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How opioid prescribing policies influence primary care clinicians' treatment decisions and conversations with patients with chronic pain

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Abstract

Objective: The 2016 Centers for Disease Control and Prevention guideline for prescribing opioids for chronic pain aimed to assist primary care clinicians in safely and effectively prescribing opioids for chronic noncancer pain. Individual states, payers, and health systems issued similar policies imposing various regulations around opioid prescribing for patients with chronic pain. Experts argued that health care organizations and clinicians may be misapplying the federal guideline and subsequent opioid prescribing policies, leading to inadequate pain management. The objective of this study was to understand how primary care clinicians involve opioid prescribing policies in their treatment decisions and in their conversations with patients with chronic pain.

Design: We conducted a secondary qualitative analysis of data from 64 unique primary care visits and 87 post-visit interviews across 20 clinicians from three health care systems in the Midwestern United States. Using a multi-step process and thematic analysis, we systematically analyzed data excerpts addressing opioid prescribing policies.

Results: Opioid prescribing policies influenced clinicians' treatment decisions to: not initiate opioids, prescribe fewer opioids overall (theme #1), and begin tapering and discontinuation of

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opioids (theme #2) for most patients with chronic pain. Clinical precautions, described in the opioid prescribing policies to monitor use, were directly invoked during visits for patients with chronic pain (theme #3).

Conclusions: Opioid prescribing policies have multidimensional influence on clinician treatment decisions for patients with chronic pain. Our findings may inform future studies to explore mechanisms for aligning pressures around opioid prescribing, stemming from various opioid prescribing policies, with the need to deliver individualized pain care.

Keywords

chronic pain; opioid prescribing policies; treatment decisions; primary care

Introduction

The United States (US) is in the midst of an opioid crisis with more than two million Americans suffering from opioid use disorder (OUD) [1]. In an effort to address the role of prescription opioids in the crisis, the Centers for Disease Control and Prevention (CDC) published a 2016 guideline to assist primary care clinicians in safely and effectively prescribing opioids for chronic noncancer pain [2]. The CDC guideline received widespread national attention by healthcare organizations, clinicians, and policymakers [3]. Individual states, payers, and health systems followed by issuing similar policies imposing various regulations around opioid prescribing for patients with chronic pain [4]. An ongoing decrease in opioid prescribing appears to have accelerated following the CDC guideline's release [5]. Yet, deaths involving opioids have continued to increase, likely due to illicit opioid use [6].

Recent reports have argued that health care organizations and clinicians are misapplying the CDC guideline, leading to inadequate pain management and potentially an inadvertent shift towards the use of illicit opioids [4 7–10]. A consensus panel of physician experts reported discussed several common challenges in implementing the CDC guideline, including a failure to involve patients in decisions to taper or discontinue chronic opioid prescriptions [7]. Furthermore, the consensus panel highlighted inflexible application of recommended dosages by the CDC guideline leading to strict dosage limits on opioids being prescribed to patients with chronic pain. Indeed, some recent evidence suggests that clinicians are using expert guidelines, such as the 2016 CDC guideline, as their rationale for reducing patients' opioid doses or discontinuing opioids [11]. Yet, to our knowledge, no study has directly examined how primary care clinicians use the CDC guideline or other opioid prescribing policies in their discussions with patients with chronic pain or in their chronic pain treatment decisions. Therefore, the objective of this study was to increase our understanding of the ways that primary care clinicians may be utilizing opioid prescribing policies in their treatment decisions and in their conversations with patients. Our findings make an important contribution to ongoing national conversations about opioid prescribing by providing point-of-care empirical evidence about how opioid prescribing policies may be affecting chronic pain care.

Methods

Source study: Overview

We used interview data and primary care clinic visit recordings collected as part of a larger study that aimed to understand primary care provider decision making when caring for patients with chronic noncancer pain, and to develop pain care decision support tools [12–14]. In this larger study, we collected data from regularly scheduled primary care visits of patients with chronic noncancer pain. We audio recorded provider-patient interactions during the visits and conducted post-visit interviews with the provider involved in each recorded patient visit. The interviews lasted approximately 60 minutes and were conducted by members of the research team. All audio recordings were transcribed. A detailed description of the data collection process is described elsewhere [12–15]. The study was approved by the Indiana University Institutional Review Board (IRB).

