worsening pain before her next dose, her pain may improve with more stable blood levels, even at a lower overall daily dose. He prescribes extended release oxycodone 15 milligrams two times a day, which is a lower overall opioid dose equal to 45 morphine milligram equivalents or MME instead of the 60 MME she was on. He continues the acetaminophen and gabapentin. Note that the provider did not assume that Michelle would need medication for breakthrough pain when he switched her to long acting opioids. And before ending the appointment, they discussed strategies for weight loss, improved sleep and stress management, and he refers Michelle to physical therapy for her hip pain. The PCP reviews a patient provider agreement with Michelle and they sign it. Over the ensuing months, Michelle reports improved pain control, allowing her to be more active.

How should patients prescribed opioids for chronic pain be monitored? Should we apply these monitoring strategies to all patients or just focus on those who are high risk? That's in our next episode.

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Production by Rococo Punch.

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I'm Ilana Hardesty. Thanks for listening.

SCOPE of PAIN: Safer/Effective Opioid Prescribing Education

Podcast - October 1, 2023

Episode 5

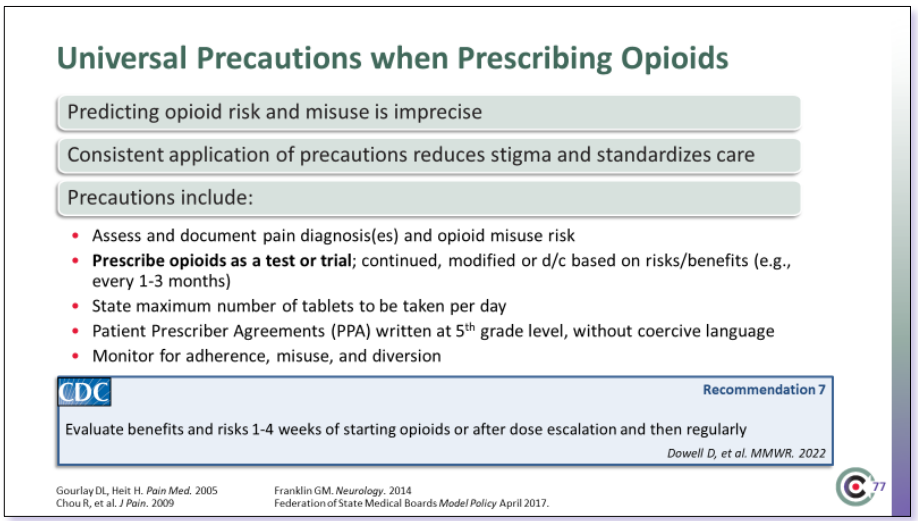
[Music]

Ilana Hardesty: Thanks for listening to Boston University Chobanian & Avedisian School of Medicine's Safer and Competent Opioid Prescribing Education: *SCOPE of Pain* Podcast Series. I'm Ilana Hardesty.

This series has eight episodes. If at any point you want more information on receiving credit, please visit our website, scopeofpain.org. There are also resources that accompany this series. All of it can be found at scopeofpain.org.

We'll be talking today with Dr. Daniel Alford and Dr. Erica Bial, along with Kristen Wason, a primary care nurse, and Patrick Kelly, a community pharmacist. In this episode, we're returning to our case study of Michelle Jones. Last time, Michelle's new PCP prescribed long acting oxycodone for her chronic hip pain and painful diabetic neuropathy.

But what are the next steps? How should patients prescribed opioids for chronic pain be monitored? And should we apply these monitoring strategies to all patients or just focus on those who are high risk?



Dr. Daniel Alford: Great question. And this is a question I get asked often because it's a lot of work to do this, but I think it's really important for people to take home that these precautions need to be applied universally. Why? Because predicting opioid misuse risk is imprecise, and we should assume that every single patient prescribed an opioid carries some risk. It also allows us to consistently apply the precautions and therefore reduce stigma. And it also standardizes care.

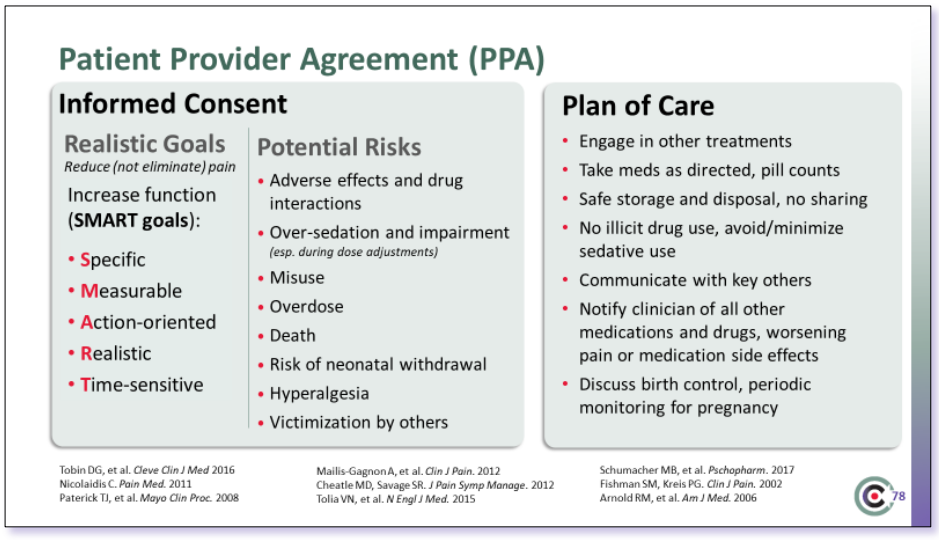
And some of the precautions would include making sure we do a full assessment and document the pain diagnosis or diagnoses, as well as evaluating the patient for opioid misuse risk; to prescribe the opioid as a test or a trial, that is, we're only going to continue if the opioid seems to be benefiting the patient, we may need to modify it or even discontinue

it based on the risks and benefits. And we should do this in the beginning often, maybe monthly, and we could then space it out probably to every three months once the patient is stabilized. It's important to state the maximum number of tablets a patient should take. When you say take 1 to 2 tablets every 4 to 6 hours, if the patient takes that literally, they could take a whole lot of tablets in one day. So it's worth saying a maximum, for instance, four tablets in one day, to keep the patient safe. We also recommend monitoring for adherence, misuse and diversion – we're going to talk more about that – and to use a patient prescriber agreement or PPA. Make sure this document is written at a fifth-grade reading level so your patient can understand it. It shouldn't be coercive, it shouldn't be a contract, but it should really be educational in terms of what the patient should expect, in terms of things like refills and how they should take the medication safely and keep it safe from other people, but also what they should expect in terms of, you know, what are my obligations in terms of keeping them safe.

I'd like to ask Kristen if you could talk more about the patient prescriber agreement and what your experience has been and using an agreement with your patients who are being prescribed chronic opioid therapy?

Kristin Wason: Yeah. So some of the components that we would have is that it can help set up shared goals for the person's care moving forward. And so a lot of times patients, their goal is to like, I want to have no pain and no pain is not necessarily realistic or achievable. And so what we're really trying to do is talk about more sort of how we can improve, again, like your quality of life and reduce your pain. And so it helps set up those expectations. And so that way we're moving towards the same target. It also can include things like informed consent. It talks about those realistic goals, but also how basically the medications and the treatment interventions aren't going to cure their pain, but they're going to sort of decrease their risk and hopefully improve their quality of life.

Dr. Daniel Alford: So when I talk to patients, I often use SMART goals to frame those expectations. SMART goals stand for **specific**, **measurable**, **action** oriented, **realistic** and **time** sensitive. So as opposed to a patient saying, I just want to feel better, which you could not measure when you see the patient at the next visit, you want to create something that you can measure. Like I want to start going to the grocery store once a week or I want to be able to do my own laundry or I want to be able to play with my grandson twice a week. And that would be something that's specific. It's



measurable, action oriented, realistic and time sensitive. And you can have your conversation at the next visit to see how they were able to achieve or not achieve that smart goal.

Kristen, now that we've talked about setting goals, how do you talk to patients about the risks associated with opioids?

Kristin Wason: So we can talk about adverse reactions, we can talk about side effects, we can talk about things like dependence occurring. And so if you were to stop your medication, suddenly you might experience withdrawal. We'll talk about how certain medications have risk for developing a substance use disorder. There's a risk of an overdose, especially if used in combination with other substances, and how for anyone that has child bearing capacity, if they're on an opioid for an ongoing period of time, like they are going to develop dependence. And so if they do become pregnant and deliver the baby, it doesn't mean that it's going to necessarily be harmful during their pregnancy, but it does mean that that child is likely going to experience a Neonatal Opioid Withdrawal Syndrome, that then requires sort of different treatments after delivery.

