

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?

Universal Precautions when Prescribing Opioids

Predicting opioid risk and misuse is imprecise


Consistent application of precautions reduces stigma and standardizes care

Precautions include:

- Assess and document pain diagnosis(es) and opioid misuse risk
- **Prescribe opioids as a test or trial**; continued, modified or d/c based on risks/benefits (e.g., every 1-3 months)
- State maximum number of tablets to be taken per day
- Patient Prescriber Agreements (PPA) written at 5th grade level, without coercive language
- Monitor for adherence, misuse, and diversion

CDC Recommendation 7
Evaluate benefits and risks 1-4 weeks of starting opioids or after dose escalation and then regularly
Dowell D, et al. MMWR. 2022

Gourlay DL, Heit H. Pain Med. 2005
Chou R, et al. J Pain. 2009 Franklin GM. Neurology. 2014
Federation of State Medical Boards Model Policy April 2017.



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


Patient Provider Agreement (PPA)

<p>Informed Consent</p> <p>Realistic Goals <i>Reduce (not eliminate) pain</i></p> <p>Increase function (SMART goals):</p> <ul style="list-style-type: none"> • Specific • Measurable • Action-oriented • Realistic • Time-sensitive 	<p>Potential Risks</p> <ul style="list-style-type: none"> • Adverse effects and drug interactions • Over-sedation and impairment <i>(esp. during dose adjustments)</i> • Misuse • Overdose • Death • Risk of neonatal withdrawal • Hyperalgesia • Victimization by others
<p>Plan of Care</p> <ul style="list-style-type: none"> • Engage in other treatments • Take meds as directed, pill counts • Safe storage and disposal, no sharing • No illicit drug use, avoid/minimize sedative use • Communicate with key others • Notify clinician of all other medications and drugs, worsening pain or medication side effects • Discuss birth control, periodic monitoring for pregnancy 	

Tobin DG, et al. *Cleve Clin J Med* 2016
Nicolaidis C. *Pain Med*. 2011
Paterick TJ, et al. *Mayo Clin Proc*. 2008

Mallis-Gagnon A, et al. *Clin J Pain*. 2012
Cheatle MD, Savage SR. *J Pain Symp Manage*. 2012
Tolia VN, et al. *N Engl J Med*. 2015

Schumacher MB, et al. *Psychopharm*. 2017
Fishman SM, Kreis PG. *Clin J Pain*. 2002
Arnold RM, et al. *Am J Med*. 2006



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.

Kristin, 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

Monitoring and Documentation: Office Visits

Six A's

- Analgesia**
- Activities**
- Adverse effects**
- Aberrant behaviors**
- Affect**
- Adherence**

Subjective reports from patient, co-care providers, caregivers and "reliable" family members (beware of family members with secondary gain for giving inaccurate information)

Objective information (observations, drug tests, pill counts, PDMP)

Also review...Opioid use using a **24-hour inventory** "Tell me how you are taking your medications."

Know federal and state guidelines and regulations: www.deadiversion.usdoj.gov/pubs/manuals/index.html

Templates in Resources at: www.scopeofpain.org and mytopcare.org

Passik SD, et al. Clin Ther. 2004

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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 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 regimen? 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,

Community Pharmacist

- Ensure that prescriptions are for “legitimate medical purposes”
- Help with medication choices, doses and substitutions
- Interact with patients
 - Educate on risks, proper use, storage and disposal, drug take-back programs, use of naloxone
 - Check PDMP, monitor for worrisome behaviors
 - Identify potential drug-drug interactions
 - Assist with formularies and prior authorizations
- Prescribers can help by including:
 - Diagnosis or indication on prescription
 - Parameters for when script should be filled

Gregory T. Gregory L. J Pharm Pract. 2020

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?

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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.