Source Study: Participants & Data Collection

Between April 2016 and July 2018, we recruited adult primary care providers authorized to prescribe opioids. To increase diversity in our sample, we recruited providers from urban, suburban, and rural clinics that spanned three health care systems in Indiana and Illinois. Consented providers worked with the research team to identify visits involving patients 18 years or older with chronic noncancer pain, including those who were and were not currently being prescribed opioids. Both providers and patients provided written informed consent to participate. Providers received a $100 gift card for each interview in which they participated and were able to participate in up to 5 interviews, each involving a different patient. Each patient received a $25 gift card for participating in an audio recorded visit.

Secondary Study: Data Extraction Procedures & Analysis

For this study, we used all transcripts from the clinic visits and interviews collected as part of the original study. Through a multi-step process described below, we extracted specific clinic visit and interview excerpts addressing providers' use of opioid prescribing policies in their discussions with patients and in their clinical decisions. We used these selected excerpts to create a data set for our qualitative analysis.

We defined opioid prescribing policies as any clinical guidelines, including the CDC guideline, state laws, specific hospital system/clinic policy, insurance company policy, opioid-related rules (local, state, regional or national), and recommendations related to opioid prescribing for patients with chronic pain. Our rationale for using a broad definition comes from the fact that opioid prescribing guidelines in general, and CDC guideline in particular, were influential in development of the state laws, insurance companies and individual health system/clinic policies and recommendations around opioid prescribing [4].

Keyword identification

We began our process by developing a list of 11 keywords based on the review of the sample of the clinic visits and interviews transcripts by three analysts, ED, SD, and OM. Next, we used an automated Python script to search interviews and clinic visits transcripts for these 11 keywords [16]. Following this step, to identify additional relevant keywords, three analysts

reviewed the full text of a 25% random subset of the remaining transcripts. The analysts concluded the process after three rounds of independent review and group discussion, which resulted in 21 total keywords (See Appendix 1). Next, we searched all transcripts for these keywords using the automated Python script and divided the resultant transcripts equally among the analysts. The analysts read the discussion around each keyword identified in each transcript line by line. The analysts identified all text excerpts relevant to opioid prescribing policies and erred on the side of inclusion, flagging any excerpts for which they were uncertain about inclusion. The three analysts then met to discuss and come to consensus on inclusion of any excerpts about which they were uncertain. The resulting set of excerpts was used as a basis for the qualitative analysis.

Codebook creation

To analyze the resulting set of excerpts, the three analysts began by independently reviewing a 25% random sample of text excerpts from clinic visits and interviews to identify candidate codes. The codes captured topics discussed by clinicians in each excerpt. For example, codes captured information about opioid prescribing contracts, the stopping and tapering of opioids, the prescription culture change, presented scientific evidence and research on the safety of opioid use, etc. The three analysts met to discuss and reach an agreement on the final list of codes to be applied for text excerpts from clinic visits and interviews. Next, the analysts applied these final codes to the 25% random sample of text excerpts from clinic visits and interviews. All three analysts met to discuss and reach an agreement on whether certain codes should be applied to a particular excerpt.

Preliminary theme identification, consensus coding, theme analysis

The remaining 75% of the excerpts were divided between three analysts and each of them applied codes individually. Next, the codes with corresponding excerpts were divided, such that a pair of analysts read and reviewed all excerpts from the corresponding code line-by-line to identify preliminary themes following a thematic analysis approach [17]. We defined a theme as “an abstract entity that captures the nature or basis of the experience into a meaningful whole” [18]. Through this process, each pair of analysts identified definitions and examples for each preliminary theme that emerged. Next, a pair of analysts that was assigned a code with corresponding excerpts met to discuss preliminary themes and reach a consensus on the theme and identified illustrative quotes. Finally, two analysts reviewed all final themes. Next, they met and reached an agreement on which final themes captured clinician treatment decisions and conversations with patients around opioid prescribing policies. We produced participant demographics using descriptive statistics, such as means, frequencies, and percentages.

Results

Participant characteristics

Our final analytic dataset included 87 interviews across 20 clinicians and 64 unique patient clinic visits. Clinicians had between 2 and 34 years of clinical practice expertise. Clinicians’ disciplines included family medicine, general medicine, and internal medicine. Clinicians were trained medical doctors (n=16), osteopathic physicians (n=2), and nurse practitioners

(n=2). Over half of clinicians received some type of pain management training/education such as pain management continuing medical education (n=11), state in-service (n=1), and back pain conference attendance (n=1). The majority of clinicians were White (n=16), while the rest identified as African-American (n=2) or Asian (n=2). Half of clinicians were female (n=10). Four clinicians practiced in rural primary care clinics and one practiced in a suburban setting. Clinician age ranged from 27–67 years old with an average age of 45. Patients varied in age from 26 to 91 years old with an average age of 55. Over half of patients were female (n=44). Most patients identified as white (n=45) while approximately a third identified as African-American (n=19).