Dr. Daniel Alford: So, Kristin, I just want to jump in for a moment and be super, super clear about the term dependence. You mentioned that if someone's been on opioids for a while, they'll become dependent. And we used to, not so long ago, use the term opioid dependence to mean opioid addiction. But you and I know we no longer refer to opioid addiction as dependence. We talk about an opioid use disorder. And I know when you said dependence, you were referring to physical dependence, which is that biological adaptation to being on chronic opioids, which means if you stop the opioids abruptly, you'll go through withdrawal.

Moving on, you talked about informed consent as part of the patient provider agreement. I think it's also important to talk about the plan of care. Can you give us some insight on that?

Kristin Wason: Yeah. So that can include things like how often we expect to see you; other parts of the treatment. And so with chronic opioid therapy, no matter for the reason, you always want to make sure we're doing things like toxicology screening. So it might talk about the expectation of toxicology screenings. It could talk about the refill process and so how to obtain your refills, what happens about where you're storing your medication? If your medication were to get lost, stolen or destroyed, how would we address that? And putting all of those sort of conditions out at the beginning so that way, if something were to happen throughout the plan, that way, we sort of both know how we're going to intervene and what the expectations are for each other about the way to kind of keep that patient safe and keep their pain managed as effectively as possible.

Ilana Hardesty: Dr. Bial, you've talked about urine drug testing as one way to monitor patients. Can you dive a bit deeper into that?

Dr. Erica Bial: We talked a little bit about the many tools that we have to try to assess misuse and urine drug testing is just one of those tools; it was the first one I mentioned earlier. The benefit of things like urine drug testing is this provides us with some objective

data. So it gives us information both about therapeutic adherence and it might give us some potential information about the use or nonuse of illicit substances as well. So we don't need to be sneaky about it, right? We want to discuss urine drug testing very openly with our patients. I like to ask a question like if I send your urine right now, what will I find in it? And patients will typically tell us, which has been a surprise in the past, in my experience, when talking with referring doctors and they say, how did you get the patient to tell you that that was happening? I say, I just asked. And then we want to document the time of the patient's last medication use. We should recognize that this is just one medical data point and we need to integrate it with all of the other information that's before us with our patients. So we can't discriminate elective substance use from substance use disorder and diversion. Concentrations also really cannot determine how much opioid is being taken. So it's important to recognize that dedicated deceivers can and will beat the system. But the CDC recommends, and I agree, we should be using strategies to mitigate risk, including toxicology testing.

So urine drug screens themselves come in two big categories. Usually point of care tests are immunoassays. The advantage of these is they're quick, they're inexpensive, and they're often point of care tests, so we get immediate results. But you need to know what's included in your particular testing panel. There is a risk of false negatives due to cutoffs as well as false positives due to cross-reactions. Now, if you get unexpected findings, they could certainly be verified with definitive testing. So these are very specific tests because using GCMS or LCMS testing, we can identify specific molecules. But there are downsides to those send out urine tests. They are more expensive and they take longer.

So you also need to remember that opioid metabolism that we talked about earlier, for example, hydrocodone can be metabolized to hydromorphone and oxycodone to oxymorphone. And so if your patient tests positive on individual molecular identifying tests for a metabolite, it doesn't necessarily imply that the patient is not using their medications as directed. But if you're unsure, if you get back an unexpected or spurious result, and you think it might be within the range of possibility of what your patient is prescribed, contact your lab toxicologist for questions.

Dr. Daniel Alford: Yeah. Erica, I just want to chime in with personal experience around urine drug testing. And I have found that when I do the screen and it's an unexpected finding and that I then call up my patient and say, "you know, there was a surprising result with the urine drug test. Now, I haven't confirmed it, but I want to let you know that I found, for instance, cocaine. And I can you tell me about it? And before you answer that, remember, it could be a false positive. I haven't sent it for confirmatory testing, but if you tell me it's false, then I will send it for additional testing. And if it turns out to be truly positive, I'm going to be doubly worried that you didn't feel comfortable talking to me about it." So I think I've saved the system a little bit of money by using that approach. And I'll tell you that more often than not, the patient will say, "Yes, I was worried about telling you that. But you're right, I did use some cocaine." And that allows me to then talk a little bit about their cocaine use and the risks and so forth.

Dr. Erica Bial: I fully agree. I think patients are often very surprised that if we ask questions in a non-judgmental way, they usually tell us the truth. Not 100%, but often.

Dr. Daniel Alford: So I want to move on to some other things we would recommend people use to monitor their patients for safety. And one would be medication count. And this really gives you information on medication adherence; that is, are they taking the medication as prescribed? But also can give you some information that might be concerning for diversion. That is, do they have fewer tablets remaining than you would expect? The other tip I would give is we now give 28-day supplies instead of 30-day supplies. So why do we do that? Well, that's exactly four weeks. And therefore, if I prescribe the month prescription on a Tuesday and I give them a 28-day supply, it's going to be due again on a Tuesday when I'm in clinic and I can sign that prescription. If you're giving a 30-day supply, either it's going to eventually start running out on the weekends or the patient's going to be hoarding tablets. So a 28-day prescription seems to be a useful strategy that we've used in our clinical practice and it's paid off.

The other monitoring tool would be the prescription drug monitoring program, which all states now have available, and it serves two purposes. Information on harmful polypharmacy and information on multiple providers. The good news is that some states allow delegation of authority. That is, I can allow someone else on my behalf to look up the PDMP report for a particular patient before we submit a refill. It's important to note that methadone that's being dispensed at an addiction treatment program will not show up on the PDMP. And also, I just want to say that when it's been looked at in terms of efficacy, there's insufficient evidence that implementation either increases or decreases nonfatal or fatal overdoses.

So, Pat, I know as a pharmacist, you guys use the PDMP all the time before you dispense an opioid. Can you talk about the pharmacist's role in using the PDMP in order to again, safely dispense opioids to our patients?

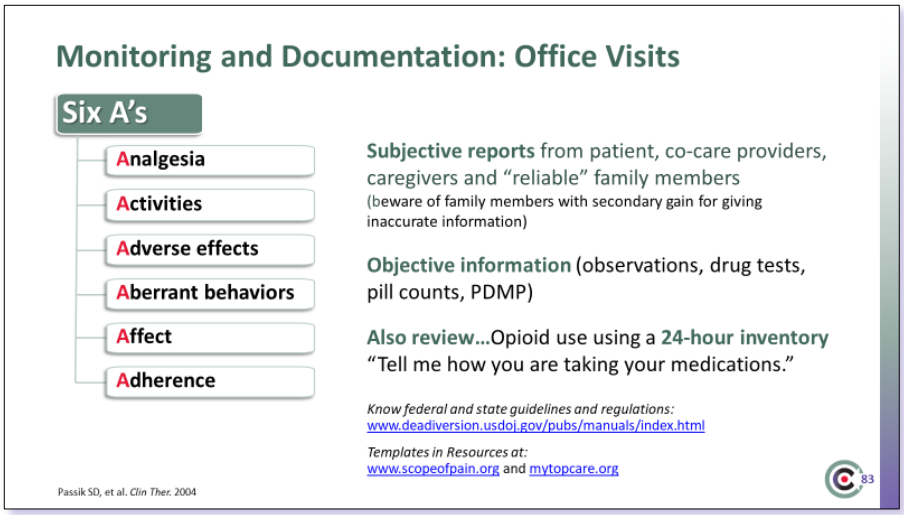
Patrick Kelly: Well, yeah. The state PDMP have come a long way even in the last five or six years. The data is going to be reported by the pharmacy, and that information, for the most part, is being entered on a daily basis. But it all depends on the jurisdiction you're in. Some states require every 24 hours. Other states may require maybe you have a longer period of time to report. And in some areas they may actually report things in more or less real time ongoing basis. So that's how the information gets there. The pharmacist is using that information frequently. Any time a prescription comes across their desk, especially if it's going to be a controlled substance, whether it's an opioid or non-opioid drug, that pharmacist's best practice should be querying that system to say, okay, does this patient have fills elsewhere? Are there any other medications on board that maybe isn't filled here, but, you know, could be problematic? So, you know, that, at least in best practice, should be checked with every controlled substance prescription, whether there's a law or regulation that enforces that, once again, that depends on where you're practicing.

Dr. Daniel Alford: All right. So we've talked a lot about different monitoring tools, and probably one of the most common questions I get asked is how often? How often should you do urine drug testing? How often should you do pill counts and so forth. And the answer is it depends on the patient's risk profile. And you could do your own risk assessment looking at patient-level risks, you know, do they have a history of mental illness

and do they have a history of substance use disorder and so forth? Or you could use one of the validated tools that Erica talked about, the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain tool. Regardless, you're going to try to classify your patient as low, moderate, or high risk, and based on their risk level, will determine how often you should do the monitoring or even how often you should see the patient.