Below we describe three salient themes that emerged from the analysis of the interviews and clinic visits. The first two themes describe the influence of opioid prescribing policies on treatment decisions, and the third theme captures mentions of the prescribing policies in patient-provider conversations. Table 1 contains several quotes to provide further illustration of the themes presented below.

1. Opioid prescribing policies influenced clinicians' decisions to not initiate opioids and use less opioids overall for patients with chronic pain—Several clinicians described how opioid prescribing policies influenced their decisions to not initiate opioids and to reduce opioid use altogether for patients with chronic pain. As one clinician described her approach for not starting patients on opioids due to a new state law and other opioid prescribing policies in the interview: (PAT 38, Interview PRO11): *I think I've done a pretty good job of not starting new people on narcotics. My threshold for starting it is very different* [since the new guidelines came out]. *I'm really much more insistent on we have to try all other options.*

When clinicians discussed these decisions, they often explained how current opioid prescribing policies shifted their mindset on opioid prescribing. In the interviews, clinicians described the shift from liberal to limited use of opioids in their personal practice, driven by several factors, including the American Pain Society's 5th vital sign campaign [19], the Joint Commission report [20], and the 2016 CDC guideline. Several clinicians described a collective shift in primary care from overreliance to restricted use of opioids driven by safety, abuse, and dependency concerns. This illustrative quote from an interview summarizes how a clinician described this collective shift (PAT 05 Interview PRO02):

> I say now and I would have said in 2014 is that things have changed. You know, that our approach to pain has changed. You know, we used to try to use these medications in higher doses because we thought, at the time, [..]that was a more accepted and a more common approach. And it was thought that it would improve pain and improve outcomes. But we have learned since then that, in fact, these medicines have a lot more side effects than we thought and that being on high doses of them for years is probably not the best idea for most patients. I always emphasize that. And you know, patients are -- they've almost always heard that before.

Furthermore, some clinicians noted that opioid prescribing policies did not always align with their own clinical judgment when prescribing opioids for patients with chronic pain.

Although clinicians perceived that the current restricted opioid approach may be applicable to the overall patient population, they expressed concern that it may put some patients at risk of not receiving needed care. In some instances, clinicians expressed concern that strict adherence to guidelines would lead to suboptimal care (or poor patient outcomes), especially when access to non-opioid options is limited (i.e., insurance coverage restrictions). As one clinician described the dilemma of adhering to opioid prescribing policies while effectively addressing patients' care needs (PAT 14 Interview PRO03):

> So yeah, I think, I feel like we rush, okay, this is a new MIDWEST STATE law which is great. We're [clinicians are] not thinking of the individual patient, but we're saying we're going to implement this from now on so we can show we are cutting edge and are relying on these principles…. Okay this is what we're going to do with those who don't have private insurance to … go to a pain clinic somewhere on their own: You're [the patient] like left hanging. You didn't get more of the Norco. You're miserable but nobody cares.

2. Opioid prescribing policies influenced clinician' treatment decisions to initiate opioid tapering and discontinuation—Several clinicians described how various provisions of opioid prescribing policies, including the strict dosage limits, influenced their decisions to reject a patient's requests for dose increase, limit prescriptions, perform regular pill counts, and consider tapering (i.e., using lower doses) or discontinuing patients currently on opioids. For instance, in the interviews, several clinicians described how they initiated almost universal tapering and discontinuation of their patients currently prescribed opioids in response to opioid prescribing policies. As one clinician described how she had to initiate a taper and eventually discontinue almost all patients in response to new state laws and insurance regulations in an interview (PAT 29 Interview PRO05):

> The first wave was like the state, and so we had to do morphine equivalent. We [clinicians] got everybody [patients] down to the morphine equivalent. Now it's like 12 weeks insurance is requiring prior authorizations for pain medicine, a lot of them are, and then they're refusing it. We're [clinicians are] getting people off that way because insurance won't pay for it. And then I'm just looking at it and I only have a couple people with cancer and then the rest of them I'm slowly... or I'll say okay I'll wait 'til you get to this specialist appointment but then we're really weaning you off.

Similarly, another clinician referenced this almost universal tapering and discontinuation approach during a clinic visit, to explain the rationale for no longer prescribing opioids for more than a one-week supply to the patient (PAT30 Clinic Visit PRO04): *So maybe you know for a week that's fine, but you know we're really switching everyone over to safer medications for their pain*.