So, for instance, if they're low risk, you can see them four times a year and maybe do these monitoring strategies a couple of times a year. But if they're high risk, you might want to see them every couple of months and do these monitoring strategies every couple of months. It's really important, though, to know what your state laws are because they may mandate a certain level of monitoring. For instance, I practice in Massachusetts and they require me to check the PDMP every single time I refill the opioid. So that could be monthly. You also want to keep in mind that monitoring could be more intensive during the first six months of opioid therapy, while you're trying to sort out one, is this patient benefiting? And two, can they take the opioids safely? before you start spacing it all out.

Well, how do you document all this stuff in your visit note? And I think it's useful to use something called the Six A's. One is **analgesia**; two, **activities** or function; three, any **adverse** effects; four, **aberrant** behaviors (any worrisome behaviors?); **affect** is the fifth, that is, does the patient have a mood disorder that you didn't diagnose? And then finally, the sixth A is **adherence**. Is the patient adherent with your marketing strategies, but also adherent with all of the other treatment options that you've recommended for this patient? It's important to document subjective reports from the patient, any co-care providers, care givers, and I usually say reliable family members in quotation, because you need to be aware that some family members have secondary gain for giving inaccurate information. Maybe they're getting some of the opioids from your patient and so they're going to give you a history to support that. Or they had a fight with your patient and they want to harm them in some way and they give you misleading information. So it can be useful information, but you really need to understand where it's coming from.



You also want to, in addition to documenting subjective reports, document objective information, like what did the drug test show? Was it consistent with what you would expect? Any observations that you've seen in clinic, pill counts, PDMP. I find it's really useful to do what's called a 24-hour inventory. I'll say to my patient, "Okay, so what time do you wake up? When do you take your first tablet? When do you take your next tablet and your next tablet?" And sometimes you can find some really useful information about how a

patient is taking their medication, which may be very different than the way you think they're taking it. So take a 24-hour inventory as well.

Now, I'm going to throw this back to Kristin and ask you from a nursing perspective, how does all this monitoring work and what is the role of nursing to do this?

Kristin Wason: Yeah, these can be really interesting conversations, actually. I think a lot of folks, especially in the past several years, they've really been paying attention to the media. They're aware that our community members are really struggling with a substance use and overdose epidemic. And so by having these conversations, I think more often now they're expected. Patients understand that we are concerned about their safety. Sometimes patients do get defensive. And so I think that it's important to say like, Well, but I am worried about you, like I am worried about your safety. This medication does have some risk." And so it's important that we understand that risk because I always feel like my job as a nurse is to make sure that patients are informed consumers. And so I just want to make sure that they understand really the details about their treatment so that that way they can help use them appropriately and when needed, and that they keep us informed if they're struggling with any sort of new symptoms or with taking their medication as directed or with safe storage. And so those discussions about the importance of toxicology screening, about the importance of monitoring, are something that needs to be had. And they can sort of bring up some really interesting points with the patients, just about that with stigma and and how this is sort of a universal precaution that we're taking for everyone now.

Dr. Daniel Alford: Now, we've talked a lot about things that we need to do, and it's sometimes I think we lose sight of what is our role in all of this? And I certainly don't want folks to leave this training thinking they need to be a judge or a DEA agent or a police officer, because that's certainly not our role. We really should be a clinician, which is exactly what we went to school to become.

And how do we do that? Well, we use a risk benefit framework like we do with any other treatment for any chronic disease or disorder. Anything that we recommend, especially around medications, has a risk benefit profile. We definitely do not want to be judging a patient. We want to judge the treatment like anything else that we do in primary care or clinical practice, for that matter.

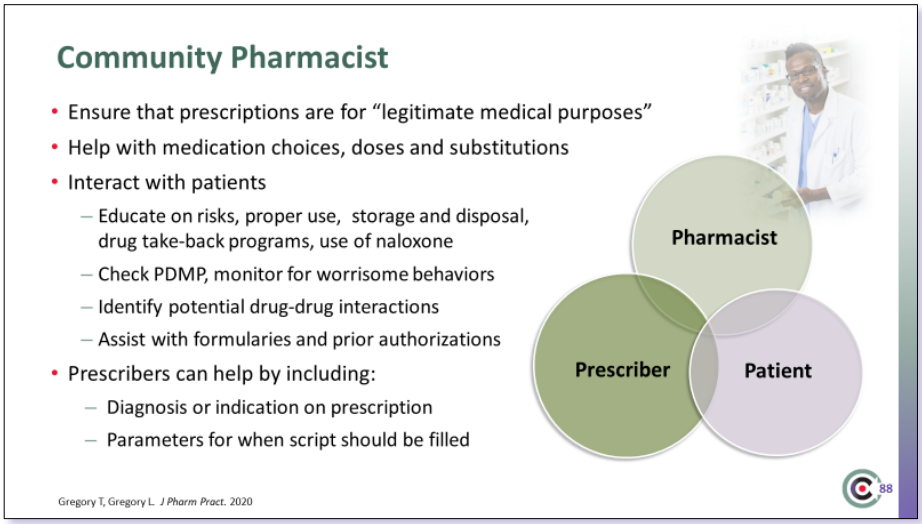
Ilana Hardesty: Putting myself in the shoes of the clinicians who are listening to this. This sounds like a lot of work. How do you get it done?

Dr. Daniel Alford: Yeah, no question that safer opioid prescribing is a lot of work. But in primary care we do a lot of things that are time consuming, like managing patients who have type two diabetes and hyperlipidemia and hypertension and sometimes chronic kidney disease. And we manage it. We figure out how to do it. And when it comes to safer opioid prescribing, I would start by saying your office should have policies and procedures and they should be agreed upon and followed. And one way to monitor if they're being followed is to have patient registries, which allows your practice managers to track how these procedures are being followed.

Importantly, I would say utilize the entire health care team. This can't be all on the prescriber. I'm talking about involving nurses, pharmacists, psychologists, medical assistance, front desk staff. Anyone that works within your practice can help with some of these monitoring practices. And then finally, I would make sure that I have a referral and support resource list. That is, if you have a patient who needs addiction treatment or needs a referral for behavioral health, that you have these resources available to you at the point of care.

So at this point, I want to turn it back over to Pat Kelly, our pharmacist. Pat, in terms of, you know, opioid prescribing and dispensing, what's the role of the community pharmacist? And how can we in primary care collaborate more effectively with our community pharmacists?

Patrick Kelly: As a pharmacist, you work under that pretense of good faith that if you're receiving a prescription, it's for a valid medical purpose for the individual that it's written for. There is an element of that that needs to be kind of brewing in the background, but it doesn't mean that you put your blinders on. In fact, you shouldn't. So to determine if something is legitimate or for a medical use, you use best practices. Even sometimes you use common sense. You say, okay, is this a prescription for – do we know the condition? Do we know the diagnosis code? Does this drug match the condition? Does this dose or this frequency or this regiment? Does this match what, based on my education, training, experience, would be useful for this condition? And then you go into the next steps of, all right, what else is this person taking? Does this cocktail make sense? Is there a drug combination here that is particularly curious or troublesome? And then you add on that kind of retail politic level of it: do I know this person? Have I filled for them before? Does all of this make sense? Is this behavior normal or typical or baseline for this person? And also, is this, you know, prescriber – in your opinion and your education as a pharmacist – does all of this make sense? After that, after all those kind of conditions are satisfied? That's where that good faith element comes in to say, okay, I'm releasing this. I have a custodial role over these substances. All those things have been satisfied. You know, you have to have that good faith that, yes, everything else is hopefully panning out in the background.



Dr. Daniel Alford: So what can I as a prescriber do to make that whole process easier for my community pharmacist, in order to better collaborate on these patient care issues?

Patrick Kelly: You know, open and clear communication is critical. When these prescriptions are transmitted to the pharmacy, and most are electronic now, is to utilize,

you know, two little areas on that prescription and it can save a lot of headache and assuage a lot of the pharmacist's concerns. One, is there a diagnosis or an indication? You don't necessarily have to find the diagnosis code and find the ICD-10. No, if you can write something as simple as "PRN lower back pain," you know, "knee pain," "bilateral elbow pain," something like that, that puts it in perspective for the pharmacist. And then in the notes field, if you have that capability, if this is something where someone's on something chronically or as the prescriber, hey, "I've already had a conversation about a unique situation with my patient. They're going on vacation. They're going to be about a week early. They're going somewhere where they can't go visit a pharmacy" or, "hey, this patient had some kind of issue at their home or there was a fire or a flood and they lost something." You may have had all that conversation and deemed that, of course, it's appropriate; I should release this early. I should continue the therapy. But if that's not relayed to the pharmacist, they're starting from square one saying, "hey, why is this early? What's going on here?" And until you can figure all those things out, you know, at best you're dealing with a delay of care and potentially at worst, you're putting that prescriber in a tough situation. The patient is kind of sitting around saying, "hey, I did nothing wrong. I told my doctor this." And, you know, it's all lack of transparency in communication. So utilizing that diagnosis code or indication, especially if it's a PRN drug, and then utilizing that note's field for those kind of, you know, one off situations.