Furthermore, some clinicians explicitly referenced the strict dosage limits that were part of several opioid prescribing policies in their treatment decisions, including tapering and discontinuation. As one clinician explained to the patient her decision against writing a prescription with a higher opioid dose due to dosage limits imposed by the local health system (PAT48 Clinic Visit PRO11): *The reason that I'm bringing that up is, there is a limit*

to the types of narcotics that I can prescribe and the amount I can prescribe for you. My concern is, if we should find that you need more than that, I can't. Similarly, a clinician brought up the CDC guideline warning against using high opioid doses with a patient (PAT33 Clinic Visit PRO06): *The CDC came out with some guidelines and we're kind of exceeding those.*

3. Clinical precautions, described in the opioid prescribing policies, were directly invoked during routine care for patients with chronic pain—Many clinicians discussed various clinical precautions described in the opioid prescribing policies during clinic visits with patients with chronic pain. For instance, during clinic visits, clinicians had to discuss and update the opioid contract, explain the rationale for a routine urinary drug screen (UDS), complete required risk assessments, and prior authorizations. One clinician discussed the need for a UDS due to legal requirements during a visit (PAT46 Clinic Visit PRO12):

> Clinician: Did you give a urine sample when you came in or not?
>
> Patient: No.
>
> Clinician: Can you give one today?
>
> Patient: Sure.
>
> Clinician: The only reason I ask is, its been a very long time, a year and legally we have to do that each year.
>
> Patient: Oh okay.
>
> Clinician: Its always been appropriate. So, if we can get that, that will be helpful. That will allow me to legally write your refill.
>
> Patient: Hey, well we don't want to be outside the law.

Similarly, a clinician had a discussion with a patient on the importance of maintaining and adhering to an opioid contract during a visit (PAT09 Clinic Visit PRO01):

> Clinician: I am very serious about [inaudible] contracts. I trust all my patients, okay? I can't tell who's being honest [inaudible] because I don't go out and investigate. There is no way for me to do that. However, if I have any reason to not trust my patients, then I have to stop prescribing them their medicine. So that contract is something that we both have to respect, right? I have that contract because it's my responsibility to only give you medicine I think is helping you and I have the power to give you medicine I think potentially could be very harmful, you know? That's why it's really important that we have a mutual respect of the clinic rules and procedures for prescribing narcotics.
>
> Patient: Yeah, sounds reasonable and probably even helpful to be able to see … how many [pills] I've got to get me through the week so.

Furthermore, in the interviews, some clinicians discussed the heightened importance of regularly engaging in certain clinical precautions, such as a need to check state prescription drug monitoring program (PDMP). This quote from an interview captures the importance of

strict adherence to clinical precautions described in the opioid prescribing policies (PAT 55 Interview PRO10):

> With opioids you [clinicians] gotta be very disciplined. The STATE PDMP reports are a must. UDSs are a must. You looking at them objectively are a must. I mean you can't - my opinion is you cannot be blinded by the doctor-patient relationship in that sense.

Discussion

The purpose of this study was to qualitatively examine how opioid prescribing policies influenced clinician prescribing decisions and conversations with patients with chronic pain. We found that clinician treatment decisions were influenced by opioid prescribing policies in several ways. First, clinicians described their reluctance to initiate opioids for patients with chronic pain, and collectively reduce their prescribing of opioid medication for almost all patients with chronic pain. Furthermore, several clinicians felt that the current collective reduction in opioid medications did not always align with their clinical judgment and strict adherence to guidelines could have negative effects for some patients with chronic pain.

Our findings reinforce expert panel remarks on the inflexible application of opioid prescribing policies, including the CDC guideline [7]. Importantly, the CDC guideline, which was in effect during the study period, allows for individualized treatment of patients with chronic pain. For instance, clinicians may prescribe more than 90 MME/day if the clinician can justify that the benefits of opioid use outweigh the risks for the patient. Similarly, although opioid prescriptions should be written for the shortest necessary duration (i.e., 7-day supply), clinicians may prescribe beyond these limits if pain persists or cannot be sufficiently controlled by nonopioid therapies [2]. Thus, our findings support the widespread concerns about inflexible application of the CDC guideline. Notably, existing opioid prescribing policies significantly differ in their level of prescriptiveness on potential treatment decisions for patients with chronic pain. Clinical guidelines, including the CDC guideline, include vague descriptions of recommended treatment decisions for opioid prescribing [2 4 7]. In contrast, state and local health systems' policies are more likely to have explicit provisions, such as exact dose limits, with which providers must comply when prescribing opioids for patients with chronic pain [21 22]. For instance, Indiana, a state in which many of our participants practiced, had or enacted several laws aimed at addressing inappropriate opioid prescribing, including PDMP checks, morphine milligram equivalent daily dose limits, and days' supply limit laws during our study [23]. Furthermore, local health systems and individual clinics implemented at least one additional policy which triggers certain mandatory clinical documentation, such as placing an order for a UDS, at specific opioid dose thresholds [24]. As an exception, one local health system's opioid prescribing policy that was in effect during our study period provided a dose threshold instead of exact dose limit that triggered additional paperwork for providers. Additional research is warranted to understand how providers resolve potential contradictory recommendations stemming from different opioid prescribing polices when making treatment decisions for patients with chronic pain.

Second, clinicians described how opioid prescribing policies, which often included strict dosage limits, influenced their treatment decisions to initiate an almost universal opioid tapering and discontinuation for patients with chronic pain. Our findings build on prior research which found that clinicians applied local policies and expert guidelines, such as the CDC guideline, across the board as their rationale for tapering or discontinuing opioids [11]. Our findings support expert concerns of clinicians possibly using the opioid prescribing policies as “blunt instruments” to taper and discontinue patients with limited regard to whether patients may need and benefit from longer duration or higher dosages of opioid therapy. Furthermore, such uniform approaches to tapering and discontinuation goes against patient preferences [7 25]. The CDC recommends that clinicians employ tapering plans that meet individual patients’ unique health needs rather than use a uniform approach. Such plans should include non-opioid treatments as opioids are being tapered or discontinued. However, strict opioid prescribing rules found in some governmental policies may limit providers’ ability to individualize care. Importantly, an increasing number of patients that were tapered and discontinued in recent years were more likely to have emergency department visits or hospitalizations for opioid poisoning, opioid dependency, and adverse effects of opioid use and die from an overdose [26–28]. Given the negative consequences associated with tapering and discontinuation, additional research is needed to support providers in safely tapering and discontinuing opioids while maintaining an ability to provide patient-centered care for patients with chronic pain.

Another key finding of our study is that clinical precautions (e.g., requirement to maintain an opioid contract, conduct periodic UDS, etc.) recommended by several opioid prescribing policies were directly invoked during routine care visits of patients with chronic pain. Furthermore, some clinicians reported a heightened importance of engaging in these clinical precautions, such as checking state PDMP, for patients with chronic pain. Importantly, some of these clinical precautions, such as checking state PDMP and collecting regular UDS, were made mandatory during our study period [24 29 30]. Thus, appearance of these clinical precautions during routine care visits may be interpreted as provider compliance with newly established opioid prescribing policies.

Additionally, our findings are reassuring in that clinicians are implementing certain clinical actions that are not mandated, but are known to reduce the risk of aberrant drug-related behaviors among patients with chronic pain, such as signing an opioid contract [31]. Nevertheless, it is plausible that by performing these additional clinical precautions, clinicians may have less time to discuss a patient’s everyday experiences with opioids, the opioid tapering process, their social relationships, and their emotional state. These patient-provider communications on social and emotional factors were identified by patients with chronic pain as important precursors to successful opioid tapering and discontinuation [25]. Thus, prospective studies are needed to design tools that would aid clinicians in balancing the need for engaging in additional, often mandated clinical precautions (opioid contract, UDS) for prescribing opioids, with systematic assessments of patient’s social and emotional states.

Limitations

Since our study is a secondary analysis of data collected for related-research questions, we acknowledge that the results may not be a comprehensive representation of policy related decision making or policy related conversations with patients with chronic pain. Similarly, we acknowledge the questions from the interviews did not seek to gather policy related information explicitly. However, these interviews, which sought to understand how primary clinicians make treatment decisions for their patients with chronic pain, do provide a genuine initial understanding of how clinicians are using these policies to make their decisions. Furthermore, due to the secondary nature of our analysis we were unable to continue sampling to confirm thematic saturation.

Given that our study took place in the Midwestern US, our findings may not be generalizable to other settings. However, the Midwestern US has been particularly affected by the opioid overdose crisis, making it an important area to study. Our clinician sample was comparable to some national race estimates for family medicine physicians [32]. However, our sample did not capture some racial groups (Hispanic or American Indians/Alaska Natives/Native Hawaiian or Pacific Islanders) and included proportionally more female family medicine clinicians (50% compared to 38.4%) [32 33]. Additionally, our clinician sample was younger in age than national estimates for family medicine/general practice physicians (80% compared to 55.5% under age 55) [34]. Furthermore, our findings may be affected by selection bias of individuals who were willing and able to participate in the provider interviews and clinic visits. As a result, we may have missed some aspects of how opioid-related policies may influence clinicians' treatment decisions and conversations with patients with chronic pain. It is also plausible that clinician conversations with patients could have been affected by being audio recorded. However, we believe that by using a discreetly placed audio-only recorder, such effects were minimal. Additionally, unless identified by name, we were often unable to determine which opioid prescribing policies were discussed by clinicians in the interviews and conversations with patients.