[Music]

Ilana Hardesty: Thank you. Patrick Kelly, Kristin Wason, Dr. Daniel Alford, and Dr. Erica Bial.

After her last appointment, Michelle went to the emergency room in opioid withdrawal, asking for an early refill of her oxycodone prescription because she ran out early. Join us next time when Michelle goes back to her PCP after that ER visit. Is she addicted to oxycodone? How would you respond to this worrisome behavior?

[Music]

SCOPE of Pain was developed in collaboration with the Federation of State Medical Boards, and is supported by an independent educational grant from the Opioid Analgesic Risk Evaluation and Mitigation Strategy, or REMS, Program Companies.

Production by Rococo Punch.

To follow up on any of the material you heard today, please visit our website, scopeofpain.org, for visuals and other relevant materials. To receive credit, you'll need to listen to all eight episodes and then go to scopeofpain.org to complete a post-test and evaluation.

I'm Ilana Hardesty. Thanks for listening.

SCOPE of PAIN: Safer/Effective Opioid Prescribing Education

Podcast - October 1, 2023

Episode 6

[Music]

Ilana Hardesty: Thanks for listening to Boston University Chobanian & Avedisian School of Medicine's Safer and Competent Opioid Prescribing Education: *SCOPE of Pain* Podcast Series. I'm Ilana Hardesty.

This series has eight episodes. If at any point you want more information on receiving credit, please visit our website, scopeofpain.org. There are also resources that accompany this series. All of it can be found at scopeofpain.org.

In this episode we'll speak again with Dr. Daniel Alford and Dr. Erica Bial. Let's go back to our case. Michelle had been doing well on her pain treatment plan for her painful diabetic neuropathy and chronic hip pain for 11 months. Then her PCP was notified that Michelle was seen in the emergency room of a local hospital requesting an early refill of her oxycodone prescription. The ED physician noted that she was in moderate to severe opioid withdrawal and gave her a prescription for enough oxycodone pills to last until her next PCP appointment in one week.

At the follow-up appointment, Michelle noted that her foot pain had worsened in the last month and is a ten out of ten most days. She started taking an extra pill every day and ran out early. She's concerned that she's become used to the current dose and says her husband thinks she's addicted. She has trouble going to work and trouble sleeping and requests an increase in her dose. Her PCP reeducate her about the serious risks of self-escalating her dose.

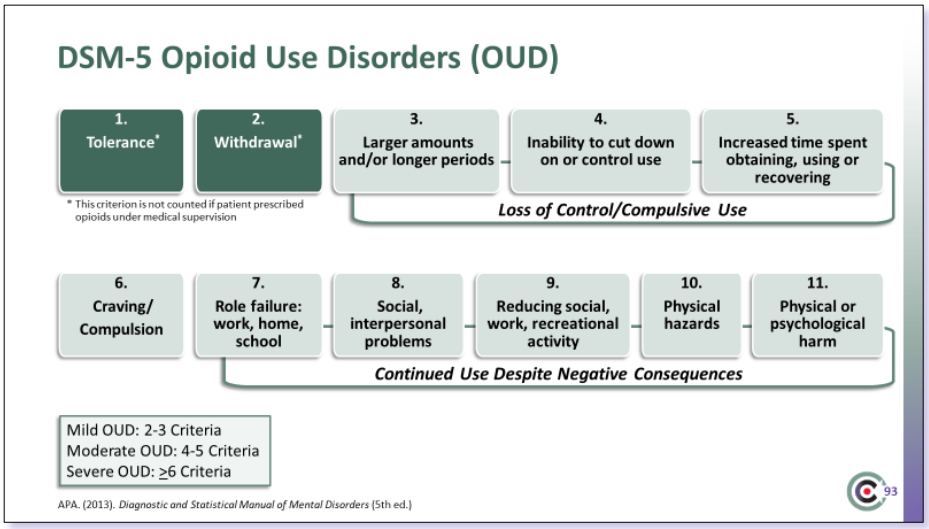
Dr. Alford, what do you think is happening with Michelle and how would you respond to this recent worrisome behavior?

Dr. Daniel Alford: So, it's certainly worrisome. And I think the important thing is to think about it in a differential diagnosis. Is this behavior because she's substance seeking? That is, does she have an opioid use disorder? Has she developed an addiction? Maybe she's self-treating other symptoms. We know that opioids make people feel better. So maybe she's treating an anxiety or insomnia. Maybe there's some diversion, which could be sharing or selling her opioids.

But on the other side, maybe it's all pain relief-seeking. Maybe her disease, her neuropathy has worsened. Maybe she has some new painful condition that she's self-medicating. Maybe her pain is actually not very opioid responsive, and we didn't realize that initially. Maybe she has developed opioid analgesic tolerance. Maybe she has withdrawal-mediated pain, or maybe she's developed something called opioid induced hyperalgesia.

Let me just take a step back for a moment and say, remember that someone who's on opioids around the clock will develop physical dependence. There may be times during the day where their opioid level drops to a point where they actually have some withdrawal that's experienced as worsening pain. They take their opioid, their pain feels better. Are they treating withdrawal or are they treating their pain? That is part of the rationale for thinking about using long acting opioids to prevent that up and down and potential for withdrawal-mediated pain.

We talked about substance-seeking and pain relief-seeking as potential explanations for this worrisome behavior. But maybe it's a combination of all the above. Maybe she has worsening pain. Maybe she's developed an opioid addiction, and maybe she's diverting some for income.



Now, I keep referring to opioid use disorder. And let me just remind everybody, what is it? And it's really based on the diagnostic criteria of the DSM-5. It includes 11 symptoms. The first two are tolerance and withdrawal. And remember that when a patient is on chronic opioids for chronic pain, they're going to have tolerance and potential withdrawal or physical dependence. And so the DSM-5 says we can't use those two criteria in making the diagnosis of an opioid use disorder in someone who's being prescribed opioids. But that leaves us with nine other criteria, three of which are really talking about loss of control and compulsive use. Is the person taking it more than expected, or are they just having a hard time controlling their use? Then there are five criteria that deal with continued use despite negative consequences. That is, as a result of being on opioids, is this person performing poorly at home and school or work? Are they having some interpersonal social problems? Is the opioid use basically worsening their function and worsening their quality of life? Yet they still want more. And then finally, the last criterion would be craving compulsion. That is, is the patient describing this urge to take an opioid every single day beyond their pain? And based on the number of these criteria, you could diagnose a mild, moderate, or severe OUD depending on the number of criteria.

Dr. Erica Bial: You know, it's really hard to talk about possible OUD with our patients. And so when we recognize opioid use disorders, what I might suggest is that we give really specific and timely feedback. So don't wait to talk to your patient about concerns. You want to give specific and timely feedback about behaviors that are raising your concerns for possible or OUD. You know, "I noticed you seem to have a loss of control," or that they're meeting the criteria for compulsive use; talk about their demonstration of continued use

despite evidence of harm. And you know, it's important to remember that patients may suffer from both chronic pain and OUD. Ultimately, patients might just really disagree with us and we might need to agree to disagree with the patient. But at the end of the day, the conversation really needs to focus on the idea that the benefits are no longer outweighing the risks. And that on balance, and I sort of suggest to providers that are uncomfortable talking about this with their patients, that they just practice like a mantra saying aloud, "I cannot possibly responsibly continue prescribing opioids because I feel it would cause you more harm than good." Right? Or some other way to say it would be unconscionable for me as a person who cares about you to continue prescribing a medication that is causing you more harm than good. And you should always feel comfortable to offer a referral to addiction treatment when you think addiction exists, even if the patient disagrees.