Finally, we only captured a single clinical visit in an ongoing patient-clinician relationship, thus we may have missed other instances of treatment decisions and conversations related to opioid-prescribing policies. Furthermore, we did not collect data on treatment decisions and patient-clinician conversations during the pre-opioid prescribing policy enactment period. Nevertheless, given the pervasive nature of opioid prescribing policies, we believe that our findings are capturing instances of treatment decisions and conversations that routinely occur during chronic pain-related primary care visits.

Conclusions

By using direct observations of clinical visits and qualitative interviews with primary care clinicians from multiple health systems we derived an initial understanding on how opioid prescribing policies are influencing clinicians' treatment decisions and conversations with their patients with chronic pain. Building on our work, future studies should focus on exploring ways to align pressures around opioid prescribing stemming from specific opioid prescribing policies, with the need to deliver individualized, patient-centered pain care. Additionally, researchers should explore clinician awareness of how to individualize patient

treatment under specific opioid prescribing policies and determine clinician willingness to deliver individualized care.

Appendix 1.: List of Keywords

1. cdc
2. advice
3. guideline
4. polic
5. stud
6. rule
7. restriction
8. news
9. research
10. recommend
11. prior authorization
12. law
13. state
14. evidence
15. uds
16. drug
17. tox
18. monitor
19. pdmp
20. legal
21. narcotic

References

1. Abuse S Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19–5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality. Substance Abuse and Mental Health Services Administration 2019
2. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. JAMA 2016;315(15):1624–45 [PubMed: 26977696]
3. Traylor C Center for Medicare and Meidcaid Services. CMCS Informational bulletin: Medicaid strategies for non-opioid pharmacologic and non-pharmacologic chronic pain management. Updated February 22, 2019. https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf

4. Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. N Engl J Med 2019;380(24):2285–87 [PubMed: 31018066]
5. Bohnert AS, Guy GP Jr, Losby JL. Opioid prescribing in the United States before and after the Centers for Disease Control and Prevention's 2016 opioid guideline. Ann Intern Med 2018;169(6):367–75 [PubMed: 30167651]
6. Wilson N Drug and opioid-involved overdose deaths—United States, 2017–2018. MMWR. Morb Mortal Wkly Rep 2020;69
7. Kroenke K, Alford DP, Argoff C, et al. Challenges with implementing the centers for disease control and prevention opioid guideline: a consensus panel report. Pain Med 2019;20(4):724–35 [PubMed: 30690556]
8. CDC advises against misapplication of the guideline for prescribing opioids for chronic pain. Centers for Disease Control and Prevention website. Updated April 24, 2019. https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html.
9. Health Professionals for Patients in Pain. Professionals call on the CDC to address misapplication of its guideline on opioids for chronic pain through public clarification and impact evaluation. Updated March 6, 2019. https://dontpunishpainrally.com/wp-content/Flyer-Files/CPP%20News%20Source/Professionals%20Call%20on%20CDC%20to%20Address%20Misapplication%20of%20Guidelines.PDF
10. Food and Drug Administration. FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering. Food and Drug Administration website. Updated April 9, 2019. https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.
11. Kennedy LC, Binswanger IA, Mueller SR, et al. "Those conversations in my experience don't go well": A qualitative study of primary care provider experiences tapering long-term opioid medications. Pain Med 2018;19(11):2201–11 [PubMed: 29126138]
12. Militello LG, Anders S, Downs SM, et al. Understanding how primary care clinicians make sense of chronic pain. Cognition, Technology & Work 2018;20(4):575–84
13. Harle CA, DiIulio J, Downs SM, et al. Decision-Centered Design of Patient Information Visualizations to Support Chronic Pain Care. Appl Clin Inform 2019;10(04):719–28 [PubMed: 31556075]
14. Information needs and requirements for decision support in primary care: an analysis of chronic pain care. AMIA Annual Symposium Proceedings; 2018. JAMIA
15. Militello LG, Hurley RW, Cook RL, et al. Primary Care Clinicians' Beliefs and Strategies for Managing Chronic Pain in an Era of a National Opioid Epidemic. J Gen Intern Med 2020:1–7
16. Python Releases for Windows. Updated 2019. https://www.python.org/downloads/windows/.
17. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. Nurs Health Sci 2013;15(3):398–405 [PubMed: 23480423]
18. DeSantis L, Ugarriza DN. The concept of theme as used in qualitative nursing research. West J Nurs Res 2000;22(3):351–72 [PubMed: 10804897]
19. APS 1995 presidential address. Pain Forum; 1996. Elsevier.
20. Baker DW. History of The Joint Commission's pain standards: lessons for today's prescription opioid epidemic. JAMA 2017;317(11):1117–18 [PubMed: 28241189]
21. Davis CS, Lieberman AJ, Hernandez-Delgado H, Suba C. Laws limiting the prescribing or dispensing of opioids for acute pain in the United States: A national systematic legal review. Drug Alcohol Depend 2019;194:166–72 [PubMed: 30445274]
22. Heins SE, Frey KP, Alexander GC, Castillo RC. Reducing high-dose opioid prescribing: state-level morphine equivalent daily dose policies, 2007–2017. Pain Med 2020;21(2):308–16 [PubMed: 30865779]
23. Association ISM. Indiana Pain Management Prescribing Final Rule. Indiana State Medical Association website. Updated October 25, 2016. https://www.ismanet.org/pdf/legal/IndianaPainManagementPrescribingFinalRuleSummary.pdf.