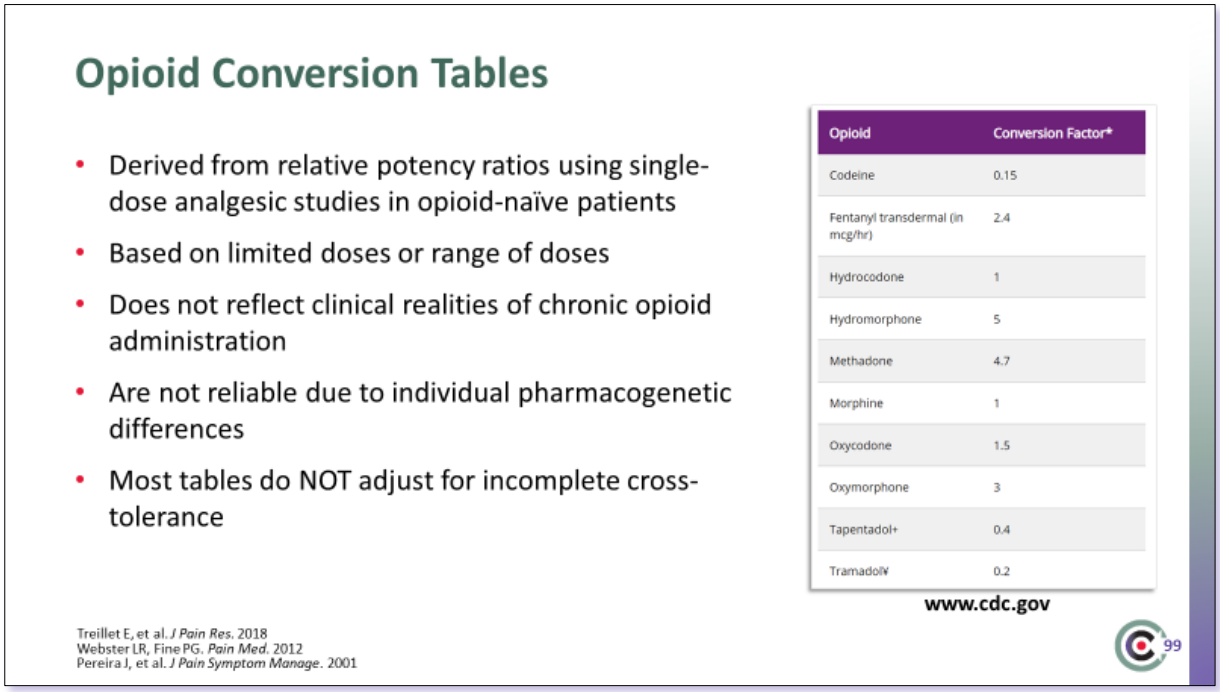
Dr. Daniel Alford: I also realize that we've used the term opioid induced hyperalgesia. It's this strange, paradoxical enhancement of pain sensitivity in a patient who's taking opioids chronically. It doesn't happen to all patients on chronic opioids, but it happens to some. Unfortunately, the underlying pathophysiology and how common it is – what's the true incidence – are unknown, and unfortunately there are no official criteria or guidelines for diagnosing it. But what do I see clinically? I see kind of a generalized, diffuse, ill-defined pain that's not necessarily located at the source of the original pain. Some patients have a really hard time appreciating that this might be their problem. That is, they're saying, "I have terrible pain and I need more opioid." And I'm thinking, well, maybe it's opiate induced hyperalgesia and we need to decrease the dose, which seems very counterintuitive to patients and can be a very challenging discussion to have with them. But if I'm convinced that the patient isn't benefiting and this is a possibility, I'm going to try to educate them about it and then move in that direction, which would be to taper your opioids. And unfortunately, there's also no standardized approach on how to taper opioids to manage this. But I would start to decrease the dose and start to increase other treatments for their pain.

Dr. Erica Bial: I agree it's such a leap of faith for patients when I try to explain that on the basis of this diagnosis that I think that your medication might be paradoxically making you more sensitive to pain.

But I think we need to have a really open and honest conversation with our patients when we're recognizing a lack or loss of benefit. So, you know, what are the next steps? We want to reassess factors that are affecting the patient's pain and try to re attempt to treat underlying disease and co-morbidities. And sometimes those co-morbidities might be seemingly unrelated to the pain generator. So if the patient has high stressors at home, if the patient's nutrition is poor, if their sleep is poor, if they are suffering from depression or symptoms of anxiety, for example, all of these things can kind of magnify the pain experience, and treating them will improve the patient's global level of function. So we want to consider adding or increasing non-opioid and nonpharmacologic treatments. Let's not forget about those. We could add breakthrough medications. We could switch to a different opioid, so thinking about what we used to call opioid rotation. But we want to avoid dose escalation, if we can, to high dose opioids.

So in considering breakthrough medication, the first choice, which can be surprising to many, is a non-opioid. So if a patient is maintained on a chronic opioid medication, like our example patient, we might consider adding a nonsteroidal anti-inflammatory medication or even acetaminophen. Sometimes exploiting that synergy gives us some added benefit. We could consider adding in a short acting opioid, either the same molecule or a different molecule, or we could consider adding a dual mechanism agent like tapentadol or tramadol that we talked about before.

Dr. Daniel Alford: There are three potential reasons to consider switching from one opioid to another. One is to restore analgesic efficacy, that is to try to get some benefit when the other opioid is no longer benefiting the patient or didn't benefit them in the first place. Two, to limit any adverse effects. So maybe the opioid they're currently on is causing them some intolerable adverse effect that a new opioid might not. And then three, finally, is to try to decrease the overall opioid dose that is, decrease the overall morphine milligram equivalent. It's important to remember that the rationale behind switching from one opioid to another is based on the large intra-individual variation in response to different opioids. We talked about this earlier, but not all patients respond to the same opioid in the same way. And remember, it's based on variants of the mu opioid receptors and how opioids are metabolized. But this concept of opioid rotation is really based on limited evidence, as most trials looking at it, have been retrospective and have studied small numbers of patients.



Now, if you're going to go that route and switch to a different opioid, you're going to need to go to a conversion table or an equal analgesic table. What does equal analgesic mean? It means it's the dose at which two opioids at steady state provide the same pain relief. These tables are derived from relative potency ratios using single dose analgesic studies in opioid-naive patients. And they're really based on limited doses and ranges of doses, and they don't reflect the clinical realities of our patients on chronic opioid therapy for chronic pain.

And they're often not reliable because of the individual pharmacokinetic differences between patients that we talked about earlier.

And one of the most important take homes here is that most tables do not adjust for incomplete cross-tolerance. Cross-tolerance is the development of tolerance to the effects of pharmacologically-related drugs, particularly those that act on the same receptor site. In this case, we're talking about opioids acting at the mu opioid receptor. So what's meant by incomplete cross-tolerance? Well, when switching from one opioid to another, you need to assume that cross tolerance is incomplete, which means that the starting dose of the new opioid needs to be reduced in order to prevent overdosing, like sedation or respiratory depression.

Dr. Erica Bial: So why don't we do some math? If we think about our sample patient. Where would you start if we're going to convert her away from her current oxycodone?

Dr. Daniel Alford: All right, so let's remember that she's on long acting oxycodone, 15 milligrams twice a day or 30 milligrams of oxycodone, which is the equivalent of 45 morphine milligram equivalents. So that's our starting point. And I would go to – there are various sites to make these conversions – but I like globalRPH.com, which is a fancy calculator that allows me to put in that oxycodone 30 milligram total daily dose then allows me to make a reduction due to that incomplete cross tolerance that we talked about. And it's a totally inexact science. The recommendations are to decrease by 25 to 50%. So let's pick something in the middle: a 33% reduction. And then I put in the opioid that I want to switch to, let's say, for example, morphine. And I say calculate. And it says the dosage for morphine based on that 33% reduction would be 30 milligrams total daily dose. So I'm going to dose it as long acting morphine, 15 milligrams twice a day, which is the equivalent of 30 morphine milligram equivalents, which is 15 less than we started.

So again, I'm trying to achieve three things. One, hopefully with this morphine dose will get improved analgesia. Two, we'll get rid of some adverse effect that she was suffering with the oxycodone, for example. And then three, we've already made the reduction in the total morphine milligram equivalents just by making this conversion.

[Music]

Ilana Hardesty: Thank you, Dr. Alford and Dr. Bial. Over the next 18 months, Michelle's pain improved on a stable morphine dose of 15 milligrams twice per day, and she had no recurrent, worrisome medication-taking behaviors. Along with the morphine, her acetaminophen was continued and her gabapentin was titrated up, and low dose nortriptyline was added at night for her neuropathic pain. Michelle attended acupuncture therapy and a monthly chronic pain support group. Her individual PEG scores remained between five and six on the ten-point scale. She remained employed and remained adherent with treatment and monitoring. She continued with her regularly scheduled follow- up visits.

Next time we'll look at some other possible scenarios for how this case might go, including what happens when the opioid rotation doesn't help and the patient doesn't improve. We'll discuss what the next steps might be.

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SCOPE of PAIN: Safer/Effective Opioid Prescribing Education

Podcast - October 1, 2023

Episode 7

[Music]

Ilana Hardesty: Thanks for listening to Boston University Chobanian & Avedisian School of Medicine's Safer and Competent Opioid Prescribing Education: *SCOPE of Pain* Podcast Series. I'm Ilana Hardesty.

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In this episode, we'll find out what happens when an opioid rotation for our case study, Michelle, does not help her pain. And in a separate scenario, we'll follow Michelle when she demands to be tapered due to the stigma she's experiencing at her PCP's office and at the pharmacy.

We'll be speaking with Dr. Daniel Alford and Dr. Erica Bial, and we'll bring back our patient, Don, who has chronic pain managed with long term opioid therapy.

First, let's look at what happens when the clinician has switched opioids but with no effect. Remember from the last episode that Michelle had been switched from oxycodone to morphine. Despite one trial dose increase of the morphine, she demanded that she be changed back to oxycodone. After being converted back to oxycodone, her pain did not improve. She is now on medical leave from her job and, according to her husband, spends most of the day in bed. She's been adherent with urine drug testing and pill counts, but clinic staff reported on multiple occasions that she was rude and confrontational when she tried to be seen without an appointment. She states that she's now smoking marijuana to help with her pain.

Dr. Alford, what do we know about marijuana and pain?

Dr. Daniel Alford: I'm getting this question a lot from patients these days, mainly because cannabis is being legalized in many states. And it's important to remember that when we talk about cannabis, we're really talking about over 60 pharmacologically-active cannabinoids, and this includes both the psychoactive THC and cannabidiol or CBD. There are meta-analyzes that have found moderate quality evidence that cannabinoids can be effective for treating chronic pain, particularly neuropathic pain. So let's compare their efficacy compared to the things that we normally prescribe. So for example, for a 30% pain reduction, the number needed to treat to get that 30% pain reduction is about 24 for cannabinoids. And that's in comparison to 4 to 10 for tricyclic antidepressants, opioids, gabapentinoids, and SNRIs. So while they may be effective for treating pain for some

individuals, fewer patients will benefit from them compared to the things that we have available to us to prescribe.

I'd say the other piece that's a little confusing from a prescriber perspective is, what is my patient actually getting? We're sending them to a dispensary. Which pharmacologically-active cannabinoid are they actually getting? And so it's a little tricky to say, okay, go to the dispensary and get a cannabinoid when you don't know exactly what they're getting and whether or not they're going to get benefit. But the bottom line is some patients may benefit, but it's not nearly as effective as the medications that we have available to prescribe.

Ilana Hardesty: So it seems like we're at an important decision point for our patient's care. Do we continue to escalate her opioid dose like she wants? How do we talk with her about it? I can imagine that if you decide not to increase her dose, it's going to be a very uncomfortable conversation.

Dr. Erica Bial: You know, sometimes it is, but I don't think it has to be. I think that we need to continue to use that usual medical model and talk openly about the patient's continued lack of benefit. You know, not all chronic pain is opioid-responsive, as much as I think oftentimes we wish it would be. It's just a really imperfect treatment. And more opioid is not necessarily better, which can be counterintuitive for many patients as well as providers. More opioid might increase the risk of adverse effects, and it's important to remember, and I have actually seen it clinically many times, that some chronic pain paradoxically improves after opioid tapers for many reasons.

So how do we talk about continued lack of benefit? I think it is central to the conversation, and to having that conversation not be so uncomfortable, to stress how much you believe in and empathize with the patient's pain severity and the impact of that pain on the patient's daily life. Expressed frustration: "I wish that I had a good pill or an easy treatment that would fix this, and I don't. And this is complicated." So focusing on the patient's strengths, recognizing the things that the patient can do and the skills that the patient does have, that we can capitalize on to improve their global wellness. And encourage therapies for coping with pain. I think there's really a level of acceptance that has to come with this. I have this conversation probably on a daily basis where the patient says, you know, "Okay, Doc, but I just don't want any of this pain." And I try to set realistic expectations. I say, "you know, there's nothing that I have in my toolbox that will make your pain zero. But I want to make the impact of the pain less in your life," and really come up with therapies that help the patient to cope with their pain. We want to show commitment to caring about the patient and their pain, even without the opioid, that we're not firing the patient, that we are firing the treatment that has failed. And then we want to schedule very close follow up during and after a taper. And this is a very critical importance when we decide to lower the dose or discontinue an opioid.

Dr. Daniel Alford: So discontinuing opioids can be challenging for sure. But let's just emphasize that you don't need to prove with 100% certainty that the person has developed an addiction or that they're diverting. You only need to assess and reassess the risk-benefit ratio. That is, if the patient's unable to take the opioids safely or they're not adherent with

monitoring, then discontinuing opioids is completely appropriate, even in the setting of benefits. You then need to determine how urgent you should discontinue the opioids, and it's based on the severity of the risks and harms. Make sure you document the rationale for discontinuing your opioids, and sometimes you don't even need to taper the opioids if the person doesn't have physical dependence.

I just want to emphasize what Erica had said, and that is you are not abandoning the patient. You are abandoning the opioid, either because it's not helping or it's hurting or both. Now, when you discontinue opioids, you need to keep in mind that there are some risks to doing so. Well, there've been some recent observational studies that have identified harms, like increased rates of suicide and overdose, that are associated with opioid tapering or discontinuation. There was a recent comparative effectiveness study of well over 200,000 individuals who were on stable, long term opioid therapy, stable being defined as there was no evidence of opioid use disorder or opioid misuse. They found that opioid tapering was actually associated with a small but absolute increase in opioid overdose and suicide compared to maintaining somebody on a stable opioid dose. And in that article, I think they importantly summarized the following: and that is that tapering or discontinuation of opioids should **not** be considered a harm reduction strategy for patients who are receiving stable, long term opioid therapy without any evidence of misuse. And when you do decide to taper someone because of lack of benefit or misuse, you need to do it carefully. And keep in mind that there is an increased risk of suicide and overdose.

Dr. Erica Bial: So it really brings us back to this idea of the risk-benefit framework. And I know that you and I have talked so much about this in many aspects of the treatment of patients with opioids. But here again, we want to use that risk benefit framework and how we talk with our patients, weighing the benefits of the opioid – so pain, function, and quality of life – against the risks and harms – misuse, addiction, overdose, or other adverse effects.

So when I make the decision where I think that the risks are outweighing the benefits, I find that many patients might be very fearful of that process. And it's really useful to be ready to avoid a number of pitfalls. So patient might say, "But I need the opioid," or make it about the provider patient relationship: "Don't you trust me?" You know, "I thought we had a good relationship; I thought you cared about me." "If you don't give them to me" – and I hate this one, the scary ultimatum – "I will drink, use drugs, harm myself," or, you know, they want to terminate the relationship with you. "Can't you just give me enough and I'll find a new doctor?"

And your response needs to come back to that risk-benefit framework and a useful mantra. "I cannot continue to prescribe a medication that is not helping you or is hurting you or both."

[Music]

Ilana Hardesty: Despite her PCP's best efforts to explain to Michelle why the treatment plan will include tapering off opioids due to a lack of adequate benefit, and focusing on increasing non-opioid pain treatments, including cognitive behavioral therapy, Michelle keeps on insisting that she needs a higher dose of oxycodone. Though she's offered

alternative pain treatments, she becomes increasingly angry, stating that she's going to find a new doctor. Michelle storms out of the office and says she'll be calling patient advocacy. Let's think about other ways that Michelle's case study can end. Let's go back to when she was on her original dose of oxycodone. She was doing well on her pain treatment plan, including oxycodone, for her painful diabetic neuropathy and chronic hip pain for 11 months. But then she started to struggle and become frustrated with the rules and stigma of taking opioids. Michelle calls her PCP after being unable to refill her oxycodone prescription because of new insurance requirements. She's angry and crying with frustration and notes the stigma that she feels in her treatment by her family, by the staff at the PCP office and at the pharmacy. She says she's tired of being treated with suspicion, and like a drug addict and criminal, and just wants to get off the pills. This is a great time to hear again from Don, our patient.

This is a great time to hear again from Don, our patient. Don, what have been your challenges in continuing on a therapy that works for you, even with its risks?

Don (Patient): One way to describe it would be that you would go to the doctor's office, pick up the prescription, you would bring it to the pharmacy. And it was sort of like a trail of stigma, you know, sort of they get used to seeing you like once a month. And, you know, they're here to give you the prescription and just the people at the desk. Right. Just the sort of administrative people that you're walking past. And then sometimes they're put in a position of having to say, I can't give this to you until you go downstairs and pee in the bottle. And then you're sort of walking past the lab people. And it's hard to imagine that anybody would see being drug-tested as neutral, certainly not positive. I mean, it's an index of some kind of suspicion. And then, you know, of course, you get the same thing from practitioners that don't know you.

At one point, I was given a contract that was, I don't know, written by an angry physician. And it said things like, "under no circumstances will a lost supply of pills be replaced before the next month. We don't care whether the dog ate it; t fell down the drain. We've heard all the stories." That seemed like a bizarre way for a caregiver to be addressing patients. But clearly, I mean, a lot of a lot of prescribers, I think, have felt burned and basically gotten angry. And some of that anger, I think, gets pointed at people who need medication. I think that's in some ways the ultimate stigma because it's being reduced from an individual human being to just sort of an irritating category of patient.