24. Opioid prescribing requirements. 844 IAC 5–6-8 Drug monitoring testing. Updated August 22, 2016. Indiana State Medicial Association website. https://www.ismanet.org/pdf/FinalRule102516.pdf
25. Henry SG, Paterniti DA, Feng B, et al. Patients' experience with opioid tapering: A conceptual model with recommendations for clinicians. The Journal of Pain 2019;20(2):181–91 [PubMed: 30243859]
26. Mark TL, Parish W. Opioid medication discontinuation and risk of adverse opioid-related health care events. J Subst Abuse Treat 2019;103:58–63 [PubMed: 31079950]
27. Oliva EM, Bowe T, Manhapra A, et al. Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation. BMJ 2020;368
28. James JR, Scott JM, Klein JW, et al. Mortality after discontinuation of primary care–based chronic opioid therapy for pain: a retrospective cohort study. J Gen Intern Med 2019;34(12):2749–55 [PubMed: 31468341]
29. Indiana State Medical Association. A comparison of the CDC opioid prescribing guidelines for chronic pain and and the Indiana opioid prescribing rule. Indiana State Health Department website. Accessed October 20, 2020. https://www.in.gov/isdh/files/31_Comparison%20of%20CDC%20v.%20Indiana%20Rx%20Guidelines.pdf.
30. Opioid prescribing requirements. 844 ICA 5–6-7 INSPECT report. Updated October 7, 2014. Indiana State Medicial Association website. https://www.ismanet.org/pdf/FinalRule102516.pdf
31. Sekhon R, Aminjavahery N, Davis CN Jr, Roswarski MJ, Robinette C. Compliance with opioid treatment guidelines for chronic non-cancer pain (CNCP) in primary care at a Veterans Affairs Medical Center (VAMC). Pain Med 2013;14(10):1548–56 [PubMed: 23746149]
32. Xierali IM, Nivet MA. The Racial and Ethnic Composition and Distribution of Primary Care Physicians. J Health Care Poor Underserved. 2018;29(1):556–570 [PubMed: 29503317]
33. Association of Amercian Medical Colleges. Active Physicians by Sex and Specialty, 2015. Accessed Feburary 24, 2021. https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-sex-and-specialty-2015
34. Association of Amercian Medical Colleges. Active Physicians by Age and Specialty, 2015. Accessed Feburary 24, 2021. https://www.aamc.org/data-reports/workforce/interactive-data/active-physicians-age-and-specialty-2015

Table 1:

Emergent Themes with Illustrative Quotes

Theme	Illustrative Quote
Opioid prescribing policies influenced clinicians' decisions to not initiate opioids and use less opioids overall for patients with chronic pain	I think I've done a pretty good job of not starting new people on narcotics. My threshold for starting it is very different. I'm really much more insistent on we have to try all other options. (PAT 38 Interview PRO11) For the last five or six years I really haven't been starting anybody on chronic pain medicine. (PAT 76 Interview PRO20) No one is starting people on chronic opiates anymore basically. (PAT 03 Interview PRO01) I say now and I would have said in 2014 is that things have changed. You know, that our approach to pain has changed. You know, we used to try to use these medications in higher doses because we thought, at the time, that we, you know -- when she was started on these higher doses of medicines, that was a more accepted and a more common approach. And it was thought that it would improve pain and improve outcomes. But we have learned since then that, in fact, these medicines have a lot more side effects than we thought and that being on high doses of them for years is probably not the best idea for most patients. So I always emphasize that. And you know, patients are -- they've almost always heard that before. (PAT 05 Interview PRO02) We all used to give out... we were pretty generous with the fifth vital sign, blah, blah, blah, and it's all changed so dramatically, and it's like it's come in waves. (PAT 29 Interview PRO05) This is not just me wanting you to cut down, this is my bosses, this is the CDC telling us doctors in general that this is what needs to be done and it's really important, and it's important to your safety. So I think it helps them to know that this is like an initiative by everybody. But there isn't a lot of good patient handouts to explain that. I found some ones for providers but there needs to be a handout to say this is why taking a benzo and an opioid is not safe. (PAT 18 Interview PRO04) I think, I feel like we rush, okay, this is a new MIDWEST STATE law which is great, we're [clinicians are] not thinking of the individual patient, but we're not saying we're going to implement this from now on so we can show we are cutting edge and are relying on these principles, but we don't have. Okay this is what we're going to do with those who don't have private insurance to then go to a pain clinic somewhere on their own. You're [Patients are] like left hanging, this is good, you didn't get more of the Norco, you're miserable but nobody cares. (PAT 14 Interview PRO03)
Opioid prescribing policies influenced clinician' treatment decisions to initiate opioid tapering and discontinuation	The first wave was like the state, and so we had to do morphine equivalent. We [Clinicians] got everybody down to the morphine equivalent. Now it's like 12 weeks insurance is requiring prior authorizations for pain medicine, a lot of them are, and then they're refusing it. We're getting people off that way because insurance won't pay for it. And then I'm just looking at it and I only have a couple people with cancer and then the rest of them I'm slowly... or I'll say okay I'll wait 'til you get to this specialist appointment but then we're really weaning you off. (PAT 29 Interview PRO05) So maybe you know for a week that's fine, but you know we're really switching everyone over to safer medications for their pain. (PAT30 Clinic Visit PRO04) The reason that I'm bringing that up is, there is a limit to the types of narcotics that I can prescribe and the amount I can prescribe for you. My concern is, if we should find that you need more than that, I can't (PAT48 Clinic Visit PRO11) The CDC came out with some guidelines and we're kind of exceeding those (PAT33 Clinic Visit PRO06) The rules are I'm not allowed to write you any more than two a day but I'm going to make this gradual, though. Because you've been on this and we're going to see do you qualify to go for a pain clinic. It's nothing against you personally. It's what is happening. There are more deaths in Indiana from narcotics than from motor vehicle accidents. This is nothing personal. We're going to work around this. It was more like this is the policy now. Let's see how we can gradually do it with you so that it's not - so you can still have a quality of life. So that helped say I'm not ignoring your pain. This is the new reality. (PAT 19 Interview PRO03)
Clinical precautions, described in the opioid prescribing policies, were directly invoked during routine care for patients with chronic pain	Clinician: Did you give a urine sample when you came in or not? Patient: No. Clinician: Can you give one today? Patient: Sure. Clinician: The only reason I ask is, its been a very long time, a year and legally we have to do that each year. Patient: Oh okay. Clinician: Its always been appropriate. So, if we can get that, that will be helpful. That will allow me to legally write your refill. Patient: Hey, well we don't want to be outside the law (PAT46 Clinic Visit PRO12). Clinician: We need a few things and we are done today…We have to do a drug screen today. Have you sign[ed] our contract, which we do every year. Patient: That's another thing, because I got my contract here and I didn't want anywhere else end up messing it up. (PAT78 Clinic Visit PRO19) Clinician: I am very serious about *[inaudible]* contracts. I trust all my patients, okay? I can't tell who's being honest *[inaudible]* because I don't go out and investigate. There is no way for me to do that. However, if I have any reason to not trust my patients, then I have to stop prescribing them their medicine. So that contract is something that we both have to respect, right? I have that contract because it's my responsibility to only give you medicine I think is helping you and I have the power to give you medicine I think potentially could be very harmful, you know? That's why it's really important that we have a mutual respect of the clinic rules and procedures for prescribing narcotics. Patient: Yeah, sounds reasonable and probably even helpful to be able to see how this how many I've got to get me through the week so. (PAT09 Clinic Visit PRO01). With opioids you gotta be very disciplined. The STATE PDMP reports are a must. UDSs are a must. You looking

Theme	Illustrative Quote
	at them objectively are a must. I mean you can't - my opinion is you cannot be blinded by the doctor-patient relationship in that sense. (PAT 55 Interview PRO10)