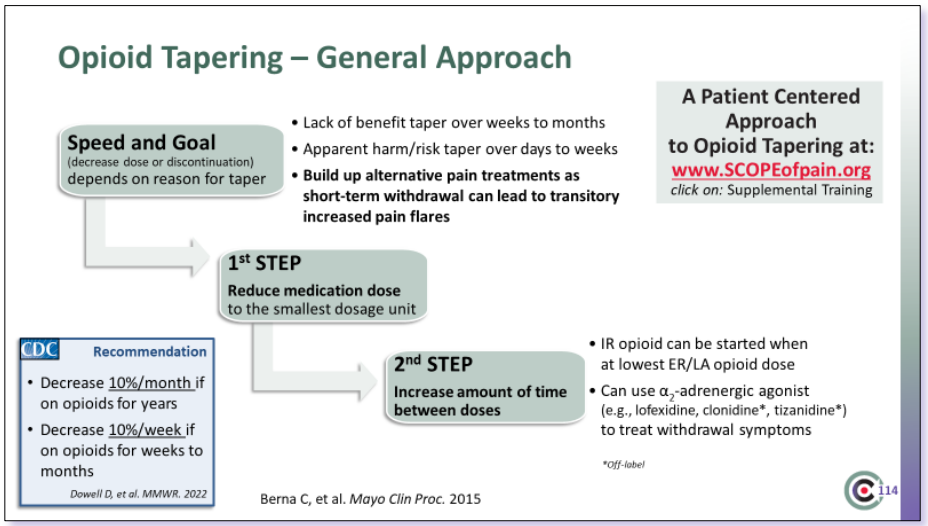
Ilana Hardesty: Dr. Bial, how do you taper someone like Michelle, who's requesting to come off opioids and do it safely?

Dr. Erica Bial: So this is actually quite challenging question because there are no validated protocols in patients on opioids for chronic pain in terms of how we should necessarily assume is the right way to taper. There is some very low-quality evidence that suggests that several types of opioid tapers might be effective and that pain, function, quality of life, they all might improve for some patients with decreased opioid use, as we've talked about before. There was a study that found that 62% of patients in a pain clinic who completed a voluntary, patient-centered opioid taper over four months with a greater than 50% dose reduction, found that neither their pain intensity nor the pain's interference with their lives

increased with opioid reduction. And surprisingly, maybe, success was not predicted by the patient starting dose, baseline pain intensity, or how long the patient had been prescribed the opioids, or any other identified or measured psychosocial variable.

There was an additional study of over 100,000 patients also on long term opioids and found that annual tapering increased and was more likely in women and those on higher dose opioids at the starting point. 19% of those patients had a maximum dose reduction rate that exceeded the usual 10% per week that is commonly recommended. But it's important to recognize that in the situation of both of these studies, these are quite specialized, maybe non-typical, non-generalizable patient populations: they volunteered.

So maybe a general approach to opioid tapering is again that risk to benefit kind of delicate balance. We want to think hard about what's our speed and what is our goal. How quickly do we need to decrease the patient's opioid will really depend a lot on the reasons for that taper. So if the patient's just suffering a general lack of benefit but there isn't acute harm, you might take weeks or months or maybe even, in a patient on a very high dose, a year to gradually, gently bring them down off their opioid. But if there is apparent harm or risk, if the patient has suffered a recent overdose event, for example, that might be much more rapid – days, two weeks. And while we are in the process of tapering their medication, I think it's really important to remember to build up alternative pain treatments as short-term withdrawal can absolutely lead to transitory increases in pain flares, as Dan mentioned earlier.



So how do you do it in practicum? First step is look at the patient's overall daily dose and reduce their medication dosage. So if a patient is on a long acting opioid, they're taking it twice daily. We want to gently start to lower that to the smallest dosage unit. And then you might find you run out of what's available in that smallest dosage unit. And so a next step might be to try to increase the amount of time between doses. And we could transition the patient from a long acting formulation to a short acting formulation once we have run out of that lowest available dose. Also, consider that you can use Alpha-2 adrenergic agents like – granted it's off-label use – but like clonidine or tizanidine, or on-label use with medications like lofexadine, to help to blunt withdrawal symptoms. So the CDC has some recommendations here, and these are very general: that we could decrease opioids as slowly as 10% per month if the patient has been on opioids for many years, and it's really just for lack of benefit. We could decrease their patient's opioid as quickly as 10% per week, if the patient has been on opioids for weeks to months or if we have more urgent reasons for discontinuation.

Dr. Daniel Alford: Erica, I just want to give a lesson learned that I've learned over the years, and that is what you don't want to do is give the patient a 30 day taper because more often than not they will come back and say, "I finished my opioids and I'm only two weeks into the taper," because they didn't follow the exact tapering instructions. So I really give short duration of opioids, and I'm very clear in saying I'm not going to refill your opioid early. And I think that really sells the importance of following the taper as prescribed.

Dr. Erica Bial: I agree. And also, that's a time when we want to increase our monitoring. And so I might see the patient week-to-week or every time that I'm making an adjustments that there's no opportunity, or certainly a decreased opportunity, for those overuse or potential overdose events.

[Music]

Ilana Hardesty: Thank you, Dr. Bial and Dr. Alford, and thanks again to Don, our patient.

Over six months, Michelle successfully tapered off oxycodone. Her neuropathic pain was moderately controlled on a combination of acetaminophen, nortriptyline, gabapentin, and capsaicin cream. Michelle joined a monthly chronic pain support group. Her individual PEG scores remained between four and five on the ten-point scale. She remained employed and remained adherent with treatment and monitoring. She continued with her regularly scheduled follow up visits.

Join us for our final episode, when we discuss another possible scenario where Michelle was doing well on her oxycodone but then had an unexpected urine drug test result: it was negative for her prescribed oxycodone. Is she diverting her oxycodone? How would you respond to this worrisome development?

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SCOPE of Pain was developed in collaboration with the Federation of State Medical Boards, and is supported by an independent educational grant from the Opioid Analgesic Risk Evaluation and Mitigation Strategy, or REMS, Program Companies.

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I'm Ilana Hardesty. Thanks for listening.

SCOPE of PAIN: Safer/Effective Opioid Prescribing Education

Podcast - October 1, 2023

Episode 8

[Music]

Ilana Hardesty: Thanks for listening to Boston University Chobanian & Avedisian School of Medicine's Safer and Competent Opioid Prescribing Education: *SCOPE of Pain* Podcast Series. I'm Ilana Hardesty.

This series has eight episodes. If at any point you want more information on receiving credit, please visit our website, scopeofpain.org. There are also resources that accompany this series. All of it can be found at scopeofpain.org.

In this final episode, we'll speak with Dr. Erica Bial, Kristin Wason, and Dr. Daniel Alford.

[Music]

Let's open with our case study, Michelle. She's been doing well on her pain treatment plan, including oxycodone for her painful diabetic neuropathy and chronic hip pain, for 11 months. Her urine drug tests consistently returned expected results except once when it was opiate positive but negative for oxycodone, raising concerns for opioid misuse, including possible diversion. Michelle asserted that she had been taking her prescription on schedule and denies sharing or giving her oxycodone to others. A confirmatory test could not be done due to the urine sample being too small. She has forgotten to bring in her pill bottles for pill counts on two occasions. The PCP shares his concern with Michelle and tells her that since these instances put her at greater risk for harm, he'll be monitoring her more closely, including more frequent urine drug tests and pill counts. There were no additional unexpected test results over the next two months.

Dr. Bial, how would you talk to patients if you're worried they may be diverting some of their opioid pain medications?

Dr. Erica Bial: It can be a very tough conversation, and I think it's really an important one. So talking about possible diversion with our patients oftentimes starts with education. We should remind our patients that prescription drug diversion is one form of opioid misuse. So this will be defined as the giving, selling, or trading of prescription medications. So why do we care so much? Because surveys indicate that family and friends are actually the most common source of diverted opioids in our communities. So we want to discuss very openly and with great care and compassion why we're concerned about diversion. So, for example, if a patient comes in and the patient's urine drug screen was negative for the prescribed opioid, or there have been non-adherence with pill counts, or some other objective measure as to why you are concerned, talk about it openly. It's also important to be prepared to discuss your inability to continue to prescribe opioids if the opioid is being diverted to others.

[Music]

Ilana Hardesty: Two months later, Michelle is brought to the emergency department by ambulance after suffering an overdose. Her husband explains that he found her on the bathroom floor and administered naloxone, to which she responded. And then he called 911. Her husband reports that Michelle's pain has increased recently, resulting in her taking extra oxycodone pills and taking some of her father's morphine. She's been sleeping a lot and calling in sick to work. He acknowledges he may be in denial about Michelle's problem, and he's been trying to focus on work instead. He reports Michelle has not been able to visit with friends or engage in her hobbies, and he was rationalizing, assuming it was due to the pain and not the medications. He reports hearing a staff person at the ED refer to Michelle as a drug abuser, and he's upset by this characterization.

Let's turn to Kristin Wason, our primary care nurse. Kristin, what have you experienced around the use of stigmatizing language by members of the health care team? And how do you address the issue?

Kristin Wason: I try to address it right away. I find a lot of times it's not mal intended. A lot of times our care team members, our coworkers, are using language that is like well ingrained in them that they've been saying for decades. They don't realize how harmful it is actually, and how disrespectful it is to the patient and how it can be very counterproductive to forming a therapeutic relationship. And so why are you calling this patient with a substance use disorder an addict? It's something that we don't say like they're more than just their disease. They're a person first. And so we really need to sort of make sure that we're modeling that appropriate language for our patients. And a lot of times patients will still say things like addict or alcoholic. But in our setting, we don't say that. We're treating a medical condition and we need to make sure our patients know that this is a safe place where they're going to be respected. And we want to make sure we're not documenting that stigmatizing language either. Especially now patients have access to their chart. It can make it seem like we don't care about them when really we care a lot about them.

Ilana Hardesty: So, Michelle had an overdose. Dr. Alford, does her treatment plan change after this?

Dr. Daniel Alford: So my treatment plan would change. And at this point, it's important to highlight that there were a couple of studies recently published that identified some important treatment gaps following an opioid overdose. One is that opioids were dispensed to over 90% of patients after a non-fatal overdose, and that may be truly indicated. However, we need to realize that these patients are at particularly high risk for a subsequent overdose. What they found in this study was that there was a 7% repeat overdose rate in those patients who continued to get opioid prescriptions, and that the two-year cumulative incidence of a repeated overdose was as high as 17% for patients who were on high opioid doses after that index overdose. So really keep in mind that these patients are particularly high risk for a subsequent overdose. The second finding in these studies was that less than a third of opioid overdose survivors ended up receiving a life-sustaining medication for their opioid use disorder in the subsequent 12 months. And the reason why

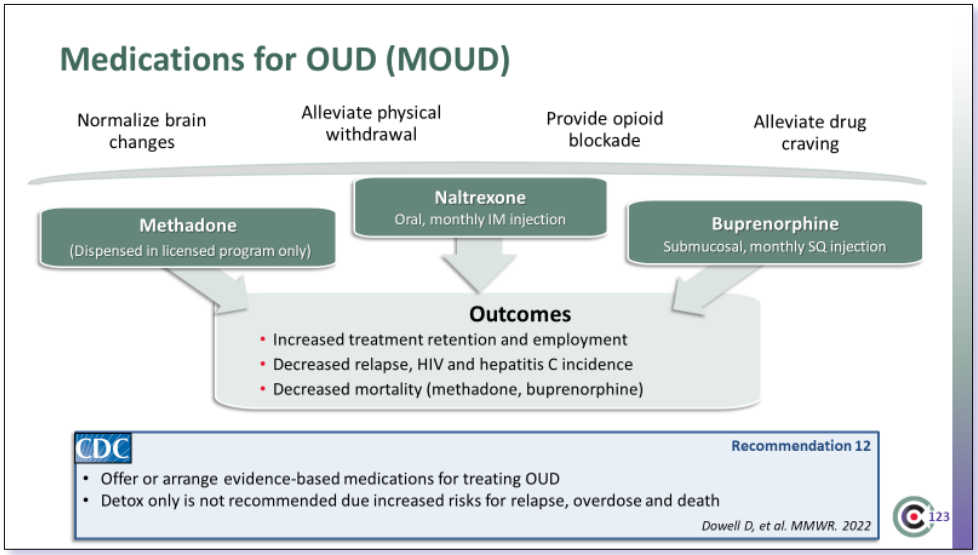
that's important is that those that did receive a medication for their opioid use disorder, there was a decrease in all cause and opioid-related mortality.

Now, we talked about how to diagnose an opioid use disorder by the DSM-5 criteria. But keep in mind that, in general, we should think about opioid use disorder as a chronic relapsing brain disorder that's characterized by compulsive use despite negative consequences. And it involves changes to the brain involved in the reward and stress and self-control pathways, and that these changes in the brain can persist even after the drug use has stopped. And like other chronic diseases or disorders, opioid addiction often involves cycles of relapse and remission, and that without treatment, opioid use disorder is progressive and can result in disability or premature death.

The good news is we have medications that we can use to treat opioid use disorders, and they're highly effective. Kristin, can you talk about the medications and what your experience has been in treating patients with them?

Kristin Wason: Yeah, this is a part of my work that I really, really enjoy. Working with patients with substance use disorders has been like truly one of the best things I have done with my career. It's amazing to see patients really engage in treatment and then, you know, the symptoms of their disease decrease and they thrive. You know, they feel so much better, they function so much better. And not only do their symptoms go away, but their life just gets so much better. And they're so grateful that you were able to sort of like work with them on that, that like really stigmatized condition. Right. And so the medications are highly effective.

We have three to treat an opioid use disorder: methadone, buprenorphine, and naltrexone, and all three of them can decrease cravings to use illicit opioids. All three of them can decrease use of illicit opioids. All three of them can be dosed like once a day. Naltrexone and buprenorphine also have once monthly injectable formulations available on the market now, which is really attractive to most patients who are looking for a simplified regimen. But methadone or buprenorphine in particular, like patients can start them pretty easily, just within about a day of last use of a substance like fentanyl. And instead of going into withdrawal like every 1 to 2 hours, which happens with fentanyl now, they can start treatment and they can feel normal all day. It's like amazing to them. And so it's really cool that like partner with patients on that and be a part of that journey with them.



Dr. Daniel Alford: Now I know you know, obviously buprenorphine and naltrexone can be prescribed in a primary care practice, but methadone cannot. Can you talk about that a little bit?

Kristin Wason: With methadone: it can be prescribed at a pharmacy for pain management, but for an opioid use disorder, patients really need to have that medicine dispensed to them. What we'll do is if a patient is identified as having an opioid use disorder, we'll talk to them about the three different forms of medication. Again, I like to make sure my patients are informed consumers and we give them a menu of services they can help choose what works best for them. And if they're looking, or we come to the conclusion that methadone is the best medicine for them, I really have to call a methadone clinic and try to facilitate a warm handoff because we can't just prescribe that methadone for their opioid use disorder. It really needs to be dispensed an opioid treatment program due to those federal and state regulations.

Dr. Daniel Alford: So speaking about naltrexone and buprenorphine, now there is no needed additional training or a waiver to be able to prescribe buprenorphine. There's still a reluctance among many to take this type of treatment on whether it be naltrexone or buprenorphine in primary care. Why do you think that is?

Kristin Wason: Yeah, it's interesting, right? For basically 20 years buprenorphine, if you wanted to prescribe it, you had to go, you know, federally-required and approved training and then essentially get a special DEA license in order to prescribe it. And so it's interesting that we have such a severe overdose epidemic. And then we have this condition that is very treatable with like highly effective medicine, but people had to like opt in to treat it. It wasn't sort of just like part of the standard of care. And so I think now people got very comfortable choosing not to opt in. They built up panels, they're busy, I get it. But at the same time, like again, this is an extremely rewarding condition to treat: people's lives get so much better. And so, you know, I really wish people now would be more apt to just like take this on. There is a lot of education out there for it. Our patients need our help.

[Music]

Ilana Hardesty: Michelle's PCP continues the buprenorphine started in the ED, but doses at three times per day rather than once per day in order to treat both her chronic pain and OUD. Months later, because Michelle's hip pain from her end stage arthritis is affecting her function and quality of life, she's scheduled for a right hip arthroplasty.

Now that Michelle is taking buprenorphine, how should her surgical pain and OUD be managed perioperatively?

Dr. Daniel Alford: So that is one of the most common questions that I get asked, as an addiction medicine specialist. There is growing consensus on perioperative pain management in patients on medications for opioid use disorders. And the best available evidence suggests that patients with an opioid use disorder history are often more sensitive to painful stimuli. The recommendation is to continue their methadone or their buprenorphine throughout the perioperative period And then we need to treat their pain,

their post-operative pain, with analgesics on top of the patient's daily medications for their opioid use disorder. And patients like this may need higher doses of opioid analgesics because of their increased pain sensitivity. We also know that ineffective pain management for these patients can absolutely result in disengagement in care.

[Music]

Ilana Hardesty: Michelle did well following the surgery with improved pain control of her right hip. Her painful diabetic neuropathy is well controlled on a combination of buprenorphine, duloxetine, and nortriptyline. Her gabapentin was discontinued due to the misuse risk. Her PEG scores remain between five and six on the ten-point scale, her OUD is in sustained remission with MOUD and outpatient addiction counseling. She regains employment and continues with regularly scheduled follow up visits.

[Music]

Thank you, Dr. Alford and Dr. Bial. And thank you to all our guests over this series: Kristin Wason, Patrick Kelly, and our patient, Don.

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I'm Ilana Hardesty. Thanks for listening.